MINUTES OF 329th MEETING OF REGISTRATION BOARD HELD ON 6th to 8th JUNE, 2023

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

329th meeting of Registration Board was held on 6th to 8th June, 2023 in the Committee Room, Drug Regulatory Authority of Pakistan, G-9/4, Islamabad.

The meeting was chaired by Dr. Muhammad Fakhruddin Aamir, Chairman, Registration Board, DRAP. The meeting started with recitation of the Holy Verses.

Following members attended the meeting:

1.	Lt. Gen.(R) Prof. Dr. Karamat A. Karmat, (HI-M, SI-M), Former Surgeon General Pakistan, Rawalpindi (On line)	Co-opted Member
2.	Mr. Muhammad Aslam, Additional Draftsman, M/o Law & Justice, Islamabad	Member
3.	Mr. Sartaj Khan, Drug Analyst. Rep of Director DTL, Govt. of KP	Member
4.	Mr. Muhammad Hafeez ur Rehman, DDC, Rep of Director DTL, Govt. of Punjab	Member
5.	Dr. Ali Jan, Director, DTL, Govt. of Baluchistan Quetta	Member
6.	Syed Adnan Rizvi, Director DTL. Govt. of Sindh. Karachi	Member
7.	Mr. Ajmal Sohail Asif, Director, QA&LT, DRAP, Islamabad.	Member
8.	Mr. Ahmad Din Ansari, Director, Division of BE&R	Member
9.	Ch. Zeeshan Nazir, Additional Director	Secretary
10.	Mr. Ghyour Ahmed, Assistant Director, Rep. of Director, MD&MC Division	Member
11.	Mr. Iftikhar A Chaudhary, Ex-Hospital Pharmacist, Lahore	Co-opted Member
12.	Dr. Qurban Ali, Ex-Director General, Veterinary Expert	Co-opted Member
13.	Dr. Khalid Ashfaque, Animal Husbandry Commissioner, M/o NFS	Co-opted Member

Mr. Nadeem Alamgir (Pharma Bureau), Mr. Jalal-ud-Din (PPMA) and Mr. Ziaulhaq & Mr. Amir Ilyas (PCDA) attended the meeting as observers.

Item No. I. Confirmation of Minutes of 326th meeting of Registration Board

326th meeting of Registration Board was held on 14th to 16th March, 2023. Accordingly, draft minutes of the meeting were prepared and circulated among the members through email on 03rd May, 2023 for their perusal / approval / comments (if any) by 08th May, 2023 (10 am). None of the members gave any comments. Hence minutes of 326th meeting of Registration Board stand approved.

Accordingly, fair minutes of 326th meeting of RB has been processed for perusal/approval of Chairman, Registration Board. After approval of Chairman, Registration Board, approved minutes of 326th meeting of Registration Board has been circulated among relevant Divisions / Sections for implementation / compliance of decisions.

Decision: Registration Board noted the information and unanimously confirmed the minutes of 326th meeting of Registration Board.

Item No. II. Confirmation of Minutes of 327th meeting of Registration Board

327th meeting of Registration Board was held on 13th April, 2023. Accordingly, draft minutes of the meeting were prepared and circulated among the members through email on 29th May, 2023 for their perusal / approval / comments (if any) by 01st June, 2023 (10 am). Mr. Ali Jan, Director, DTL, Baluchistan responded as ***"Agreed with the comments and decision of board for approval of minutes provided that all codal formalities are fulfilled"*** Rest of the members did not comment. Hence minutes of 327th meeting of Registration Board stand approved.

Accordingly, fair minutes of 327th meeting of RB has been processed for perusal/approval of Chairman, Registration Board. After approval of Chairman, Registration Board, approved minutes of 327th meeting of Registration Board has been circulated among relevant Divisions / Sections for implementation / compliance of decisions.

Decision: Registration Board noted the information and unanimously confirmed the minutes of 327th meeting of Registration Board.

Item No. III. Confirmation of Minutes of 328th meeting of Registration Board

328th meeting of Registration Board was held on 19th May, 2023. Accordingly, draft minutes of the meeting were prepared and circulated among the members through email on 19th May, 2023 for their perusal / approval / comments (if any) by 19th May, 2023 (1230 Hrs). Syed Adnan Rizvi, Director, DTL, Sindh through email responded as ***"Acknowledged. Agreed and endorsed the decision of policy board."*** Mr. Ajmal Sohail, Director, QA&LT Division, DRAP, Islamabad responded as ***"Agreed, please".*** Mr. Ali Jan, Director, DTL, Baluchistan responded as ***"Respected sir very appreciative step as inj- Heparin is out of stock in market since long. as it's emergency medicine has no alternative. I agree with Registration board's today's decision."*** Mr. Imranullah, Director, DTL, Peshawar responded as ***"Agreed with draft minutes."*** Hence minutes of 328th meeting of RB stand approved.

Accordingly, fair minutes of 328th meeting of RB has been processed for perusal/approval of Chairman, Registration Board. After approval of Chairman, Registration Board. Approved minutes of 328th meeting of Registration Board has been forwarded to Division of Biological Evaluation & Research for implementation / compliance of decisions.

Decision: Registration Board noted the information and unanimously confirmed the minutes of 328th meeting of Registration Board.

Item No. IV. Miscellaneous Agenda Items:

Case No. 1 Expert Working Group for the review of "Human Formulations of Pharmaceutical Drug Products":

Human Pharmaceutical Formulation Products are being registered on the basis of evidence of approval of the formulations by any of the reference regulatory authorities adopted by Registration Board in 275th meeting. PE& R division has come across cases wherein various reference regulatory authorities have declared varying particulars regarding, formulation, manufacturing method, dosage administration etc. Also there are formulations which had been previously authorized by the reference regulatory authorities but have been declared as "Discontinued" recently for which the reason has not been evident.

For the above referred reasons and other issues regarding the review of formulations it is proposed that an Expert Working Group for **"Human Formulations of Pharmaceutical Drug Products".**

Decision: Registration Board while acknowledging the above proposal from PE&R Division authorized its Chairman for the constitution of Expert Working Group for "Human Formulations of Pharmaceutical Drug Products".

Case No. 2 Review of Reference status of "Cephradine for suspension" 125mg/5ml":

Registration Board in its various meetings deferred the cases of **Cephradine for suspension" 125mg/5ml** due to discontinued status of the said product by USFDA and non-availability of evidence of approval in other reference regulatory authorities. The Discontinued status by US FDA has not been elaborated whether it was due to safety efficacy reason or on basis of commercial reasons.

Cephradine for suspension has been approved by MHRA of UK in strength of 250mg/ml while the 125mg/ml strength has also been previously registered in Pakistan.

The matter is placed before the Board for further deliberation please.

Decision: Registration Board referred the formulation of "Cephradine for suspension" 125mg/5ml" for review to Expert Working Group for "Human Formulations of Pharmaceutical Drug Products", constituted in instant meeting.

Case No. 3 Minutes of the meeting of working group for deliberation regarding semaglutide.

Registration Board in its 316th meeting decided to constitute a working group for deliberation regarding semaglutide. Accordingly, Chairman Registration Board constituted the working group.

The 1st meeting of working group for deliberation regarding semaglutide was conducted on 01-11-2022 at 10:00 AM in committee room of DRAP. The meeting was chaired by Ch. Zeeshan Nazir Bajar, Additional Director, PE&R Division. The meeting started with recitation of the Holy Verses.

The following attended the meeting:

1. Ch. Zeeshan Nazir Bajar, Additional Director, PE&R Division, DRAP.
2. Mr. Saadat Ali Khan, Assistant Director, BE&R Division, DRAP.
3. Dr. Muhammad Haseeb Tariq, Assistant Director PE&R Division, DRAP.
4. Mr. Nadeem Alamgir (Observer on behalf of Pharma Bureau)
5. Mr. Muhammad Imran Iqbal (Observer on behalf of Pharma Bureau)

No observer from PPMA attended the meeting and PPMA secretary general through its letter dated 29-October 2022 requested to delay the subject meeting for 10-15 days and informed that few technical members from South wish to join however they are travelling for CPHI. The meeting was therefore ended without any final conclusion.

The 2nd meeting of working group for deliberation regarding semaglutide was conducted on 03-05-2023 at 10:00 AM in committee room of DRAP. The meeting was chaired by Ch. Zeeshan Nazir Bajar, Additional Director, PE&R Division. The meeting started with recitation of the Holy Verses.

The following attended the meeting:

1. Ch. Zeeshan Nazir Bajar, Additional Director, PE&R Division, DRAP.
2. Mr. Muhammad Kashif, Deputy Director, BE&R Division, DRAP.
3. Dr. Muhammad Haseeb Tariq, Deputy Director PE&R Division, DRAP.
4. Mr. Nadeem Alamgir (Observer on behalf of Pharma Bureau)
5. Mr. Hasnain Ahmad (Observer on behalf of Pharma Bureau)
6. Mr. Siraj Mehmood (Observer on behalf of Pharma Bureau)
7. Mr. Jalal Uddin (Observer on behalf of PPMA)
8. Mr. Imtiaz (Observer on behalf of PPMA)
9. Mr. Shaharyar Khalid (Observer on behalf of PPMA)

Mr. Muhammad Kashif attended the meeting as a representative from Division of Biological Evaluation & Research in place of Dr. Muhammad Ahsan Hafiz, Deputy Director, BE&R Division, DRAP.

CONCLUSION & RECOMMENDATIONS OF THE COMMITTEE:

The committee thoroughly reviewed the matter, considered the point of view and documents submitted by PPMA and Pharma Bureau, and the recommendations from the representative from Division of Biological Evaluation & Research. The committee observed that following important points:

1. Semaglutide is a drug product produced using recombinant DNA technology in yeast (Saccharomyces cerevisiae) as evident from the assessment reports of European Medicine Agency as well as Food and Drug Administration.
2. The definition of Biologicals under Schedule-I of DRAP Act, 2012 which specifies that *biotechnology products which are primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology or other processes involving site specific genetic manipulation techniques*, does not support the stance of PPMA regarding the number of amino acids as per USFDA definition, for dealing semaglutide product as pharmaceuticals.
3. The innovator's product is manufactured in a dedicated facility for manufacturing of Biological products.
4. Manufacturing of Biological products requires dedicated and self-contained facilities as per clause
   5.2 of Schedule B-1 of the Drugs (Licensing, Registering & Advertising) Rules, 1976, under the Drugs Act, 1976.
5. For approval of Biological products, it is essential that similarity has been thoroughly investigated and backed up with sufficient data to make the bridging to the reference product acceptable.
6. Registration Board has already approved Semaglutide in Injectable and Tablet dosage form for the innovator product "Ozempic® Dual Dose" and "Rybelsus Tablet" of M/s Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd, Denmark in 293rd and 308th meeting as a biological drug product respectively.

Based upon the above stated points, the committee recommends that Semaglutide shall be considered as a biological drug product for local use as well as for export, and be dealt by the Division of Biological Evaluation & Research. The manufacturing of this product shall be performed in dedicated and self- contained facilities for Biological drugs as per clause 5.2 of Schedule B-1 of the Drugs (Licensing, Registering & Advertising) Rules, 1976.

Following cases have been received in Pharmaceutical Evaluation Cell.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee),
1.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan.	Cmag 7mg Tablet Each Tablet Contains: Semaglutide…7mg	Form-5F Dy.No 30265 dated 05-11-2021 Rs.75,000/- dated 06-10-2021
2.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan.	Cmag 14mg Tablet Each Tablet Contains: Semaglutide…14mg	Form-5F Dy.No 30266 dated 05-11-2021 Rs.75,000/- dated 06-10-2021

Manufacturer of API	Zhejiang Peptites Biotech Co. Ltd. No. 08 Hengyizhi Road Sanjie Town Shengzhou, Zhejiang, China		
API Lot No.	2020022801		
Documents confirming import of API	Firm has submitted copy of commercial invoice cleared by AD I & E Dated 06-03-2020 specifying import of 30 gram Semaglutide.		
Cmag 7mg Tablet			
Batch No.	21SB-117-01	21SB-118-02	21SB-119-03
Batch Size	350 Tablet	350 Tablet	350 Tablet
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	22-02-2021	22-02-2021	22-02-2021
Cmag 14mg Tablet			
Batch No.	21SB-120-01	21SB-121-02	21SB-122-03
Batch Size	350 Tablet	350 Tablet	350 Tablet
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	01-03-2021	01-03-2021	01-03-2021

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee),
3.	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan	Semtide 3mg Tablet Each Tablet Contains: Semaglutide…3mg	Form-5F Dy.No 35497 dated 07-12-2022 Rs.75,000/- dated 08-11-2022
4.	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan	Semtide 7mg Tablet Each Tablet Contains: Semaglutide…7mg	Form-5F Dy.No 35498 dated 07-12-2022 Rs.75,000/- dated 08-11-2022
5.	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan	Semtide 14mg Tablet Each Tablet Contains: Semaglutide…14mg	Form-5F Dy.No 35499 dated 07-12-2022 Rs.75,000/- dated 08-11-2022
Manufacturer of API	Zhejiang Peptites Biotech Co. Ltd. No. 08 Hengyizhi Road Sanjie Town Shengzhou, Zhejiang, China		

API Lot No.	G06210801		
Documents confirming import of API	Firm has submitted copy of commercial invoice cleared by AD I & E Dated 30-12-2021 specifying import of 45 gram Semaglutide.		
Semtide 3mg Tablet			
Batch No.	480DS04	480DS05	480DS06
Batch Size	440 Tablet	440 Tablet	440 Tablet
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	17-03-2022	17-03-2022	17-03-2022
Semtide 7mg Tablet			
Batch No.	543DS01	543DS02	543DS03
Batch Size	440 Tablet	440 Tablet	440 Tablet
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	17-03-2022	17-03-2022	17-03-2022
Semtide 14mg Tablet			
Batch No.	544DS01	544DS02	544DS03
Batch Size	440 Tablet	440 Tablet	440 Tablet
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	17-03-2022	17-03-2022	17-03-2022

Sr. No.	**Name & Address of Manufacturer / Applicant**	**Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification**	**Type of Form, Initial Diary & Date, Fee (including differential fee),**
6.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar	Semdi 3mg Tablet Each Tablet Contains: Semaglutide…3mg	Form-5F Dy. No 4219 dated 14-02-2023 Rs.75,000/- dated 31-12-2021
7.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar	Semdi 7mg Tablet Each Tablet Contains: Semaglutide…7mg	Form-5F Dy.No 4220 dated 14-02-2023 Rs.75,000/- dated 31-12-2021
8.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar	Semdi 14mg Tablet Each Tablet Contains: Semaglutide…14mg	Form-5F Dy.No 4221 dated 14-02-2023 Rs.75,000/- dated 31-12-2021

Manufacturer of API	Zhejiang Peptites Biotech Co. Ltd. No. 08 Hengyizhi Road Sanjie Town Shengzhou, Zhejiang, China		
API Lot No.	ZG06210303		
Documents confirming import of API	Firm has submitted copy of License to import drugs for examination, test or analysis (Form 6) issued by AD I & E Dated 17-05-2021. Firm has also submitted copy of airway bill dated 24-05-2021 specifying 230gm.		
Semdi 3mg Tablet			
Batch No.	T01	T02	T03
Batch Size	1200 Tablet	1200 Tablet	1200 Tablet
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	27-06-2021	27-06-2021	27-06-2021

Semdi 7mg Tablet			
Batch No.	T04	T05	T06
Batch Size	1200 Tablet	1200 Tablet	1200 Tablet
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	27-06-2021	27-06-2021	27-06-2021
Semdi 14mg Tablet			
Batch No.	T07	T08	T09
Batch Size	1200 Tablet	1200 Tablet	1200 Tablet
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	27-06-2021	27-06-2021	27-06-2021

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee),
9.	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	Ludin 3mg Tablet Each Film Coated Tablet Contains: Semaglutide…3mg	Form-5D Dy.No 2031 dated 06-12-2016 Rs.50,000/- dated 06-12-2016
10.	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	Ludin 7mg Tablet Each Film Coated Tablet Contains: Semaglutide…7mg	Form-5D Dy.No 2027 dated 06-12-2016 Rs.50,000/- dated 06-12-2016
11.	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	Ludin 14mg Tablet Each Film Coated Tablet Contains: Semaglutide…14mg	Form-5D Dy.No 2030 dated 06-12-2016 Rs.50,000/- dated 06-12-2016

Manufacturer of API	Zhejiang Peptites Biotech Co. Ltd. No. 08 Hengyizhi Road Sanjie Town Shengzhou, Zhejiang, China
API Lot No.	G06210801
Documents confirming import of API	Firm has submitted copy of commercial invoice cleared by AD I & E Dated 27-01-2022 specifying import of 16 gram Semaglutide.

Ludin 3mg Tablet			
Batch No.	22PD-0159-02-SB	22PD-0160-03-SB	22PD-0161-04-SB
Batch Size	200 Tablet	200 Tablet	200 Tablet
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	01-06-2022	01-06-2022	01-06-2022
Ludin 7mg Tablet			
Batch No.	22PD-0191-01-SB	22PD-0192-02-SB	22PD-0193-03-SB
Batch Size	200 Tablet	200 Tablet	200 Tablet
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	01-06-2022	01-06-2022	01-06-2022
Ludin 14mg Tablet			
Batch No.	22PD-0442-01-SB	22PD-0443-02-SB	22PD-0444-03-SB

Batch Size	200 Tablet	200 Tablet	200 Tablet
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	02-11-2022	02-11-2022	02-11-2022

Following cases have been received in BE&R Division.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee),
12.	M/s Macter international Limited, F-216, S.I.T.E. Karachi.	Seglutide 2mg / 1.5 ml vial solution for injection Each ml contains 1.34 mg of semaglutide. (i.e. 2 mg / 1.5 ml per vial)	Form-5F Dy.No 4861 dated 20-02-2022 Rs.30,000/- fee challan # 10008463700018
13.	M/s Macter international Limited, F-216, S.I.T.E. Karachi.	Seglutide 4mg / 3 ml vial solution for injection Each ml contains 1.34 mg of semaglutide. (i.e. 4 mg / 3 ml per vial)	Form-5F Dy.No 4862 dated 20-02-2022 Rs.30,000/- fee challan # 10008463700018

Manufacturer of API	Livzon New North River Pharmaceutical Co., Ltd. Renmin one Road, Qingyuan city, Guangdong province, China		
API Lot No.	2020022801		
Documents confirming import of API	Firm has submitted copy of commercial invoice Dated 04-03-2022 specifying import of 10 gram Semaglutide. The invoice is not cleared by AD (I & E).		
Seglutide 2mg / 1.5 ml vial solution for injection			
Batch No.	SEMA-01A	SEMA-02A	SEMA-03A
Batch Size	100 vials	200 vials	200 vials
Manufacturing Date	19-04-2022	20-04-2022	21-04-2022
Date of Initiation	22-04-2022	22-04-2022	22-04-2022
Seglutide 4mg / 3 ml vial solution for injection			
Batch No.	SEMA-01B	SEMA-02B	SEMA-03B
Batch Size	100 vials	200 vials	200 vials
Manufacturing Date	26-04-2022	27-04-2022	28-04-2022
Date of Initiation	29-04-2022	29-04-2022	29-04-2022

Submitted for consideration by the Board, please.

Decision: Registration Board deferred the case for further deliberation.

Case No. 4 Monograph of Rifaximin Tablet in BP

Division of Quality Assurance and Lab Testing has referred the instant matter through e-office Dy. No. 348/2023-E/QALT. M/s Sami Pharma, Karachi vide its letter dated 05.09.2022 addressed to Director PE&R Division / Chairman Registration Board has submitted the following:

Dear Sir,

Sub.: Monograph of Rifaximin Tablets in BP 2022

Ref.: Our Product Nixaf 550mg Tablet & Nixaf 200mg Tablet bearing Registration Nos. 073700 and 076310 respectively

We would like to respectfully submit following facts for your kind consideration:

1. *BP 2022 has lately introduced monograph of Rifaximin tablets attached herewith as Annex - A*
2. *Since the introduction of its monograph in BP, we are bound to follow the same and modify our claim as per BP 2022*
3. *However, upon analyzing against BP 2022, we have come across with following observations:*

1. ***Standard preparation:*** *Standard of 0.02% w/v for dissolution test i.e. 20mg of Rifaximin EPCRS but reference standard does not dissolve completely even on vigorous sonication and stirring*
2. ***Reading on spectrophotometer:*** *It does not mention the cell path length and when we measure the absorbance of standard solution using 1cm quartz cell at 290 nm using dissolution medium as compensation solution, absorbance value found around 4 which is even more than the upper limit of instrument*
3. ***Dissolution:*** *Unfortunately neither competitor's nor ours comply with it (NLT 75%) (Q), on changing the method of standard preparation i.e. first dissolve the standard in little amount of methanol*

   Facing the above stated issues, we contacted BP Commission who graciously acknowledged our view point and agreed to forward it to their Advisory Group, whose meeting is due to be held in September 2022; copies of communication exchanged are attached as Annex - C1 and C2.

   In addition to the above, we are currently following the USFDA dissolution method, published in USFDA dissolution data base and our products comply with the criteria of NLT 75%(Q) after 90 minutes – Annex - D and E.

   We hope below table will fully explain the situation:

Condition	***BP 2022***	***USFDA***	
	For both 200 and 550mg Tablets	***200mg***	***550mg***
Apparatus	*II (Paddle)*	*II (Paddle)*	*II (Paddle)*
RPM	*50 Revolutions per minute*	*75 Revolutions per minute*	*75 Revolutions per minute*
Dissolution Medium	*Dissolve 13.6g of Sodium Acetate in 800ml water, add 6ml of Glacial Acetic Acid and dilute to 1000ml using water. Add 2g of Sodium Lauryl Sulfate and mix*	*0.1M Sodium Phosphate buffer pH 7.4 containing 0.45% Sodium Lauryl Sulfate*	*0.1M Sodium Phosphate buffer pH 7.4 containing 0.8% Sodium Lauryl Sulfate*
Time interval	*60 minutes*	*10, 20, 30, 45, 60, 90 and 120 minutes*	*10, 20, 30, 45, 60, 90 and 120 minutes*
Volume	*900ml*	*1000ml*	*1000ml*

From the above comparison, it is clear that USFDA dissolution medium is entirely different from that of BP 2022.
USFDA also recommends different concentration of sodium lauryl sulfate because this drug is classified in BCS class IV.

In light of above discussion, which we hope you would endorse too, we would like to continue to market the product on "Manufacturer's Specs." till such time the situation is clarified.

Later on the firm has submitted another request vide letter dated 03.04.2023 addressing Director QA&LT Division as well as Director PE&R Division / Chairman Registration Board. The firm has also submitted the following documents:

1. Correspondence of the firm M/s Sami Pharma, Karachi (through Muhammad Imtiaz; muhammad.imtiaz@samipharma.com.pk) with British Pharmacopoeia Secretariat (through Peter Crowley; peter.crowley@mhra.gov.pk). The first email was sent from Sami Pharma to BP on 26.03.2022 wherein the firm stated difficulty faced by them while testing their product rifaximin tablet as per BP 2022 monograph. The firm also mentioned that they have also performed this testing after amendments in certain parameters including standard preparation and cell path length. The email was responded by BP on 27.04.2022, wherein they inform that the already available dissolution method in BP monograph was based on conditions used in an academic study. They requested further data from the firm which demonstrates the suitability of their analytical amendments, and informed to place this data in the next meeting of BPs Antibiotics Expert Advisory Group. The firm submitted detailed data on 07.05.2022. Mr. Peter Crowley from BP informed the firm on 20.09.2022 that the expert advisory group confirmed that the analytical amendments proposed by the firm should be specified and that they will prepare a letter of intent for publication on the website and the revised monograph of rifaximin tablet will be published in BP 2024.
2. Specifications and analytical method for their product Nixaf (Rifaximin) 200mg and 550mg Tablet.

G:\EORWeb\Download?AttachmentId=9902929 BP published Notice of intent to revise BP monograph for rifaximin Tablet on 10.10.2022 (https://www.pharmacopoeia.com/file/Letter-of-intent_Rifaximin- Tablets_BP2023.pdf). The contents of the notice of intent are as under:

It has come to our attention that in the Dissolution test, Solution A should be adjusted to pH 5.0 with glacial acetic acid and that the test and standard solutions should be diluted to a concentration of 0.003% w/v of Rifaximin. The monograph will therefore be revised to reflect these changes in a future publication.

Please accept this as a notice of intent to amend the monograph on behalf of the British Pharmacopoeia Commission. This letter is for information only and does not represent a legally-enforceable standard. The revised monograph will be published in a future edition of the British Pharmacopoeia - the current target publication is the BP 2024, which will come into force on 1st January 2024.

If you have any questions concerning this letter, please do not hesitate to contact the British Pharmacopoeia Secretariat (BPCOM@mhra.gov.uk).

Submitted for consideration of the Board please.

Decision: After detailed celebration/discussion, the board decided to acceded to the request of firm to continue to market the product on "Manufacturer's Specs." till such time the situation is clarified and the division of QA/LT will directly communicate with BP for clarification.

Case No. 5 Cefoperazone Sodium & Sulbactam Sodium for Injection (JP Specifications)

PPMA has submitted a request dated 10th April 2023 regarding Cefoperazone Sodium & Sulbactam Sodium for Injection. The request of PPMA is as under:

With reference to the captioned subject, we would like to respectfully submit that the subject product, of standard quality, is being produced by several local pharmaceutical manufacturers since long; its monograph has been published in Japanese and Chinese Pharmacopoeias both.

DRAP is now insisting on manufacturing this product by following JP specifications; after a detailed study, attached herewith, we noted that:

1. M/s. Pfizer (the Innovator) is manufacturing this product in different regions via Dissolution Crystallization Method (meeting Chinese Pharmacopoeial specifications) as well as Unit Lyophilization (meeting Japanese Pharmacopoeial specifications)

2. Pfizer's product specification conforming to Chinese Pharmacopoeia is stringent as compared to the Japanese Pharmacopoeia specification

Below table summarizes key points of both specifications for kind consideration:

TABLE OF COMPARISON AND JUSTIFICATION

Description	Unit Lyophilized (JP)	Dissolution Crystallization Method (Ready to Fill Product)
Innovator / Originator	Pfizer	Pfizer
Availability in SRA Countries	Japan	Poland, Slovakia, Lithuania, Czech Republic, Italy, Bulgaria (See attached EMA list)
Availability in non-SRA countries	Not available	China, Pakistan, India, Bangladesh, Indonesia, Malaysia and Brunei
Finished product availability in Pharmacopeia	JP (Japanese Pharmacopeia)	ChP (Chinese Pharmacopeia)
Stability of product	Less stable due to the high hygroscopicity (Please see attached study of Zhuhai)	More stable (Please see attached stability results)
Impurities level	Specifications of impurities is higher than dissolution crystallization method (See comparison of JP, ChP and vendor specifications)	Specifications of impurities is lower than unit lyophilized product (See comparison of JP, ChP and vendor specifications)
Water Content	1% but not stabilizing the product than dissolution crystallization method	4% but not impacting the stability and also having low impurities level than unit lyophilization product (low water content)
Quality & Safety	Established in Japan and product is available in Japan since long	1. Established in EU and other countries (i.e. Malaysia etc.) and freely available throughout the world 2. Stability studies results also found satisfactory over its shelf life and presence of water content of 3-4 % has not impact
Degradation	Having higher degradation (See attached results)	Having lower degradation than unit lyophilized product
Market share	Only in Japan	Rest of the world

Based on aforementioned evaluation, it can easily be inferred that the product manufactured through Dissolution Crystallization Method is more stable and is being used more frequently than product manufactured through Unit Lyophilization product, which is registered and available in Japan only.

We hope that the above, along with enclosed documents, will be found in order and approval will so kindly be granted for which we submit our best thanks in advance.
With

profound

regards,

Sincerely

yours,

The letter also contains the following study report.

Scope: This justification is addressing the request of following In-house Specifications for Cefoperazone Sodium & Sulbactam Sodium for Injection, instead of JP specifications.

Justification: Said product is a combination of two APIs i.e., "Cefoperazone Sodium" & "Sulbactam Sodium". Individual monographs of both API's are available in USP.

JP monograph of "Cefoperazone Sodium & Sulbactam Sodium for Injection", claimed the test for Uniformity of Dosage Unit should comply the requirement of 'Mass Variation' when performed via <6.02>JP. Where, <6.02> JP clearly indicates that in case of a solid dosage form in single dose package, having multiple components (as the case of said injection), 'Mass Variation' test will be performed if the solution is freeze-dried in final container otherwise Content Uniformity test need to be performed.

This clearly shows that the product mentioned in JP monograph is a unit lyophilized (freeze-dried solution) product, while we are manufacturing a product by direct filling of powder aseptically into the final container and hence both are considered as different products, which can have different product specifications. Therefore, we are requesting for in-house specifications for the subject product based on following discussions.

API Manufacturing Process:

As per current industrial practices, Cefoperazone Sodium is mainly manufactured by either lyophilization method or dissolution crystallization method. The technical comparison of API manufactured via both methods is as follows:

S. No.	Parameter	Lyophilization Method	Dissolution Crystallization Method
1	Deployment / Utilization	Rarely used preparation method	Mostly used preparation method
2	Impurities Level	High	Low
3	API Stability	Relatively Poor	Relatively Good
4	Degradation Rate	Fast	Slow

Each of the above parameters are discussed in detail below:

1. Manufacturing Process Utilization

Following is the difference in manufacturing process of the two most commonly used preparation methods for Cefoperazone Sodium:

Parameters	Lyophilization Method	Dissolution Crystallization Method
Manufacturing Process	Reaction product of Cefoperazone acid and sodium alkaline compounds are directly placed into the lyophilizer	Dissolve the solute in water or other organic solvents, and then add the solvent that can reduce the solubility of the solute to the crystallization, (to promote rapid precipitation of solute)
Moisture Removal	Residual moisture is removed through vacuum lyophilization method	Residual moisture is removed through filtration and/or drying method
Water Content	≤1.0% Due to lyophilization method as it does not contain crystal water	3.0 to 4.0% Due to presence of one molecule of crystal water
Particle Shape	Obtains amorphous Cefoperazone Sodium powder	Mostly obtains needle shaped crystals
Quality	Quality of final substance is relatively poor	Better particle size and quality

Utilization	Employed by few API manufacturers	Mostly employed by API manufacturers

Based on above table, the most frequency used API preparation method is 'Dissolution Crystallization Method' due to its ability to generate better quality and stable product as compared to 'Lyophilization Method'

2. Impurity Level:

Following is the specification comparison of impurities in **Cefoperazone Sodium** (API) from different pharmacopoeia:

Parameters	**JP**	**Ph. Eur.**	**USP**	**CHP**
Water content	≤ 1.0%	≤ 5.0%	≤ 5.0%	≤ 5.0%
Related Substances	Impurity I ≤ 5.0%	Any other impurity ≤ 1.5%	N/A	Impurity A ≤ 3.0%
	Impurity II ≤ 1.5%			Any other impurity except impurity A ≤ 2.0%
	Total impurities ≤ 7.0%	Total impurities ≤ 4.5%		Total impurities except impurity A ≤ 3.0%

Above data clearly shows that the material specifications proposed by JP have higher impurity allowance levels as compared to the impurity limits defined by other pharmacopeia; showing that the API manufactured via lyophilization process to meet JP requirement has its intrinsic property for generation of higher level of impurities as compared to the manufacturing process via dissolution crystallization process.

In addition, following is the specification comparison of impurities in **Cefoperazone Sodium for Injection** (Finished Pharmaceutical Product) from different pharmacopoeia:

Parameters	**JP**	**CHP**
Water content	≤ 1.0%	≤ 5.0%
Related Substances	Impurity I ≤ 5.0%	Impurity A ≤ 3.0%
	Impurity II ≤ 1.5%	Any other impurity except impurity A ≤ 2.0%
	Total impurities ≤ 7.0%	Total impurities except impurity A ≤ 3.0%

The specifications of Cefoperazone for injection also contains similar picture as API; where JP using Lyophilized product, whereas ChP using the dissolution crystallized API and hence related substances specifications of JP are broader than ChP, which clearly indicates that JP material allows higher impurity level in final product in comparison to ChP material.

Similarly, following is the specification comparison of impurities for **said product** i.e., combination of '**Cefoperazone Sodium & Sulbactam Sodium**' from different pharmacopoeia

Parameters	**JP**	**CHP**	**API Manufacturer**
Water content	≤ 1.0%	≤ 4.0%	≤ 3.0%
Related substances	R. Substance I ≤ 7.0% R. Substance II ≤ 2.0% R. Substance III ≤ 2.0% Sulbactam Penicillamine ≤ 1.0%	Cefoperazone Impurity A ≤ 1.5% Cefoperazone Impurity C ≤ 0.5% Any other impurity ≤ 1.5% Total impurities except Cefoperazone impurity A & C ≤ 3.0 %	Cefoperazone Impurity A ≤ 1.5% Cefoperazone Impurity C ≤ 0.5% Any other impurity ≤ 1.5% Total impurities except Cefoperazone impurity A & C ≤ 3.0%

It is to be noted that Impurity C given in CHP and API Manufacturer's specs is equivalent to Related Substances I as per the proposed relative retention by JP. Furthermore, all the impurities mentioned in ChP specifications are stringent and/or comparable with JP requirements.

3. API Stability & Degradation Rate:

As already discussed above, product complying JP specification is manufactured via lyophilization method, and it does not contain crystal water.

Therefore, it has a low moisture profile (i.e. ≤ 1.0%) resulting in its strong hygroscopicity & high affinity towards rapid degradation due to accumulation / introduction of free water.

On the other hand, Cefoperazone Sodium produced by dissolution crystallization method contains one molecule of crystal water.

Therefore, the hygroscopicity of non-JP grade subject material is low, resulting in low affinity towards degradation.

Based on above scientific discussion, the stability of Cefoperazone Sodium manufactured via dissolution crystallization process (Complying non-JP Specs.) is better as compared to the API stability produced via lyophilization process (Complying JP Specs.)

Reference / Comparator Product:

Cefoperazone Sodium & Sulbactam Sodium Injection by dissolution crystallization method is the brand of M/S Pfizer and being manufactured & marketed in different countries as follows:

Brand Name	Manufacturer / Marketer	Country
Sulperazon for I.V. Injection	Pfizer Japan Inc.	Japan
Sulperazon 1g	Pfizer Polska Sp. Z O.O.	Poland
Sulperazon 2g	Pfizer Polska Sp. Z O.O.	Poland
Sulperazon	Pfizer Europe Ma Eeig	Slovakia
Sulperazon	Pfizer Europe Ma Eeig	Slovakia
Sulperazon	Pfizer Limited	Lithuania
Sulperazon IM/IV	Pfizer, Spol. S R.O.	Czech Republic
Sulperazone	Pfizer Italia S.R.L.	Italy
сулперазон	Pfizer Europe Ma Eeig	Bulgaria
Sulperazon	Pfizer Indonesia	Indonesia
Magnex / Magnex Forte	Pfizer India	India
Sulperazon	Pfizer USA	For Malaysia & Brunei

Cefoperazone Sodium & Sulbactam Sodium Injection is the brand of M/S Pfizer and being marketed in India, Nepal and Sri Lanka as well with the brand name of MAGNEX & MAGNEX FORTE. Similarly, Cefpran Injection of M/s. Ontech Corporation is a registered brand of said product in Pakistan. Samples of both products were tested and water content results were found within the range of 2 – 4% (as per ChP requirement), which is in line with the product manufactured using material via dissolution crystallization method.

In addition to it, Sulperazon Injection (M/s. Pfizer) available in different countries including Bulgaria, Indonesia, Malaysia & Thailand is filled in moulded glass vials and there are no cuts on the rubber stopper. It shows that the product is not manufactured by reference product manufacturer via unit lyophilization process as desired by JP. (Pictures are attached for reference).

Sulperazon Injection 2g (Cefoperazone Sodium & Sulbactam Sodium) of M/S Pfizer from Czech Republic, Europe also clearly indicates that the final product is not a lyophilized unit as molded glass vial is used without cuts in rubber stopper. Therefore, it is clear that the reference product is not following JP specifications in European region as well. (Pictures are attached for reference).

On the other hand, Cefoperazone Sodium & Sulbactam Sodium Injection from M/S Pfizer available in Japan is unit lyophilized, as desired by JP.

Secondly, innovator product having direct powder filling process (i.e., having API via dissolution crystallization method) is in line with the monograph already published in Chinese Pharmacopeia (CHP)

The above discussion clearly shows that the Reference & Comparator Products for the said API combination exist internationally in dosage forms addressing lyophilized form (i.e. JP Specifications) only in Japan, as well as dissolution crystallized form in rest of the world (i.e., non-JP or Chinese Pharmacopoeia Specifications).

Product (In-House Specs) Efficacy & Availability:

Cefoperazone Sodium & Sulbactam Sodium Injection range is 3rd generation Cephalosporin that is regularly used in hospitals for the eradication of respiratory tract, urinary tract as well as acquired bacterial Infections. Product is available in market for more than 20 years with remarkable quality, efficacy and stability.

Moreover, please note that based on the product development as well as review of satisfactory stability studies and all above facts, it can be concluded that in-house/ChP defined limit of water content do not have any critical quality impact on said product.

Product Availability for Public Health / Patient:

Current database shows that approximately 222 different brands of Cefeperazone Sodium & Sulbactam Sodium Injection Range are registered by DRAP and available since 2003. Out of which, more than 40 products are registered in last 05 years period showing the increase patient demand & requirement of the said product

In addition to it, strength wise data as per IMS of different brands of the said product is as follows:

Strength	MAT ~ 09/2022	MAT ~ 09/2021	MAT ~ 09/2020	MAT ~ 09/2019	MAT ~ 09/2018
2g	6,792,865	6,431,668	3,488,501	2,990,379	2,423,560
1g	3,688,955	3,287,367	2,083,691	1,938,962	1,625,299
500mg	1,347,140	855,093	600,177	575,429	474,375
Total	11,828,960	10,574,128	6,172,369	5,504,770	4,523,234

The above data shows that there is a high demand & continuous need of the said product in market due to its desired quality, efficacy as well as reliability and all of the identified brands in above data are complying with In-house specifications similar to that of reference product available in SRA countries

Only 01 SRA country (Japan) is following unit lyophilized dosage form of the product while 06 European Union countries (Poland, Slovakia, Czech Republic, Italy, Lithuania & Bulgaria) have the said product via dissolution crystallization material

Conclusion:

On the basis of above justification, we are summarizing the following:

1. JP demands product via unit lyophilization process
2. Raw Material produced by lyophilization process is less stable and has high level of impurities in comparison to the raw material manufactured by dissolution crystallization

method

3. The quality & efficacy of API and subsequent FPP is not effected due to availability of 3 – 4% water in it based on stability data and it also complies with the ChP (Chinese Pharmacopeia)
4. Internationally, the reference / comparator product from M/S Pfizer exist in both JP as well as non-JP specifications
5. Combination of Cefoperazone Sodium & Sulbactam Sodium is effective as well as in high demand in market
6. Innovator product available in European region is in line with the product monograph already published in Chinese Pharmacopeia (CHP)

Based on above justification, we humbly request to you kindly accept the said product with "Innovator's Specifications", where the API used in product manufacturing is complying with Chinese or equivalent pharmacopoeia.

DRAP Authority in its 157th meeting also considered the request of PPMA and decided as under: "*The authority notes that the technical forum to address this case in Registration Board therefore, PPMA is advised to approach the Registration Board along with scientific rationale and justification for in-house specifications versus specification in the Japanese pharmacopoeia for this particular combination*".
Submitted for consideration of the Board please.

Decision: Registration Board while considering the above presented information noted the fact that JP monograph of "Cefoperazoene+Sulbactam dry powder for injection" is particular for the drug product manufactured by way of "Freeze-dried (Lyophilized) from solutions in final container while the products being manufactured by using "ready to fill" powder may have different quality profile hence after thorough deliberation, Board decided as under:

i. **Registration applications of "Cefoperazoene+Sulbactam dry powder for injection" may be approved either with Innovator's specifications or Japanese Pharmacopoeia specifications, as per the submission of the applicant.**

ii. **Registration applications in instant meeting may also be decided accordingly.**

Case No. 6 Ciprofloxacin HCl Oral Dry Powder Suspension

PPMA has submitted a request dated 17th March 2023 regarding Cefoperazone Sodium & Sulbactam Sodium for Injection. The request of PPMA is as under:
Ciprofloxacin is an effective Fluoroquinolone which is available in different dosage forms viz. Tablets, Infusions and Oral Dry Powder Suspensions with its different salts viz. Hydrochloride, Lactate etc. as required.

Since 2007, over 100 million bottles have been prescribed in Pakistan by medical practitioners with full satisfaction; desired results were timely obtained and no adverse reaction has been reported till date; last 5 years' IMS data for 125 mg and 250 mg Oral Dry Powder Suspension for retail sales, excluding institutional sales, is attached for ready reference.

This drug is also being regularly procured and used in Government Institutions and renowned private hospitals / institutes viz. Agha Khan, Indus, NICH, PIMS, SIUT and Children's Hospital to name a few.

It may please be noted that Bayer's CIPRO Oral Suspension is a combo pack; one bottle contains taste masked granules while its diluent is packed in another bottle as shown in the picture below:

Cost of the diluent, if one succeeds to develop it, will be more than the cost of dry powder suspension being manufactured locally; accordingly, revised MRP of the newly developed product would be more than double of its approved MRP which, in present circumstances, few patients would be able to afford while majority would be deprived of this effective drug. Moreover said diluent is not a drug hence it's manufacturing in Pharmaceutical Plant is also required to be considered according to current guidelines

Most of the Registration holders of Ciprofloxacin Suspension do not have Liquid Section, hence it will be a big problem for them to get it manufactured from other Manufacturers on Toll basis as to how they will get these diluents registered on Toll manufacturing arrangement
It is worth mentioning that due to enormous cost of combo pack, Bayer has NOT applied for its registration either for local manufacturing or import in finished form.
In view of the above, it is earnestly requested that the august Board may so kindly suspend its earlier decision, inform it to all concerned so that local manufacturers may continue its production as per approved formulations of Ciprofloxacin HCL without any threat/ fear from Drug Inspectors and Laboratories who have started declaring the drugs as Misbranded/ Sub-standard.

With profound regards

Sincerely yours,

Dated: 16-03-2023

5 years unit trend

CIPROFLOXACIN ORAL LIQUID ORDINARY	MAT ~ 12/2022 UN-T.UNITS UNIT	MAT ~ 12/2021 UN-T.UNITS UNIT	MAT ~ 12/2020 UN-T.UNITS UNIT	MAT ~ 12/2019 UN-T.UNITS UNIT	MAT ~ 12/2018 UN-T.UNITS UNIT
125MG	12,077,453	9,361,278	8,507,369	8,125,099	7,248,858
NOVIDAT SUSP DRY 125MG 60ML	**5,729,539**	**4,626,246**	**4,369,778**	**4,172,198**	**4,008,907**
CYROCIN SUSP DRY 125MG 60ML	2,196,701	1,450,316	1,088,667	558,131	217,700
CIPLET SUSP DRY 125MG 60ML	1,313,399	980,023	1,025,515	1,054,588	871,283
CIPESTA SUSP DRY 125MG 60ML	1,161,855	808,984	757,089	801,601	647,723
INOQUIN SUSP DRY 125MG 60ML	398,873	375,960	355,770	410,126	396,479
GAVEL SUSP DRY 125MG 60ML	290,952	257,037	269,596	322,471	321,844
EFECIP SUSP DRY 125MG 60ML	279,405	221,405	146,192	181,689	155,501
* Others *	706,729	641,307	494,762	624,295	629,421
250MG	3,656,081	2,915,466	2,510,936	2,888,608	2,675,753
NOVIDAT SUSP DRY 250MG 60ML	**1,954,973**	**1,670,816**	**1,450,487**	**1,706,387**	**1,636,778**
CYROCIN SUSP DRY 250MG 60ML	545,018	367,264	278,667	165,617	71,516
CIPESTA SUSP DRY 250MG 60ML	356,867	219,092	197,183	232,039	204,981
CIPLET SUSP DRY 250MG 60ML	268,639	205,249	204,026	249,528	223,163
CINOXIN SUSP DRY 250MG 60ML	100,576	85,470	50,244	62,037	45,770
INOQUIN SUSP DRY 250MG 60ML	93,261	76,618	77,075	97,803	99,123
GAVEL SUSP DRY 250MG 60ML	76,669	60,600	63,422	83,144	93,903
* Others *	260,078	230,357	189,832	292,053	300,519

Regulatory history of Ciprofloxacin suspension considerations by Registration Board

290th meeting of Registration Board

Registration Board after through deliberation decided to approve the formulation of ciprofloxacin granules for oral suspension containing ciprofloxacin base. The Board authorized its Chairman to issue registration letters in approved cases where revision / correction of salt form and granules of the formulation is required after submission of requisite fee.

1. All registration holders of ciprofloxacin granules for oral suspension shall ensure the supply of ciprofloxacin granules along with the solvent / diluent having following composition as per the innovator product.
    1. Soya lecithin
    2. Medium chain triglycerides
    3. Flavor
    4. Sucrose
    5. Purified water.

Issue an advisory for compliance to PPMA, Pharma Bureau and PCDA and also upload a copy on DRAP"s website for information for all stakeholders and general public.

313th meeting of Registration Board

Registration Board deliberated the matter in detail and reiterated its decision taken in 290th meeting in which all registration holders of ciprofloxacin granules for oral suspension were advised to ensure the supply of ciprofloxacin granules along with the solvent / diluent having following composition as per the innovator drug product.

- o Soya lecithin
- o Medium chain triglycerides
- o Flavor
- o Sucrose
- o Purified water

The Board observed that all pharmaceutical manufacturers have not yet complied the decision of the Board taken in 290th meeting. Keeping in view the safety, efficacy and quality of the product, the Board decided as follow:

1. All registration holders of ciprofloxacin granules for oral suspension should comply the decision of 290th meeting within 3 months.
2. All registration holders of ciprofloxacin granules for oral suspension to whom registration has been granted with ciprofloxacin hydrochloride, should revise their formulation as per the innovator product and apply for correction in salt form in the relevant section of PE&R Division within 3 months.
3. The Board also directed PE&R Division to issue an advisory in this regard to PPMA, Pharma Bureau and PCDA for compliance and also upload on DRAP‟s website for information for all stakeholders.

The matter regarding formulation and salt form of ciprofloxacin injection and extended release tablet will be discussed in forthcoming of Registration Board.

Product status in other countries.

Ciprofloxacin suspension is supplied as ciprofloxacin base in Reference Regulatory Authorities as well as other European countries like Belgium etc.
In neighboring countries like India and Bangladesh Ciprofloxacin suspension is available both as powder / granules for suspension containing ciprofloxacin hydrochloride alone as well as ciprofloxacin granules along with diluent. However, the composition of diluent or the salt for of ciprofloxacin could not be verified from online databases.

Decision: Registration Board referred the formulation of "Ciprofloxacin HCl Oral Dry Powder Suspension", for review, to Expert Working Group for "Human Formulations of Pharmaceutical Drug Products", constituted in instant meeting.

Case No. 7 Stability data submitted for applications applied on Form 5/5D.

Registration Board in its 320th meeting considered the case of "Applications submitted on Form 5 / 5-D requiring submission of stability data" and decided as under:

"Registration Board deliberated the matter in detail and observed that these applications are pending for submission of stability data/product development data by the applicants since many years. Keeping in view the pendency, the Board deliberated the matter in detail and also took opinion of PPMA and then decided that the firms shall initiate the product development and stability studies of submitted applications and intimate to Pharmaceutical Evaluation Cell (PEC) regarding procurement of raw material, initiation of product development and initiation of stability studies, by 31st December 2022. For all those applications for which Pharmaceutical Evaluation Cell will not receive any intimation regarding initiation of product development and stability studies, will be placed before the Board for decision"

The above decision of the Board was notified vide letter No. No. 320-DRB/ 2022(PE&R) dated 17-10-2022.

Later, Pakistan Pharmaceutical Manufacturers' Association through its Chairman (North) vide its letter No. PPMNAM-03312022 dated 30-12-2022 requested for Extension in Time for Submission of Stability Data of Form 5/5D.

Registration Board in its 324th meeting considered the request of PPMA and decided as under:

"Registration Board while considering the above cited request of PPMA reiterated that that the numerous applications are pending for submission of stability data/product development data by the applicants since many years causing by an un due backlog for the PE&R Division. Board also discussed that previously, opinion of PPMA was also taken while giving an opportunity to the firms to submit an intimation regarding initiation of product development & stability studies had been given to firms for submission of any had already been given a time period till by 31st December 2022. Keeping in view the above deliberation Board decided to refer the case to Authority for seeking guidance regarding timelines for submission of Stability Data of Form 5 / Form 5-D Files."

The matter was placed before the Authority in its 161st meeting held on 5-6 April, 2023 and the Authority decided as follow:

"The Authority noted that the numerous applications are pending for submission of stability data/product development data by the applicants since many years resulting in an un due backlog for the PE&R & BE&R Division. The applicants had failed to submit the requisite data after lapse of agreed deadline. Accordingly, the Authority advised the Registration Board to dispose of the cases on merit."

As per available record, stability data of following products has been submitted till 31st December, 2022 which is yet to be processed:

Name and Address of Manufacturer	Brand Name	Generic Name	Date of submission of stability data (R&I)
M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi	Glusimet XR 100/1000 mg Tablet	Sitagliptin Metformin Hcl	20210301
M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore	Valtril 200mg Tablet	Sacubitril Valsartan	20210301
M/s Reko Pharmacal Pvt Ltd. 13-Km, Multan Road, Lahore	Dexanil 30mg Capsule	Dexlansoprazole	20210302
M/s Reko Pharmacal Pvt Ltd. 13-Km, Multan Road, Lahore	Dexanil 60mg Capsule	Dexlansoprazole	20210302
M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura	Apixacol 2.5mg Tablet	Apixaban	20210315
M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura	Apixacol 5mg Tablet	Apixaban	20210315
M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura	Tenofojen 25mg Tablet	Tenofovir Alafenamide	20210315
M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad	Milna 12.5mg Tablet	Milnacipran	20210315

M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad	Milna 25mg Tablet	Milnacipran	20210315
M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad	Milna 50mg Tablet	Milnacipran	20210315
M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad	Milna 100mg Tablet	Milnacipran	20210315
M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore	Maxvir 100/400 mg Tablet	Sofosbuvir Velpatasvir	20210318
M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore	Brilliant 90mg Tablet	Ticagrelor	20210318
M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore	Davir 60mg Tablet	Daclatasvir	20210318
M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore	Sofos 400mg Tablet	Sofosbuvir	20210318

M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore	Empaglif 25mg Tablet	Empagliflozin	20210322
M/s Pharmasol (Pvt) Ltd, Plot No.549, Sundar Industrial Estate, Rawind Road, Lahore	Cinacalsol 60mg Tablet	Cinacalcet Hydrochloride	20210330
M/s Pharmasol (Pvt) Ltd, Plot No.549, Sundar Industrial Estate, Rawind Road, Lahore	Empazin 10mg Tablet	Empagliflozin	20210330
M/s Pharmasol (Pvt) Ltd, Plot No.549, Sundar Industrial Estate, Rawind Road, Lahore	Empazin 25mg Tablet	Empagliflozin	20210330
M/s Werrick Pharmaceuticals. 216-217,I-10/3, Industrial Area, Islamabad	Paineze 75mg Tablet	Tapentadol Hcl	20210409
M/s Glitz Pharma Plot No 2610. Industrial Triangle. Kahuta Road, Islamabad	Losagap-D 30mg Capsule	Dexlansoprazole	20210416
M/s Glitz Pharma Plot No 2610. Industrial Triangle. Kahuta Road, Islamabad	Losagap-D 60mg Capsule	Dexlansoprazole	20210416
M/s Otsuka Pakistan Ltd, F/4-9, Hub Industrial Tradin Estate, Distt Lasbell, Balochistan	Ibufen 400mg/100ml Injection	Ibuprofen	20210419
M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura	Ertujen 15mg Tablet	Ertugliflozin L-Pyroglutamic Acid	20210426
M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura	Ertujen 5mg Tablet	Ertugliflozin L-Pyroglutamic Acid	20210426
M/s Hudson Pharma Private Limited. Site-Plot No. D-93, North Western Industrial Zone, Port Qasim Authority, Pakistan	Brimson S 0.1% EYE Drops	Brimonidine Tartrate	20210427
M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore	Dapaglif 5mg Tablet	Dapagliflozin	20210504
M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore	Dapaglif 10mg Tablet	Dapagliflozin	20210504
M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore	Dapaglif-M 5/1000 mg Tablet	Dapagliflozin Metformin	20210504
M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore	Dapaglif-M 5/850 mg Tablet	Dapagliflozin Metformin	20210504

M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar	Ulprate 5mg Tablet	Ulipristal Acetate	20210504
M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi	Eflozin-M 12.5/850 mg Tablet	Empagliflozin Metformin Hcl	20210519
M/s Aspin Pharma Pvt Ltd. Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi 74900, Pakistan	Emaxy 10mg Tablet	Empagliflozin	20210521
M/s Aspin Pharma Pvt Ltd. Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi 74900, Pakistan	Emaxy 25mg Tablet	Empagliflozin	20210521
M/s Pharmasol (Pvt) Ltd, Plot No.549, Sundar Industrial Estate, Rawind Road, Lahore	Sofosol-V 400/100 mg Tablet	Sofosbuvir Velpatasvir	20210524
M/s Pharmasol (Pvt) Ltd, Plot No.549, Sundar Industrial Estate, Rawind Road, Lahore	Daklavin 60mg Tablet	Daclatasvir	20210524
M/s Pharmasol (Pvt) Ltd, Plot No.549, Sundar Industrial Estate, Rawind Road, Lahore	Sofosol 400mg Tablet	Sofosbuvir	20210524
M/s Pharmasol (Pvt) Ltd, Plot No.549, Sundar Industrial Estate, Rawind Road, Lahore	Sofosol-L 90/400 mg Tablet	Ledipasvir Sofosbuvir	20210524
M/s Pharmasol (Pvt) Ltd, Plot No.549, Sundar Industrial Estate, Rawind Road, Lahore	Dilazone 5mg Tablet	Metolazone	20210524
M/s High-Q Pharmaceuticals. Plot No.224, Sector 23, Korangi Industrial Area, Karachi	Myrdron 25mg Tablet	Mirabegron	20210527
M/s High-Q Pharmaceuticals. Plot No.224, Sector 23, Korangi Industrial Area, Karachi	Myrdron 50mg Tablet	Mirabegron	20210527
M/s The Searle Company Limited. 1st Floor, N.I.C.L. Building, Abbas Shaheed Road, Shahrahe Faisal, Karachi.	Peditral Low Liquid Regular Flavor	Potassium Chloride Sodium Chloride Sodium Citrate Dextrose Anhydrous	20210608
M/s The Searle Company Limited. 1st Floor, N.I.C.L. Building, Abbas Shaheed Road, Shahrahe Faisal, Karachi.	Peditral Low Liquid Orange Flavor	Potassium Chloride Sodium Chloride Sodium Citrate Dextrose Anhydrous	20210608
M/s The Searle Company Limited. 1st Floor, N.I.C.L. Building, Abbas Shaheed Road, Shahrahe Faisal, Karachi.	Peditral Low Liquid Bubble Gum Flavor	Potassium Chloride Sodium Chloride Sodium Citrate Dextrose Anhydrous	20210608

M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad	Rofscot 500mcg Tablet	Roflumilast	20210609
M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura	Cholimac 10mg Tablet	Obeticholic Acid	20210609
M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura	Cholimac 5mg Tablet	Obeticholic Acid	20210609
M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan	Wenopaa 25mg Tablet	Empagliflozin	20210614
M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan	Wenopaa 10mg Tablet	Empagliflozin	20210614
M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore	Delanz 60mg Capsule	Dexlansoprazole	20210615
M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore	Delanz 30mg Capsule	Dexlansoprazole	20210615
M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan	Empazin Plus 25/1000 mg XR Tablet	Empagliflozin Metformin Hcl	20210618
M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	Epagmin 5/1000 mg Tablet	Empagliflozin Metformin Hcl	20210621
M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	Epagmin 12.5/1000 mg Tablet	Empagliflozin Metformin Hcl	20210621
M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore	Valtril 100mg Tablet	Valsartan Sacubitril	20210621
M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore	Valtril 50mg Tablet	Valsartan Sacubitril	20210621
M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan	Azichlor 40/12.5 mg Tablet	Azilsartan as Medoxomil Chlorthalidone	20210621
M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan	Azichlor 40/25 mg Tablet	Azilsartan as Medoxomil Chlorthalidone	20210621
M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore	Trika 90mg Tablet	Ticagrelor	20210621

M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Levarol 0.63mg/3ml Inhalation Solution	Levabuterol	20210625
M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Levarol 1.25mg/3ml Inhalation Solution	Levabuterol	20210625
M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura	Jencholic 5mg Tablet	Obeticholic Acid	20210628
M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura	Jencholic 10mg Tablet	Obeticholic Acid	20210628
M/s AGP Limited. B-23, S.I.T.E. Karachi	Pixaban 2.5mg Tablet	Apixaban	20210708
M/s AGP Limited. B-23, S.I.T.E. Karachi	Pixaban 5mg Tablet	Apixaban	20210708
M/s Pharmasol (Pvt) Ltd, Plot No.549, Sundar Industrial Estate, Rawind Road, Lahore	Carsevel 800mg Tablet	Sevelamer Carbonate	20210712
M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore	Silosyn 8mg Capsule	Silodosin	20210712
M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore	Silosyn 8mg Capsule	Silodosin	20210712
M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Diacan-M 50/1000 mg Tablet	Canagliflozin Metformin Hcl	20210719
M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Diacan-M 150/1000 mg Tablet	Canagliflozin Metformin Hcl	20210719
M/s Martin Dow Limited. Plot No. 37, Sector 19, Korangi Industrial Area, Karachi	Jexma 10mg Tablet	Vortioxetine	20210802
M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore	Empaglif M 5/1000 mg Tablet	Empagliflozin Metformin Hcl	20210812
M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore	Empaglif M 12.5/500 mg Tablet	Empagliflozin Metformin Hcl	20210812
M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore	Empaglif M 12.5/1000 mg Tablet	Empagliflozin Metformin Hcl	20210812

M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore	Empaglif M 5/500 mg Tablet	Empagliflozin Metformin Hcl	20210812
M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore	Angiocare 90mg Tablet	Ticagrelor	20210920
M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Epalrest 50mg Tablet	Epalrestat	20210924
M/s Martin Dow Limited. Plot No. 37, Sector 19, Korangi Industrial Area, Karachi	Jexma 20mg Tablet	Vortioxetine	20210924
M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar	Nebival 5/80 mg Tablet	Nebivolol Valsartan	20211004
M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura	Empajen 12.5/1000 mg Tablet	Empagliflozin Metformin Hcl	20211011
M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura	Empajen 5/850 mg Tablet	Empagliflozin Metformin Hcl	20211011
M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura	Empajen 12.5/850 mg Tablet	Empagliflozin Metformin Hcl	20211011
M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura	Empajen 5/1000 mg Tablet	Empagliflozin Metformin Hcl	20211011
M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura	Esonap 500/20 mg Tablet	Naproxen Esomeprazole	20211011
M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi, Pakistan	Hilpiron 267mg Tablet	Pirfenidone	20211011
M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Amas 14mg Tablet	Teriflunomide	20211020
M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Amas 7mg Tablet	Teriflunomide	20211020
M/s Getz Pharma Pvt Ltd. 29-30/27, Korangi Industrial Area, Karachi.	Pirfen 801mg Tablet	Pirfenidone	20211026
M/s Getz Pharma Pvt Ltd. 29-30/27, Korangi Industrial Area, Karachi.	Pirfen 267mg Tablet	Pirfenidone	20211026

M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Glifzin 10mg Tablet	Empagliflozin	20211026
M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Glifzin 25mg Tablet	Empagliflozin	20211026
M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Dyspenal 100mg Tablet	Acotiamide Hcl Hydrate	20211028
M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore	Empamor 25mg Tablet	Empagliflozin	20211101
M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan	Acitan 10mg Tablet	Macitentan	20211101
M/s S.J & G Fazul Ellahie Pvt Ltd. E-46, S.I.T.E. Karachi-75700	Ates Injection 800mg/8ml	Ibuprofen	20211108
M/s S.J & G Fazul Ellahie Pvt Ltd. E-46, S.I.T.E. Karachi-75700	Ates Injection 800mg/8ml	Ibuprofen	20211108
M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan	Boschofen 400/4ml Injection	Ibuprofen	20211116
M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan	Glitab 5/500 mg XR Tablet	Dapagliflozin Metformin Hcl	20211122
M/s NovaMed Pharmaceuticals (Pvt) Ltd. 28-Km, Ferozepure Road, Lahore.	Angiocare 60mg Tablet	Ticagrelor	20211124
M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Diacan-M 50/500 mg Tablet	Canagliflozin Metformin Hcl	20211125
M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Diacan-M 150/500 mg Tablet	Canagliflozin Metformin Hcl	20211125
M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan	Boschofen 600mg Infusion	Ibuprofen	20211126
M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore	Apiban 5mg Tablet	Apixaban	20211130
M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore	Apiban 2.5mg Tablet	Apixaban	20211130
M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad	Emp-Met 5/1000 mg Tablet	Empagliflozin Metformin Hcl	20211201
M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad	Emp-Met 12.5/1000 mg Tablet	Empagliflozin Metformin Hcl	20211201

M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad	Emp-Met 12.5/500 mg Tablet	Empagliflozin Metformin Hcl	20211201
M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad	Emp-Met 5/500 mg Tablet	Empagliflozin Metformin Hcl	20211201
M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad	Sitawil XR 100/1000 mg Tablet	Sitagliptin Phosphate Monohydrate Metformin Hcl	20211206
M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad	Sitawil XR 50/1000 mg Tablet	Sitagliptin Phosphate Monohydrate Metformin Hcl	20211206
M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad	Sitawil XR 50/500 mg Tablet	Sitagliptin Phosphate Monohydrate Metformin Hcl	20211206
M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore	Empacor 25mg Tablet	Empagliflozin	20211207
M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore	Empacor 10mg Tablet	Empagliflozin	20211207
M/s NovaMed Pharmaceuticals (Pvt) Ltd. 28-Km, Ferozepure Road, Lahore.	Nesmet 12.5/500 mg Tablet	Alogliptin Metformin Hcl	20211217
M/s NovaMed Pharmaceuticals (Pvt) Ltd. 28-Km, Ferozepure Road, Lahore.	Nesmet 12.5/1000 mg Tablet	Alogliptin Metformin Hcl	20211217
M/s Pharmasol (Pvt) Ltd, Plot No.549, Sundar Industrial Estate, Rawind Road, Lahore	Glyfozin-M 12.5/500 mg Tablet	Empagliflozin Metformin Hcl	20211222
M/s Pharmasol (Pvt) Ltd, Plot No.549, Sundar Industrial Estate, Rawind Road, Lahore	Glyfozin-M 12.5/1000 mg Tablet	Empagliflozin Metformin Hcl	20211222
M/s Pharmasol (Pvt) Ltd, Plot No.549, Sundar Industrial Estate, Rawind Road, Lahore	Canazin 300mg Tablet	Canagliflozin	20211222
M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar	Emzon-M 5/1000 mg Tablet	Empagliflozin Metformin	20211222
M/s Life Pharmaceutical Company. 24-III, Industrial Estate, Multan, Pakistan	Danzo 30mg Capsule	Dexlansoprazole	20211223
M/s Life Pharmaceutical Company. 24-III, Industrial Estate, Multan, Pakistan	Danzo 60mg Capsule	Dexlansoprazole	20211223

M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan	Depxet 5mg Tablet	Vortioxetine	20220103
M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan	Depxet 10mg Tablet	Vortioxetine	20220103
M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan	Depxet 15mg Tablet	Vortioxetine	20220103
M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan	Depxet 20mg Tablet	Vortioxetine	20220103
M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Baclo 5mg/5ml Syrup	Baclofen	20220104
M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Canaloz 300mg Tablet	Canagliflozin	20220119
M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Glipan 25/5 mg Tablet	Empagliflozin Linagliptin	20220119
M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan	Esli 200mg Tablet	Eslicarbazepine Acetate	20220125
M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan	Esli 400mg Tablet	Eslicarbazepine Acetate	20220125
M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan	Esli 600mg Tablet	Eslicarbazepine Acetate	20220125
M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan	Esli 800mg Tablet	Eslicarbazepine Acetate	20220125
M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore	Bropin 400mg/ml Injection	Ibuprofen	20220131
M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar	Megron 50mg Tablet	Mirabegron	20220131
M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar	Megron 25mg Tablet	Mirabegron	20220131
M/s High-Q Pharmaceuticals. Plot No.224, Sector 23, Korangi Industrial Area, Karachi	Letrum 5mg Tablet	Linagliptin	20220209
M/s Titlis Pharma. 528-A, Sundar Industrial Estate, Raiwind Road, Lahore	Pentadol 50mg Tablet	Tapentadol	20220216

M/s Titlis Pharma. 528-A, Sundar Industrial Estate, Raiwind Road, Lahore	Pentadol 100mg Tablet	Tapentadol	20220216
M/s Titlis Pharma. 528-A, Sundar Industrial Estate, Raiwind Road, Lahore	Pentadol 75mg Tablet	Tapentadol	20220216
M/s High-Q Pharmaceuticals. Plot No.224, Sector 23, Korangi Industrial Area, Karachi	Meltog 25mg Tablet	Agomelatine	20220304
M/s Semos Pharmaceuticals (Pvt) Ltd, Plot No.11, Sector 12-A, North Karachi, industrial Area, Karachi.	Dexprazole 30mg Capsule	Dexlansoprazole	20220317
M/s Semos Pharmaceuticals (Pvt) Ltd, Plot No.11, Sector 12-A, North Karachi, industrial Area, Karachi.	Dexprazole 60mg Capsule	Dexlansoprazole	20220317
M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	Irmax 100/5 mg Tablet	Irbesartan Amlodipine	20220329
M/s Martin Dow Limited. Plot No. 37, Sector 19, Korangi Industrial Area, Karachi	Jexma 5mg Tablet	Vortioxetine	20220401
M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan	Ludil Opthalmic Solution 0.02%	Netarsudil	20220401
M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK	Esonap 500/20 mg Tablet	Naproxen Esomeprazole	20220405
M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan	Cambito Opthalmic Suspension	Brinzolamide Brimonidine	20220411
M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi	Emgly 25mg Tablet	Empagliflozin	20220415
M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi	Emgly 10mg Tablet	Empagliflozin	20220415
M/s NovaMed Pharmaceuticals (Pvt) Ltd. 28-Km, Ferozepure Road, Lahore.	Auron Tablets 25mg	Mirabegron	20220423
M/s The Searle Company Limited. 1st Floor, N.I.C.L Building, Abbasi Shaheed Road, Shahrah-e-Faisal, Karachi	Tapendol XR 250mg Tablets	Tapentadol Hcl	20220425
M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Neutrol 75mg Tablets	Tapentadol As Hcl	20220429
M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan	Swiflo 4mg Capsule	Silodosin	20220509

M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan	Swiflo 8mg Capsule	Silodosin	20220509
M/s NovaMed Pharmaceuticals (Pvt) Ltd. 28-Km, Ferozepure Road, Lahore.	Axhert 50/500 mg Tablet	Sitagliptin Metformin Hcl	20220509
M/s Aspin Pharma Pvt Ltd. Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi 74900, Pakistan	Etorid 90mg Tablet	Etoricoxib	20220519
M/s Aspin Pharma Pvt Ltd. Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi 74900, Pakistan	Etorid 120mg Tablet	Etoricoxib	20220519
M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura	Darimac 15mg Tablet	Darifenacin Hydrobromide	20220519
M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura	Darimac 7.5mg Tablet	Darifenacin Hydrobromide	20220519
M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar	Gabra 25mg ER tablet	Mirabegron	20220519
M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Glifo Met Tablet 5/1000mg	Dapagliflozin Propanediol Metformin Hcl	20220519
M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Glifo Met Tablet 5/850mg	Dapagliflozin Propanediol Metformin Hcl	20220519
M/s Paramount Pharmaceuticals. Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad	Lansodex 60mg Capsule	Dexlansoprazole	20220528
M/s Paramount Pharmaceuticals. Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad	Lansodex 30mg Capsule	Dexlansoprazole	20220528
M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan	Voxet 5mg Tablet	Vortioxetine Hydrobromide	20220603
M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan	Voxet 20mg Tablet	Vortioxetine Hydrobromide	20220603
M/s Reko Pharmacal Pvt Ltd. 13-Km, Multan Road, Lahore	Mycosin 125mg Tablet	Terbinafine Hcl	20220607
M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan	Xempo 5/1000 mg Tablet	Empagliflozin Metformin	20220608

M/s Aptcure Pvt Ltd 8- Pharma City, 30 km Multan Road, Lahore	Dezole 30mg Capsules	Dexlansoprazole	20220613
M/s Aptcure Pvt Ltd 8- Pharma City, 30 km Multan Road, Lahore	Dezole 60mg Capsules	Dexlansoprazole	20220613
M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Neutolv 30mg Tablet	Tolvaptan	20220617
M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Neutolv 15mg Tablet	Tolvaptan	20220617
M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore	Ticol 90mg Tablet	Ticagrelor	20220620
M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Lura Tablet 20mg	Lurasidone HCl	20220620
M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Emglif-M XR Tablet 10mg/1000mg	Empagliflozin Metformin	20220623
M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Emglif-M XR Tablet 25mg/1000mg	Empagliflozin Metformin	20220623
M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Rajumat 50/500mg XR Tablet	Sitagliptin Metformin	20220623
M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Rajumat 50/1000mg XR Tablet	Sitagliptin Metformin	20220623
M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan	Ocaliva/Obit/Chico Tablet 10mg	Obeticholic Acid	20220627
M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan	Ocaliva/Obit/Chico Tablet 5mg	Obeticholic Acid	20220627
M/s Martin Dow Limited, Plot No.37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan	Prelin CR tablet 82.5mg	pregabalin	20220629
M/s Mega pharmaceuticals Limited 27-km Rawind Road, Lahore	Y-Nil capsule 60mg	Orlistat	20220704
M/s Mega pharmaceuticals Limited 27-km Rawind Road, Lahore	Y-Nil capsule 120mg	Orlistat	20220704
M/s NovaMed Pharmaceuticals (Pvt) Ltd. 28-Km, Ferozepure Road, Lahore.	Empilig 10/5mg Tablet	Empagliflozin Linagliptin	20220706
M/s NovaMed Pharmaceuticals (Pvt) Ltd. 28-Km, Ferozepure Road, Lahore.	Empilig 25/5mg Tablet	Empagliflozin Linagliptin	20220706

M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore	Empazin 10mg Tablet	Empagliflozin	20220707
M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore	Empazin 25mg Tablet	Empagliflozin	20220707
M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore	Dapzin 10mg Tablet	Dapagliflozin	20220707
M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar	VasNeb 5/80mg tablet	Nebivolol Valsartan	20220707
M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	Luridon Tablet 80mg	Lurasidone HCl	20220718
M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	Luridon Tablet 40mg	Lurasidone HCl	20220718
M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	Luridon Tablet 20mg	Lurasidone HCl	20220718
M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	Luridon Tablet 60mg	Lurasidone HCl	20220718
M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan	Angiclor 90mg Tablet	Ticagrelor	20220719
M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan	EM-Met 12.5/1000mg tablet	Metformin HCl Empagliflozin	20220720
M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore	Begrem Tablet 25mg	Mirabegron	20220725
M/s Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore	Begrem Tablet 50mg	Mirabegron	20220725
M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi	Rast-VT Tablet 10/160mg	Rosvastatin Valsartan	20220801
M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi	Rast-VT Tablet 10/80mg	Rosvastatin Valsartan	20220801
M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi	Rast-VT Tablet 20/80mg	Rosvastatin Valsartan	20220801
M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi	Rast-VT Tablet 20/160mg	Rosvastatin Valsartan	20220801
M/s Aspin Pharma (Pvt) Ltd. Plot No.10 &25, Sector 20, Korangi Industrial Area, Karachi.	Dagli tablet 5mg	Dapagliflozin	20220802

M/s Aspin Pharma (Pvt) Ltd. Plot No.10 &25, Sector 20, Korangi Industrial Area, Karachi.	Dagli tablet 10mg	Dapagliflozin	20220802
M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Azilsan 40mg Tablet	Azilsartan Medoxomil	20220815
M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Esoprox 375/20mg Tablet	Esomeprazole Magnesium	20220815
M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad	Trifort DS 75/650 mg Tablet	Tramadol Paracetamol	20220815
M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi	Zontiv-CD tablet 40/12.5mg	Azilsartan medoxomil Chlorthalidone	20220816
M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi	Zontiv-CD tablet 40/25mg	Azilsartan medoxomil Chlorthalidone	20220816
M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi	Flurocort tablet 0.1mg	Fludrocortisone Acetate	20220825
M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Velamer-C 0.8g Sachet	Savelamer Carbonate	20220825
M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Velamer-C 2.4g Sachet	Savelamer Carbonate	20220825
M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi	Lulucon Cream 1% w/w	Luliconazole	20220831
M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Taflu eye drops 0.015mg/ml	Tafluprost	20220905
M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Esoprox 500/20mg Tablet	Naproxen Esomeprazole	20220907
M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Lorsin 10mg Tablets	Lorcaserin HCl	20220907
M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura	Mcbriet 534 mg tablet	Pirfenidone	20220908
M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura	Mcbriet 267 mg tablet	Pirfenidone	20220908
M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura	Mcbriet 801 mg tablet	Pirfenidone	20220908

M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar	Winovir 400mg tablet	Sofosbuvir	20220913
M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Gvia-S tablet 50/10mg	Sitagliptin Simvastatin	20220922
M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Gvia-S tablet 100/20mg	Sitagliptin Simvastatin	20220922
M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi	Brinzol Ophthalmic Suspension 10mg+2mg	Brinzolamide Brimonidine Tartrate	20220923
M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Neutaxo 5/80mg tablet	Nebivolol Valsartan	20220926
M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Aprast 10mg tablets	Apremilast	20220927
M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan	Ovuline Tablets 0.5mg	Cabergoline	20220928
M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Aprast 20mg tablets	Apremilast	20220930
M/s Martin Dow Limited, Plot No.37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan	Prelin CR tablet 165mg	pregabalin	20221003
M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Molta Tablet 665mg	Paracetamol	20221006
M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Motais Ointment 0.1%	Mometasone Furate	20221006
M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan	Tafilu ophthalmic solution 0.0015%	Tafluprost	20221007
M/s Martin Dow Limited, Plot No.37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan	Prelin CR tablet 330mg	pregabalin	20221007
M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Aprast 30mg tablets	Apremilast	20221010
M/s Aspin Pharma (Pvt) Ltd. Plot No.10 &25, Sector 20, Korangi Industrial Area, Karachi.	Dagli 5/1000mg tablet	Dapagliflozin Metformin Hcl	20221011

M/s Aspin Pharma (Pvt) Ltd. Plot No.10 &25, Sector 20, Korangi Industrial Area, Karachi.	Dagli 5/850mg tablet	Dapagliflozin Metformin Hcl	20221011
M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi	Roflubar 500mcg Tablet	Roflumilast	20221012
M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Daplozmet XR tablet 5/500mg	Dapagliflozin Metformin Hcl	20221017
M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Daplozmet XR tablet 10/500mg	Dapagliflozin Metformin Hcl	20221017
M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Daplozmet XR tablet 10/1000mg	Dapagliflozin Metformin Hcl	20221017
M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Daplozmet XR tablet 5/1000mg	Dapagliflozin Metformin Hcl	20221017
M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Ertu 5mg Tablet	Ertugliflozin	20221026
M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Ertu 15mg Tablet	Ertugliflozin	20221026
M/s High-Q Pharmaceuticals. Plot No.224, Sector 23, Korangi Industrial Area, Karachi	Satril 97+103mg tablet	Sacubitril Valsartan	20221030
M/s High-Q Pharmaceuticals. Plot No.224, Sector 23, Korangi Industrial Area, Karachi	Satril 49+51mg tablet	Sacubitril Valsartan	20221030
M/s High-Q Pharmaceuticals. Plot No.224, Sector 23, Korangi Industrial Area, Karachi	Satril 24+26mg tablet	Sacibitril Valsartan	20221030
M/s Getz Pharma Pvt Ltd. 29-30/27, Korangi Industrial Area, Karachi.	Lina 5mg Tablet	Linagliptin	20221103
M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad	Sunny D Tablet 30,000 IU	Vitamin D3	20221104
M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi	Aczo gel 5%	Dapsone	20221107
M/s Mega pharmaceuticals Limited 27-km Rawind Road, Lahore	Tamsolid 0.4mg	Tamsulosin HCl SR Pellet 2%	20221114
M/s Mega pharmaceuticals Limited 27-km Rawind Road, Lahore	Tamsolid 0.8mg	Tamsulosin HCl SR Pellet 2%	20221114
M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan	Preka oral Solution	Pregabalin	20221114
M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad	Trapeze Plus XR 100/1000 mg Tablet	Sitagliptin Metformin	20221116

M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Neuhal Cream 0.05%	Halobetasol Propionate Ointment 0.05% w/w	20221118
M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Nupreced 200mcg/2ml inejction	Dexmedetomide	20221118
M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Gluta Dry powder Vial inj.	Glutathione	20221118
M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore	Dipos Gel 5%	Dapsone	20221118
M/s AGP Limited. B-23, S.I.T.E. Karachi	Cholicin 5mg tablet	Obeticholic Acid	20221121
M/s AGP Limited. B-23, S.I.T.E. Karachi	Cholicin 10mg tablet	Obeticholic Acid	20221121
M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Idyll 20mg tabelts	Vortioxetine	20221121
M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Idyll 10mg tabelts	Vortioxetine	20221121
M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Solif-T MR 0.4+6mg	Tamsulosin Hydrochloride Solifenacin succinate	20221122
M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	Ludin 7mg tablet	Semaglutide	20221122
M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	Ludin 3mg tablet	Semaglutide	20221122
M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	Zilsar 40mg tablet	Azilsartan	20221122
M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi	Zilsar 80mg tablet	Azilsartan	20221122
M/s Pharma Lord, 12km, Lahore Road, Layyah	Dlans 30mg capsule	Dexlansoprazole	20221124
M/s Pharma Lord, 12km, Lahore Road, Layyah	Dlans 60mg capsule	Dexlansoprazole	20221124
M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan	fortazim Plus	Ceftazidime Avibactam	20221124
M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan	Otoxel otic Solution	ciprofloxacin as HCl Fluocinolone Acetonide	20221128

M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad	Valoglif 10mg tablet	Empagliflozin	20221129
M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad	Cagrelor 90mg tablet	Ticagrelor	20221205
M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa	Flexia 120mg tablet	Etroricoxib	20221206
M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa	Flexia 90mg tablet	Etroricoxib	20221206
M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi	Izolol Eye Drops 1%+0.5%	Brinzolamide Timolol	20221209
M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Ertusita 5/100 mg Tablet	Ertugliflozin Sitagliptin	20221210
M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Ertusita 15/100 mg Tablet	Ertugliflozin Sitagliptin	20221210
M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan	Zenwo 5mg tablet	Dapagliflozin	20221212
M/s EG Pharmaceuticals. Plot. No. 13-A, Industrial Triangle, Kahuta Road, Islamabad	Dexoloc Capsule 30mh	Dexlansoprazole	20221212
M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore	Migrip Tablet 10mg	Rizatriptan	20221219
M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore	Migrip Tablet 5mg	Rizatriptan	20221219
M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Ertumet 7.5/500 mg Tablet	Ertugliflozin Metformin	20221220
M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Ertumet 2.5/500 mg Tablet	Ertugliflozin Metformin	20221220
M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Ertumet 2.5/1000 mg Tablet	Ertugliflozin Metformin	20221220
M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Ertumet 7.5/1000 mg Tablet	Ertugliflozin Metformin	20221220
M/s Sami Pharmaceuticals (Pvt) Ltd, F-95, Off.Hub River Road, S.I.T.E Karachi	Elinjec 500mg /10ml injection	Ferric Carboxymaltose	20221222
M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan	Valsa 24/26mg Tablets	Sacubitril Valsartan	20221223

M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan	Valsa 49/51mg Tablets	Sacubitril Valsartan	20221223
M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan	Tacvo 90mg tablets	Ticagrelor	20221223
M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan	Linavo 5mg tablts	Liagliptin	20221223
M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan	Empaglin 25mg /5mg tablet	Empagliflozin Linagliptin	20221226
M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan	Empaglin 10mg /5mg tablet	Empagliflozin Linagliptin	20221226
M/s Highnoon Laboratories Ltd. 17.5 km, Multan Road, Lahore	Lina 5mg Tablet	Linagliptin	20221227
M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Revonap 375/20mg tablet	Naproxen Esomeprazole	20221227
M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan	Zenwo 10mg tablet	Dapagliflozin	20221228
M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Xab tablets 2.5mg	Apixaban	20221228
M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan	Xab tablets 5mg	Apixaban	20221228
M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan	wencuval 97+103mg tablet	Sacubitril Valsartan	20221228
M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Gliem-M 12.5/1000mg tablet	Ertugliflozin Metformin	20221229
M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Gliem-M 5/1000mg tablet	Ertugliflozin Metformin	20221229
M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Gliem-M 5/500mg tablet	Ertugliflozin Metformin	20221229
M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Gliem-M 12.5/500mg tablet	Ertugliflozin Metformin	20221229
M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Daplo-M XR 10/500mg tablets	Dapaglifozin Metformin HCl	20221229

M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Daplo-M XR 10/1000mg tablets	Dapaglifozin Metformin HCl	20221229
M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Daplo-M XR 5/1000mg tablets	Dapaglifozin Metformin HCl	20221229
M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Daplo-M XR 5/500mg tablets	Dapaglifozin Metformin HCl	20221229
M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Emplina 10/5mg tablet	Empaglifozin Linagliptin	20221229
M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Emplina 25/5mg tablet	Empaglifozin Linagliptin	20221229
M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Daplo 5mg tablet	Dapagliflozin	20221229
M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Daplo 10mg tablet	Dapagliflozin	20221229
M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Rexira 1mg tablet	Brexpiprazole	20221229
M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Rexira 2mg tablet	Brexpiprazole	20221229
M/s Navegal Lahoratories. 41/1-A-2, Phase -1, Industeial Estate, Hattar	Gliem 25mg tablets	Empagliflozin	20221229
M/s Hicon Pharmaceuticals, 131-Industrial Estate, Hayatabad, Peshawar	Dapxin 5mg tablet	Dapagliflozin	20221229
M/s Hicon Pharmaceuticals, 131-Industrial Estate, Hayatabad, Peshawar	Dapxin 10mg tablet	Dapagliflozin	20221229
M/s Hicon Pharmaceuticals, 131-Industrial Estate, Hayatabad, Peshawar	Empxin 10mg tablet	Empagliflozin	20221229
M/s Hicon Pharmaceuticals, 131-Industrial Estate, Hayatabad, Peshawar	Empxin 25mg tablet	Empagliflozin	20221229
M/s Hicon Pharmaceuticals, 131-Industrial Estate, Hayatabad, Peshawar	Empxin-M 5/500mg tablet	Metformin HCl Empagliflozin	20221229
M/s Hicon Pharmaceuticals, 131-Industrial Estate, Hayatabad, Peshawar	Empxin-M 12.5/1000mg tablet	Metformin HCl Empagliflozin	20221229

M/s Nawan Laboratories (Pvt) Ltd. 136 sector 15 Korangi Industrial Area Karachi.	Noxilant 60mg capsule	Deslansoprazole	20221229
M/s Nawan Laboratories (Pvt) Ltd. 136 sector 15 Korangi Industrial Area Karachi.	Noxilant 30mg capsule	Deslansoprazole	20221229
M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Ranalaz 375mg tablet	Ranolazine	20221230
M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Ranalaz 500mg tablet	Ranolazine	20221230
M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi	Ranalaz 750mg tablet	Ranolazine	20221230
M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar	Denset 2mg tablet	Dienogest	20221230
M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore	Trint 10mg tablet	Vortioxetine	20221230
M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate, Raiwind,Lahore	Trint 20mg tablet	Vortioxetine	20221230
M/s Pharmasol (Pvt) Ltd, Plot No.549, Sundar Industrial Estate, Rawind Road, Lahore	Dorisol injection 250mg	Doripenem Monohydrate	20221230
M/s Pharmasol (Pvt) Ltd, Plot No.549, Sundar Industrial Estate, Rawind Road, Lahore	Dorisol injection 500mg	Doripenem Monohydrate	20221230

Submitted for consideration of the Board, please.

Decision: Registration Board discussed the decision of Authority in detail and after through deliberations decided in line with decision of the Authority to consider only those registration applications for which stability study data has been submitted till 31st December, 2022. Stability study data shall be processed as per its queue. Registration Board further decided that all those registration applications requiring stability study data (applied on Form5/Form 5D) for which the requite data has not been submitted till 31st December, 2022, shall be considered as disposed off and the applicant firms shall submit its product development and stability data on Form-5F which will be considered on its turn in queue of Form 5F.

Item No. V Division of Pharmaceutical Evaluation & Registration

Pharmaceutical Evaluation Cell (PEC)

Sr. No	Name of Evaluator	Title
1.	Mr. Ammar Ashraf Awan	Evaluator PEC-II
2.	Dr. M. Haseeb Tariq	Evaluator PEC-III
3.	Mst. Farzana Raja	Evaluator PEC-IV
4.	Mst. Iqra Aftab	Evaluator PEC-V
5.	Mr. M. Zubair Masood	Evaluator PEC-IX
6.	Ms. Najia Saleem	Evaluator PEC-X
7.	Dr. Farhadullah	Evaluator PEC-XI
8.	Mr. Shahid Nawaz	Evaluator PEC-XIII
9.	Ms. Saima Hussain	Evaluator PEC-XV
10.	Ms. Sana Kanwal	Evaluator PEC-XX
11.	Mr. M. Tahir Waqas	Evaluator PEC-XXI
12.	Ms. Maham Misbah	Evaluator PEC-XXIII
13.	Mr. Muneeb Ahmed Cheema	Deputy Director (PE&R)
14.	Mr. Salateen Waseem Philip	Deputy Director (PE&R)

Case no. 01 Registration applications of Form 5F (Human)

1.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seraph Pharmaceutical Plot no. 210, Industrial Triangle Kahuta Road, Islamabad.**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceutical Plot no. 210, Industrial Triangle Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 2628 dated 27-01-2022
	Details of fee submitted	Rs.30,000/- dated 21-12-2021
	The proposed proprietary name / brand name	**Cyloflex 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Cyclobenzaprine Hydrochloride …….5mg
	Pharmaceutical form of applied drug	Yellow round unscored biconvex film coated tablets.
	Pharmacotherapeutic Group of (API)	Skeletal Muscle Relaxants
	Reference to Finished product specifications	USP
	Proposed Pack size	1×10’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	FLEXERIL Merck & Co. Inc., West Point, PA 19486, USA. McNeil Consumer & Specialty Pharmaceuticals, Fort Washington, PA 19034 FDA
	For generic drugs (me-too status)	Eumytic 5mg Tablet, Atco Laboratories, Reg. No. 067273
	GMP status of the Finished product manufacturer	GMP certificate issued on the basis of inspection conducted on 11/07/2019.
	Name and address of API manufacturer.	VASUDHA PHARMA CHEM LTD 78/A, Vengalrao Nagar, Hyderabad-38, Telangana-India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical

		procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 6 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (T-001, T-002, T-003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is FLEXERIL 5mg tablet by Merck & Co. Inc., West Point, PA 19486, USA, performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is FLEXERIL 5mg tablet Tablet by Merck Pharma in Acid media (pH 1.2), Buffer pH 4.5 and Phosphate Buffer (pH 6.8). The values for f2 is in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, recovery, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	VASUDHA PHARMA CHEM LTD 78/A, Vengalrao Nagar, Hyderabad-38, Telangana-India		
API Lot No.	CBP/1911044		
Description of Pack (Container closure system)	1x10 tablets in alu-alu blisters packed in card board unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	5000 tablets	5000 tablets	5000 tablets
Manufacturing Date	02-2020	02-2020	02-2020
Date of Initiation	05-02-2020	05-02-2020	05-02-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 73252/TS/2022 issued by DCA, Telangana valid till 04/03/2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No.65/2020/DRAP-AD-CD(I&E) dated 07/01/2020 is submitted. API Cyclobenzaprine HCl for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

2.	Name, address of Applicant / Marketing Authorization Holder	**M/s Kaizen Pharmaceuticals (Pvt.) Ltd., E-127-129, North Western Industrial Zone, Bin Qasim, Karachi-75020, Pakistan.**
	Name, address of Manufacturing site.	Kaizen Pharmaceuticals (Pvt.) Ltd., E-127-129, North Western Industrial Zone, Bin Qasim, Karachi-75020, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒New Drug Product (NDP) ☐Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No: 27277 dated :01.10.2021
	Details of fee submitted	Rs. 25,000/- dated 15/09/2021 Rs. 50000/- dated 04.05.2021
	The proposed proprietary name / brand name	**Tornil Mouthwash 0.25%**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: 2.5mg of Flurbiprofen
	Pharmaceutical form of applied drug	Clear pale bluish colored, methanol flavored liquid
	Pharmacotherapeutic Group of (API)	NSAIDs (Non-steroidal anti-inflammatory drugs)
	Reference to Finished product specifications	Innovator's specs

	Proposed Pack size	100ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Froben Gola 0.25% by Abbot
	For generic drugs (me-too status)	N/A
	GMP status of the Finished product manufacturer	GMP certificate granted on 16.09.2020 valid till 27.08.2021
	Name and address of API manufacturer.	Hy-Gro Chemicals Pharmtek Pvt. Ltd Plot No. 174 Progressive Industrial Society IDA Bollaram Jinnaram Mandal Sanga Reddy District Telangana India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Flurbiprofen is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (FB-2016/04/39, FB-2016/04/40 , FB-2016/04/41)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Froben Gola 0.25% by Mylan products Limited by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form)..
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		

Manufacturer of API	Hy-Gro Chemicals Pharmtek Pvt. Ltd		
API Lot No.			
Description of Pack (Container closure system)	Pet bottle		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 18 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6,9,12,18(Months)		
Batch No.	TF-03	TF-04	TF-05
Batch Size	1L	1L	1L
Manufacturing Date	Aug/2018	Aug/2018	Aug/2018
Date of Initiation	01.09.2018	01.09.2018	01.09.2018
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Rofair 500mcg Tablet", which was conducted on 25th June, 2019, and was presented in 290th meeting of Registration Board. The report confirms: □ The HPLC software is 21CFR Compliant. □ Audit trail on testing reports is available □ Firm has adequate monitoring and controls for stability chambers. Chambers are controlled and monitored through software having alarm system for alerts as well
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. L.Dis.No:54409/TS/2021 issued by Drug Control Administration Telangana India valid till 16/02/2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	DHL No.XMLPI6.2/90-1604 dated 21/03/2017
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks:

Registration Board in its 324th was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

3.2. S.4.4 Batch analysis of API by the FPP manufacturer for the batch used for manufacturing of finished product for stability testing.

3.2.S.4.5 CoA of reference standard.

3.2. P.2 Pharmaceutical equivalence studies needs to be submitted with reference product having details of brand name, batch No, manufacturer.
3.2. P.3 Batch size does not reflect the Pack size/ filled volume per pack. This needs to be clarified as the same is not mentioned in manufacturing process and not on the CoA of three batches placed on stability.
3.2. P.7 The quantity of the units produced needs to be justified w.r.t stability testing.
There CoAs submitted for API (Flurbiprofen) which indicates Mfg date of November 2018 however stability testing was initiated in Sep. 2018. This needs clarification.
Justification for not importing API with permission of DRAP. Further Copy of DHL does not reflect the date of import of API. Complete import documentation of API needs to be submitted.
Evidence of Approval of formulation in RRA.

	Query	**Response**
1.	3.2. S.4.4 Batch analysis of API by the FPP manufacturer for the batch used for manufacturing of finished product for stability testing.	The firm has submitted the Batch analysis of API indicating tests for description, solubility, Identification, M.P, LOD, residue on ignition and assay.
2.	3.2.S.4.5 CoA of reference standard.	The firm has submitted copy of COA of working standard having batch no: WS-FB-EP/JP/BP/USP/IP/KP-20-01
3.	Pharmaceutical equivalence studies needs to be submitted with reference product having details of brand name, batch No, manufacturer.	The firm has submitted pharmaceutical equivalence with Forben Gola 0.25% Mouthwash (batch No. 1082193).
4.	3.2. P.3 Batch size does not reflect the Pack size/ filled volume per pack. This needs to be clarified as the same is not mentioned in manufacturing process and not on the CoA of three batches placed on stability.	160 ml bottle is the pack size and 11 bottles per batch of 2L have been manufactured.
5.	3.2. P.7 The quantity of the units produced needs to be justified w.r.t stability testing.	The firm submitted that 3bottles per batch are used for accelerated testing and 8 bottles per batch are used for real time testing time points. However this needs justifivcation with reference to the applicable guid;eines of stability studies and product development.
6.	There CoAs submitted for API (Flurbiprofen) which indicates Mfg date of November 2018 however stability testing was initiated in Sep. 2018. This needs clarification.	COA of wrong source of API submitted by mistake. The old source does not exist anymore. We have manufactured trial batches from API purchased from Hygro Chemicals. The new baches are TF-06,07 and 08. The firm has submitted the stability data of new batches.
7.	Justification for not importing API with permission of DRAP. Further Copy of DHL does not reflect the date of import of API. Complete import documentation of API needs to be submitted.	Copy of Import License issued by DRAP Karachi dated 13.03.2019 has been submitted for import of API from M/s Hygro Chemicals Pharmtek Pvt Ltd, Telangana India.
8.	Evidence of Approval of formulation in RRA.	Firm has submitted copy of PIL for Froben Throat 250mg/100ml mouthwash indicating BGP Product Srl Rome Italy as MAH and AbbVie Srl-SR 148 Pontina Aprilia Italy as manufacturer/producer. Document was made available by AIFA on 26.01.2021.

Decision: Deferred for submission of following:

- **Scientific justification of the batch size of the trial batches against the number of units required for the performance of stability studies at both accelerated (6 months) & long term conditions (till**

	claimed shelf life) along with details of units consumed at each time point as per submitted drug product analytical procedure and stability protocol. • **Full fee of registration i.e., Rs. 75,000/- for pre-approval change in stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
3.	Name, address of Applicant / Marketing Authorization Holder	**M/s Pacific Pharmaceuticals Ltd. 30 Km Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Pacific Pharmaceuticals Ltd. 30 Km Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 30930 dated 11-11-2021
	Details of fee submitted	Rs.30,000/- dated 04-06-2021
	The proposed proprietary name / brand name	**Ritufen 1% cream**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	One gram of cream contains 10 mg Terbinafine hydrochloride equivalent to 8.89 mg of Terbinafine.
	Pharmaceutical form of applied drug	Topical Cream
	Pharmacotherapeutic Group of (API)	Allylamine antifungal ATC Code: D01BA02
	Reference to Finished product specifications	In-House specifications
	Proposed Pack size	10 gm
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Terbinafine 1 % Cream MHRA UK
	For generic drugs (me-too status)	Terbisil Cream 1% w/w Saffron Pharmaceuticals (Pvt) Ltd.
	GMP status of the Finished product manufacturer	GMP certificate issued on 01-11-2021
	Name and address of API manufacturer.	Zhejiang East-Asia Pharmaceutical Co. Ltd. Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, P.R. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers,

		description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Long-term stability studies were performed at a storage temperature of 30°C±2°C/65%±5% RH for 48 months. Accelerated stability studies were performed at a temperature of 40±2°C/75%±5% RH for 6 months.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence Studies against the reference product of "Lamisil cream" by Novartis Ltd.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificty.

STABILITY STUDY DATA			
Manufacturer of API	Zhejiang East-Asia Pharmaceutical Co. Ltd. Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, P.R. China		
API Lot No.	LDP190065		
Description of Pack (Container closure system)	Printed aluminum tubes with white plastic cap is packed in printed sale carton along with information leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 9 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9 (Months)		
Batch No.	TTC00103P	TTC00203P	TTC00303P
Batch Size	5 kg	5 kg	5 kg
Manufacturing Date	03-2020	03-2020	03-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
3.	Documents for the procurement of API with approval from DRAP (in case of import).	--

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator:

Section#	Observations	Firm's response
1.5.6	Firm has referred to the in-house specifications whereas JP monograph is available for applied formulation.	Firm has submitted that it was a drafting error.
1.6.5	Valid GMP certificate/DML of the drug substance , manufacturer shall be submitted.	Copy of GMP certificate in the name of Zhejiang East-Asia Pharmaceutical Co. Ltd. Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, P.R. China valid upto 01-23-2023 issued by China food and drug administration.
3.2.P.8	Documents confirming import of drug substance shall be submitted.	Copy of commercial invoice attested by AD I&E DRAP, Lahore, has been submitted. Batch no. HH2020887.

Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

4.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pacific Pharmaceuticals Limited 30 km, Multan Road, Lahore, Pakistan**
	Name, address of Manufacturing site.	M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 11538 dated 11-07-2019
	Details of fee submitted	Rs.20,000/- dated 11-07-2019
	The proposed proprietary name / brand name	**Levothyroxin 100mcg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Levothyroxin Sodium…100Mcg
	Pharmaceutical form of applied drug	Film-coated extended-release tablet
	Pharmacotherapeutic Group of (API)	Thyroid hormones ATC Code: H03AA01
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Eltroxin 100mcg tablets of M/s Mercury Pharma Group Ltd. approved by MHRA of UK.
	For generic drugs (me-too status)	Thyronorm 100mcg Tablets of M/s Abbott
	Evidence of manufacturing facility	Firm has submitted section approval letter no. F-1-9/89-Lic (Vol-IV) dated 22-02-2018 issued by Secretary CLB, wherein Tablet (Hormone) section has been approved as additional section.
	GMP status of the Finished product manufacturer	GMP certificate granted on basis of inspection conducted on 14-09-2021
	Name and address of API manufacturer.	M/s Azico pharmaceuticals Pvt. Ltd. Plot number 40/A, JN. Pharmacity, Parawada (Mandal), Visakhapatnam (Dist), AP,India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data on CTD format related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications and analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies of Drug substance	Firm has submitted both real time (24 months) and accelerated (6 months) stability studies data from drug substance manufacturer as per refrigerating conditions.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacturing process and process control, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the reference product of Eltroxin 100mcg tablets of M/s Mercury Pharma Group Ltd approved by MHRA of UK. CDP has been performed against the same brand that is in Acid media (pH 1.2) , Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8) media with acceptable value of f2 factor.
	Analytical method validation/verification of product	Method validation studies have submitted including, Specificity, linearity, range, accuracy, precision Repeatability, Intermediate precision, Robustness, System Suitability.

STABILITY STUDY DATA

Manufacturer of API	M/s Azico pharmaceuticals Pvt. Ltd. Plot number 40/A, JN. Pharmacity, Parawada (Mandal), Visakhapatnam (Dist), AP,India		
API Lot No.	400I/3/010/18		
Description of Pack (Container closure system)	Alu-Alu. Blisters with aluminum foil having leaflet and packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 18 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	IG0106Q	IG0206Q	IG0306Q
Batch Size	100000 Tablets	100000 Tablets	100000 Tablets
Manufacturing Date	06-2021	06-2021	06-2021
No. of Batches	03		

Documents submitted along with stability data

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	• **C**opy of License retention certificate valid till 04-03-2025Drug Control Administration, Andhra Pradesh, India
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice attested by AD I&E DRAP, Lahore, has been submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	N/A

Batch No.	**Invoice No.**	**Quantity Imported**	**Date of approval by DRAP**
400I/3/010/18	EXPPPL-05	200gm	09-07-2019

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Digital data logger record has been submitted for temperature & humidity conditions of both accelerated and long-term stability chambers.

Remarks of Evaluator[II]:

Observations	Firm's response
Submit the requisite information / documents, according to the "Guidance document for submission of application on form 5-F (CTD) for registration of pharmaceutical drug products for Human use", available on DRAP's official website	Firm has submitted the re-arranged copy of the application as per the Guidance document for submission of application on form 5-F (CTD) for registration of pharmaceutical drug products for Human use

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Case no. 02 Registration Applications against Export facilitation

5.	**Name and address of manufacturer / Applicant**	**M/s Pharmevo Private Limited., Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi**
	Brand Name +Dosage Form + Strength	Erlin-M 2.5+500mg Tablet
	Composition	Each film coated tablet contains: Ertugliflozin L-Pyroglutamic acid eq. to Ertugliflozin…….2.5mg Metformin HCl…….500mg
	Diary No. Date of R& I & fee	Dy.No 10090 dated 04-03-2019 Rs.50,000/- dated 04-03-2019
	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors A10BK04 + Biguanide
	Type of Form	Form-5D
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	7's, 10's, 14's, 20's, 28's, 30's & As per PRC
	Approval status of product in Reference Regulatory Authorities	SEGLUROMET of USFDA Approved, USFDA Approved.
	Me-too status (with strength and dosage form)	Ertuvia-M Tablet by Ferozsons (Reg. No.112542)
	GMP status	GMP inspection conducted on 22-June-2022, GMP certificate grant on 22-August 2022. Tablet (General) section approved.
	Remarks of the Evaluator :	
	Now the firm has submitted stability data detailed as under:	
STABILITY STUDY DATA		
Drug		Erlin-M 2.5+500mg Tablet
Name of Manufacturer		M/s Pharmevo Private Limited., Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi.
Manufacturer of API		Ertugliflozin: M/s Shangai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd., Daixi Street, Louyang Town, Wujin District, Changzhou, Jiangsu 213105, China. Metformin HCl: Smruthi Organics Limited A-27, MIDC Chincholi, Tal-Mohol, Solapur 413255 Maharashtra State, India.
API Lot No.		Ertugliflozin- LPGA: ETG20190101

		Metformin HCl:MET-559/19		
Description of Pack (Container closure system)		Alu-Alu Blister		
Stability Storage Condition		Real time : 30°C ± 2° C / 75% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated:0,1,2,3,4,6 (month) Real Time: 0,3,6, (month)		
Batch No.		19PD-3038-02-T	19PD-3039-03-T	19PD-3040-04-T
Batch Size		2500 tab	2500 tab	2500 tab
Manufacturing Date		11-2019	11-2019	11-2019
Date of Initiation		23-12-2019	23-12-2019	23-12-2019
No. of Batches		03		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT				
Documents To Be Provided		**Status**		
1	Reference of previous approval of applications with stability study data of the firm	Firm has referred to onsite inspection report of their product Erli Plus XR Tablet 5/1000mg, 10/1000mg, 12.5/1000mg & 25/1000mg (Empagliflozin + Metformin HCl XR) which was conducted on 05th December, 2019 and were presented in 293rd meeting of Registration Board held on 6th -8th Jan, 2020. According to the report following points were confirmed. • Firm has 21 CFR compliant HPLC software. • Firm has audit trail reports available. • Firm possesses stability chambers with digital data loggers.		
2	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copy of COA of Ertugliflozin: (Batch# ETG20190101) from M/s. Shangai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Copy of COA (Batch# RV-698/19) from M/s PharmEvo (private) Limited is submitted. Copy of COA of Metformin HCl: (Batch# MET-559/19) from M/s. Smruthi Organics Limited. Copy of COA (Batch# RV-1835) from M/s PharmEvo (private) Limited is submitted.		
3	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Yes		
4	Stability study data of API from API manufacturer	Stability study conditions: Ertugliflozin: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (ETG20170101, ETG20161202, ETG20161201) Metformin HCl: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (A-71411106004, A-71411106005, A-71411106006)		
5	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Ertugliflozin- LPGA:** Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (ETG20170101, ETG20161202, ETG20161201) **Metformin HCl:** Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (A-71411106004, A-71411106005, A-71411106006)		
6	Documents for the procurement of API with approval from DRAP (in case of import).	**Ertugliflozin- LPGA:** Copy of Drug manufacturing license (License no. JS20180935) for M/s Shangai Pharma Group Changzhou Kony Pharmaceutical Co.,		

		Ltd., China issued by China Food and Drug Administration of the People's Republic of China is submitted, valid up to 26-11-2023. **Metformin HCl:** Copy of Drug manufacturing license (License no. NEW-WHO-GMP/CERT/PD/86368/2019/11/30111) for Smruthi Organics Limited. A-27, MIDC Chincholi, Tal-Mohol, Solapur 413255 Maharashtra State, India is submitted, valid up to 13-Nov-2022
7	Protocols followed for conduction of stability study	Yes
8	Method used for analysis of FPP	Yes
9	Drug-excipients compatibility studies (where applicable)	Same excipients used as used by innovator.
10	Complete batch manufacturing record of three stability batches.	The firm has submitted copy of Trial batch manufacturing record. Details are as under: **Batch no.** / **Batch Size** / **Mfg. Started** 19PD-3038-02-T / 2500 / 11-2019 19PD-3039-03-T / 2500 / 11-2019 19PD-3040-04-T / 2500 / 11-2019
11	Record of comparative dissolution data (where applicable)	Firm has submitted Comparative dissolution study of their product with innovator Brand SEGLUROMET 2.5+500mg Tablet manufactured by Merck & Co. Inc. (USA) The details are as follows: **Feature** / **Reference Product** / **Product of PharmEvo** Brand Name / SEGLUROMET 2.5+500mg Tablet / Erlin-M 2.5+500mg Tablet Batch No. / U016206 / 19PD-3038-02-T Comparative dissolution studies have been performed in following mediums: 1. pH 1.2 HCl buffer 2. pH 4.5 Acetate buffer 3. pH 6.8 Phosphate buffer
12	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Yes
13	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports of stability studies of applied formulation.
14	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Yes
6.	**Name and address of manufacturer / Applicant**	**M/s Pharmevo Private Limited., Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi**
	Brand Name +Dosage Form + Strength	Erlin-M 2.5+1000mg Tablet
	Composition	Each film coated tablet contains: Ertugliflozin L-Pyroglutamic acid eq. to Ertugliflozin…….2.5mg Metformin HCl…….1000mg
	Diary No. Date of R& I & fee	Dy.No 10091 dated 04-03-2019 Rs.50,000/- dated 04-03-2019

	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors A10BK04 + Biguanide		
	Type of Form	Form-5D		
	Finished product Specifications	Innovator's Specification		
	Pack size & Demanded Price	7's, 10's, 14's, 20's, 28's, 30's & As per PRC		
	Approval status of product in Reference Regulatory Authorities	SEGLUROMET of USFDA Approved, USFDA Approved.		
	Me-too status (with strength and dosage form)	Ertuvia-M Tablet by Ferozsons		
	GMP status	GMP inspection conducted on 22-June-2022, GMP certificate grant on 22-August 2022. Tablet (General) section approved.		
	Remarks of the Evaluator :			
	Now the firm has submitted stability data detailed as under:			
STABILITY STUDY DATA				
Drug		Erlin-M 2.5+1000mg Tablet		
Name of Manufacturer		M/s Pharmevo Private Limited., Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi.		
Manufacturer of API		Ertugliflozin: M/s Shangai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd., Daixi Street, Louyang Town, Wujin District, Changzhou, Jiangsu 213105, China. Metformin HCl: Smruthi Organics Limited A-27, MIDC Chincholi, Tal-Mohol, Solapur 413255 Maharashtra State, India.		
API Lot No.		Ertugliflozin- LPGA: ETG20190101 Metformin HCl:MET-559/19		
Description of Pack (Container closure system)		Alu-Alu Blister		
Stability Storage Condition		Real time : 30°C ± 2° C / 75% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated:0,1,2,3,4,6 (month) Real Time: 0,3,6, (month)		
Batch No.		20PD-3091-03-T	20PD-3092-04-T	20PD-3093-05-T
Batch Size		2500 tab	2500 tab	2500 tab
Manufacturing Date		1-2020	1-2020	1-2020
Date of Initiation		13-2-2020	13-2-2020	13-2-2020
No. of Batches		03		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT				
Documents To Be Provided		**Status**		
1	Reference of previous approval of applications with stability study data of the firm	Firm has referred to onsite inspection report of their product Erli Plus XR Tablet 5/1000mg, 10/1000mg, 12.5/1000mg & 25/1000mg (Empagliflozin + Metformin HCl XR) which was conducted on 05th December, 2019 and were presented in 293rd meeting of Registration Board held on 6th -8th Jan, 2020. According to the report following points were confirmed. • Firm has 21 CFR compliant HPLC software. • Firm has audit trail reports available. • Firm possesses stability chambers with digital data loggers.		
2	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	• Copy of COA of Ertugliflozin: (Batch# ETG20190101) from M/s. Shangai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Copy of COA (Batch# RV-698/19) from M/s PharmEvo (private) Limited is submitted.		

		• Copy of COA of Metformin HCl: (Batch# MET-559/19) from M/s. Smruthi Organics Limited. Copy of COA (Batch# RV-1835) from M/s PharmEvo (private) Limited is submitted.
3	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Submitted
4	Stability study data of API from API manufacturer	**Ertugliflozin- LPGA:** Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (ETG20170101, ETG20161202, ETG20161201) **Metformin HCl:** Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (A-71411106004, A-71411106005, A-71411106006)
5	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Ertugliflozin- LPGA:** Copy of Drug manufacturing license (License no. JS20180935) for M/s Shangai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd., China issued by China Food and Drug Administration of the People's Republic of China is submitted, valid up to 26-11-2023. **Metformin HCl:** Copy of Drug manufacturing license (License no. NEW-WHO-GMP/CERT/PD/86368/2019/11/30111) for Smruthi Organics Limited. A-27, MIDC Chincholi, Tal-Mohol, Solapur 413255 Maharashtra State, India is submitted, valid up to 13-Nov-2022
6	Documents for the procurement of API with approval from DRAP (in case of import).	**Ertugliflozin- LPGA:** Copy of Form 6, & Commercial Invoice No: PSPW-190116-1 Dated: 16-01-2019 from M/s Shangai Pansopharm Technology Co. Ltd. is submitted attested by AD I&E (Karachi) dated ; 1-02-2019 for Ertugliflozin L-pyroglutamic acid eq to Ertugliflozin L-Pyroglutamic acid quantity 1.2Kg **Metformin HCl:** Copy of Commercial Invoice No: E-009 Dt.17.04.2019 Dated: 17-04-2019 from Smruthi Organics Limited is submitted attested by AD I&E (Karachi) dated; 29-04-2019 for Metformin HCl.
7	Protocols followed for conduction of stability study	Submitted
8	Method used for analysis of FPP	Submitted
9	Drug-excipients compatibility studies (where applicable)	Same excipients used as used by innovator.
10	Complete batch manufacturing record of three stability batches.	The firm has submitted copy of Trial batch manufacturing record. Details are as under: **Batch no.** / **Batch Size** / **Mfg. Started** 20PD-3091-03-T / 2500 / 1-2020 20PD-3092-04-T / 2500 / 1-2020 20PD-3093-05-T / 2500 / 1-2020
11	Record of comparative dissolution data (where applicable)	Firm has submitted Comparative dissolution study of their product with innovator Brand SEGLUROMET 2.5+1000mg Tablet manufactured by Merck & Co. Inc. (USA) The details are as follows: **Feature** / **Reference Product** / **Product of PharmEvo**

		Brand Name: SEGLUROMET 2.5+1000mg Tablet / Erlin-M 2.5+1000mg Tablet Batch No.: T042906 / 20PD-3091-03-T Comparative dissolution studies have been performed in following mediums: 1. pH 1.2 HCl buffer 2. pH 4.5 Acetate buffer 3. pH 6.8 Phosphate buffer
12	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports of stability studies of applied formulation.
14	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr.#	Observations	Firm's response
1.	Submit valid GMP certificate/DML for manufacturer of Metformin HCl i.e., M/s Smruthi Organics Limited.	Firm has submitted copy of GMP certificate No. NEW-WHOGMP/ CERT/PD/86368/2019/11/30111issued by Food & Drug Administration India.

Decision: Registration Board approved the applications of Erlin-M 2.5+500mg Tablet & Erlin-M 2.5+1000mg Tablet with Innovator's specifications. The firm shall submit fee of Rs. 7500/- for each strength for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letters.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**

Case no. 03 Deferred cases

7.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Daneen Pharma Private Limited 27-Sundar Industrial Estate, Sundar Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ **Is involved in none of the above (contract giver)**
	Status of application	☐ **New Drug Product (NDP)** ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Evidence of manufacturing facility	Section approval letter declaring grant of Beta-Lactam (penem) section

	Dy. No. and date of submission	Dy.No 27307 dated 04-10-2021
	Details of fee submitted	Rs.75,000/- dated 29-09-2021
	The proposed proprietary name / brand name	**ERTAP 1gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Ertapenem sodium equivalent to Ertapenem ……. 1gm
	Pharmaceutical form of applied drug	White to light yellow powder
	Pharmacotherapeutic Group of (API)	Anti-bacterial
	Reference to Finished product specifications	As per innovator's specifications
	Proposed Pack size	1's
	Proposed unit price	As per PRC
	The status in reference regulatory authorities	**Invanz Injection** by Merck & CO.,INC , FDA Approved.
	For generic drugs (me-too status)	Ernem Injection by M/s Genix Pharma Reg no: 081179
	GMP status of the Finished product manufacturer	GMP granted on 07/10/2021 Capsule section approved.
	Name and address of API manufacturer.	**SAVIOR LIFETEC CORPORATION,** 29, Ke-Jhong Rd., Chunan Chen, Miaoli, County 35053, Taiwan, R.O.C.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, , specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is **Invanz Injection**

	Analytical method validation/verification of product	Method verification studies have been submitted including justification of system suitability, specificity, linearity, accuracy, precision-repeatability.

STABILITY STUDY DATA			
Manufacturer of API	**SAVIOR LIFETEC CORPORATION,** 29, Ke-Jhong Rd., Chunan Chen, Miaoli, County 35053, Taiwan, R.O.C.		
API Lot No.	80S019AA001		
Description of Pack (Container closure system)	Glass vial		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated:0,3 & 6(Months) Real Time: 0,3, 6, 9 ,12,18 & 24 (Months)		
Batch No.	001I042	002I042	003I042
Batch Size	7434 vials	7558 vials	7791 vials
Manufacturing Date	09-2017	02-2018	07-2018
Date of Initiation	15-10-2017	15-03-2018	29-08-2018
No. of Batches	03		

Administrative Portion		
a	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
b	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	--
c	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Purchase Invoice No. S180201 attested by DRAP dated 06.06.2018 is submitted
d	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
e	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted

f	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator[II]:

Section#	Observation	Firm's response
1.6.5	Valid GMP certificate of drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP issued by Ministry of Health & Welfare, Taiwan, valid till 23/01/2024
3.2.S.5	• Justification shall be submitted for using Ertapenem sodium lyophilized powder as working standard instead of the pure Ertapenem sodium. • Submitted drug substance analytical procedure mandates use of Ertapenem as working standard whereas submitted COA is of Ertapenem sodium lyophilized powder.	We received working standard Ertapenem sodium as lyophilized powder from supplier. Saviour Lifetech Corporation here by confirmed that Ertapenem sodium lyophilized powder is more suitable as working standard than Ertapenem sodium due to its longer retest period. 24 m. In this case, Ertapenem sodium lyophilized powder can be used in a more reliable way. The actual assay can be calibrated by method calculation. The Ertapenem sodium lyophilized powder is preferable as working standard by our expert's perspective. Therefore, the submitted COA of Ertapenem sodium lyophilized powder was provide din 3.2.S.5.
3.2.S.7.3	Justification shall be submitted for conducting drug substance stability studies at refrigerating conditions.	As Ertapenem sodium lyophilized powder will be directly filled in to vial, the quality of Ertapenem sodium lyophilized powder is very critical and should be preserved in conservative way at lower temperature. Therefore based on this concept we chose to conduct the stability studies of drug substance in storage conditions of 5 $\pm$3ºC to ensure quality.
3.2.P.1	• Justification shall be submitted for proposed fill weight per vial of Ertapenem sodium considering the actual content of sodium declared in the drug substance analysis and content of sodium bicarbonate in the drug substance. • Details of accompanying reconstitution diluent shall be submitted.	• The justification is as under: 1gmof Ertapenem for injection (Bulk sterile) will contain following: Ertapenem monosodium ….. 809.60mg Sodium bicarbonate …….. 135.40mg NaOH…….. 55.0mg Total……. 1000.0mg Factor = Ertapenem sodium/Ertapenem = 497.50/475.5 = 1.046 Then, 1000.0mg x 1.046 1046.00mg appx. 1050mg. The filled weight of 1340mg against the determined potency of 78.20% of drug substance is justified as per above referred calculations.

		• Diluent is not the part of finished pack.
3.2.P.2.2.1	• Submit justification of not performing tests of pH, sterility, water content, endotoxins and particulate matter in Pharmaceutical equivalence studies.	Due to insufficient qanity of innovator sample, we performed appearance, identification and Assay. As per requirements from DRAp, we performed all test on new innovator sample "Invanz injection".
3.2.P.2.6	• Compatibility studies with the reconstitution diluent shall be submitted.	Submitted with 0.9% sodium chloride solution.
3.2.P.5	• Justification shall be submitted for not including tests of completeness and clarity of solution, pH, & water content in the drug product specifications, as recommended by the Innovator product.	The material Ertapenem sodium is lyophilized sterile powder and ready to fill material, we performed these test during API testing.
3.2.P.6	• Justification shall be submitted for using Ertapenem sodium lyophilized powder as working standard instead of the pure Ertapenem sodium.	Same as above in section 3.2.S.6
3.2.P.8	• Justification shall be submitted for not performing tests of completeness and clarity of solution, pH, & water content during stability studies. • Complete batch manufacturing record shall be submitted for the three stability batches. • Microbial reports shall be submitted for the sterility testing during stability studies. • Documents confirming import of drug substance with approval form DRAP shall be submitted.	• The material Ertapenem sodium is lyophilized sterile powder and ready to fill material, we performed these test during API testing in order to reduce the test on finished product testing and on basis of supplier stability studies of real time as well as accelerated. It is concluded that the API is stable throughout the shelf life. • BMRs have been submitted.

Decision of 323rd meeting: Deferred for scientific justification for:

- Use of Ertapenem sodium lyophilized powder as working standard instead of the pure Ertapenem sodium since submitted drug substance analytical procedure mandates use of Ertapenem as working standard whereas submitted COA is of Ertapenem sodium lyophilized powder.
- Not including tests of tests of completeness and clarity of solution, pH, & water content in drug product specifications and stability studies.

Firm's response:

- Drug substance manufacturer has used Ertapenem sodium lyophilized powder in analysis, therefore we have used and submitted the same COA. Response from supplier is as follows:
  "We, Savior Lifetec Corporation hereby confirmed that Ertapenem sodium \due to its longer retest period. In this case Ertapenem sodium lyophilized powder (bulk) can be used in a more reliable way. The actual assay and purity value of pure Ertapenem sodium can be used in a more reliable way. The actual assay and purity value of Ertapenem sodium can be calibrated by method calculation. Thus Ertapenem sodium lyophilized powder is preferable as working standard by our expert's perspective. We hereby provide chromatogram data of HPLC and FTIR as the qualification documents for working standard Ertapenem sodium lyophilized powder from reference standard Ertapenem sodium.

• Firm has submitted revised test method including tests of completeness and clarity of solution, pH, & water content.		
Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
8.	Name, address of Applicant / Marketing Authorization Holder	**M/s SAMI Pharmaceuticals (Pvt) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi.**
	Name, address of Manufacturing site.	M/s SAMI Pharmaceuticals (Pvt) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 25927 dated 17-09-2021
	Details of fee submitted	PKR 30,000/-: dated 07/09/2021 PKR 45,000/-: dated 25/10/2021
	The proposed proprietary name / brand name	**Provas Advance 500mg Tablet** **Alternate brand name: PROVAS NOVO 500mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Paracetamol ……. 500mg
	Pharmaceutical form of applied drug	White to off-white colored capsular shaped film coated tablet, break line on one side and other side is plain
	Pharmacotherapeutic Group of (API)	NSAID ATC Code: N02BE01
	Reference to Finished product specifications	USP
	Proposed Pack size	10’s, 20’s, 30’s, 50’s & 100’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Panadol Advance 500mg Tablet, M/s. GSK, approved by MHRA of UK
	For generic drugs (me-too status)	Not applicable
	GMP status of the Finished product manufacturer	GMP certificate issued dated: 11-08-2020
	Name and address of API manufacturer.	**Name:** HEBEI JIHENG (GROUP) PHARMACEUTICAL CO., LTD SHENZHOU PLANT (shortened as Jiheng Shenzhou)

		Address: Southeast Xijingming Village Donganzhuang Township, Shenzhou County Henshui City, Hebei Province, CHINA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, characterization, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted details of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity J, K, F, individual impurity and total impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, working standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 60 Months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is PANADOL ADVANCE 500mg tablet by M/s. GSK. CDP has been performed against the same brand that is PANADOL ADVANCE 500mg tablet by M/s. GSK in Acid media (pH 1.2-4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have been submitted including Linearity, Accuracy & Precision including Repeatability & Specificity.

STABILITY STUDY DATA	
Manufacturer of API	HEBEI JIHENG (GROUP) PHARMACEUTICAL CO., LTD SHENZHOU PLANT, CHINA
API Lot No.	31709016
Description of Pack (Container closure system)	Alu/PVC Blister
Stability Storage	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Condition			
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Lab-07	Lab-08	Lab-09
Batch Size	2000 Tablets	20000 Tablets	2000 Tablets
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	14-4-2021	14-4-2021	14-4-2021
No. of Batches	03		
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted reference of last onsite panel inspection for instant dosage form conducted during last two years i.e. EMPOLI (Empagliflozin) 10mg & 25mg Tablets which was presented in 290th meeting of the registration board & hence approved & registered by registration board Date of inspection: 13th June 2019. The inspection report confirms following points • The HPLC software is 21CFR Compliant. • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and	

		monitored through software having alarm system for alerts as well.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. HE20180054 issued by Hebei CHINA FOOD AND DRUG ADMINISTRATION valid till 08/07/2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice (Invoice# 1708ZP03 dated 19th October 2017 with received quantity i.e. 5000 kgs) for the purchase of Paracetamol from M/s Hebei Jiheng Shenzhou Pharmaceutical Co., Ltd. China with attestation of DRAP dated 01-11-2017
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC for all test intervals.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[II]:

- Regarding justification of specifications of drug product, firm has submitted as under:
  "The dissolution parameters and testing procedure is as per USP Pharmacopeia but as the Paracetamol is rapidly dissolving drug and falls in BCS Class I, we stringent the dissolution specifications from 30 minutes to 10 minutes
  The selection of specified time for Dissolution is based on the BCS classification of API, as the drug is independent over physiological pH range (i-e from 1.2 to 6.8) and ·as per USP General chapter <1092>, the dissolution of rapidly dissolving product is achieved within 15 minutes therefore we established our dissolution time within 10minutes."

- Firm has submitted following comparison between the applied formulation and conventional paracetamol tablet already available in market:

Parameters	**PROVAS Novo 500mg Tablet**	**Paracetamol 500mg Tablet**
Dosage Form	Tablet	Tablet
Dosage Design	Immediate release film coated tablet	Immediate release uncoated tablet
Route of Administration	Oral	Oral
Dosage Strength	500mg	500mg
Pharmacokinetics	The special technology allows **PROVAS Novo 500mg Tablet** to begin dissolving in 5 minutes and start to relieve pain within 15 minutes	Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 30 minutes to 2 hours after ingestion
Patient's Acceptance & Compliance	• Capsular shape makes it easy to swallow • Bitter taste of Paracetamol is masked through film coating • Quick & Effective Pain Relief Stomach Friendly	• Round shape makes it difficult to swallow • Bitter Taste Delayed Pain Relief
Technology Used	**PROVAS Novo 500mg Tablet** is a Paracetamol formulation that contains an advance technology to rapid the onset of action	**Paracetamol 500mg Tablet** formulated using a conventional wet granulation process

Key Features	• It has unique delivery system as **PROVAS Novo 500mg Tablet** is a Paracetamol formulation that contains a rapid dispersion and dissolution technology which breakdown Paracetamol tablets in the stomach so that the drug is absorbed fast and pain relief can start within 15 minutes after ingestion • The technology contains three main ingredients viz.: o **Alginic Acid** draws fluid from the stomach into the tablet causing it to swell and break apart o **Calcium Carbonate** works together with Alginic Acid to boost disintegration of the tablet o **Crospovidone** acts as a super-disintegrant due to its ability to dissolve well in water • The absorption of Paracetamol occurs in the small intestine and as such is dependent on the rate of emptying of stomach contents into the small intestine and is therefore not associated with gastric irritation. The technology used in **PROVAS Novo 500 mg** Tablet increases gastric emptying time of the drug. • **PROVAS Novo 500mg Tablet** with this advance technology disperses up to five times faster than standard paracetamol tablets Suitable for all such patients requiring low sodium content in their diet	Onset of action is slow, as peak plasma concentrations occurring about 30 minutes to 2 hours after ingestion

Section#	Observations	Firm's response
3.2.P.5.1	• Limits for disintegration test i.e., NMT 30 minutes are inconsistent with the limits of dissolution test i.e., NLT 80% (Q) in 10 minutes.	We set disintegration specification according to USP general monograph for Disintegration <701> which specifies NMT 30minutes for film coated tablets. Our product is fast dissoving with a dissolution specs of NLT 80% (Q) in 10 minutes and disintegration time of our product is also found within 01 minute which co relates with dissolution. We have revised the specification of DT from NMT 30 minmutes to NMT 10 minutes.
3.2.P.6	• Submitted COA of working standard declares the "Valid till" date as January 2021, whereas trial batches have been manufactured and analyzed subsequent to this date. • Submitted COA of working standard is of BP grade, whereas drug product specifications have been	Firm has submitted new COA of working standard, which had been standardized in January 2021 having validity date as of Jan, 2022. Firm has submitted that the working standard complies with both & USP monograph of Paracetamol, since both the monographs are harmonized.

claimed as per USP monograph.	

Decision of 320th meeting: The Board was apprised that the firm has applied for two products with the similar formulation that is Paracetamol, film coated tablet with slight difference in method of manufacturing and qualitative composition. The Board after due deliberation decided to defer the case for clarification whether an applicant can apply for registration of more than two products having same composition or otherwise.

Firm's response:

PANADOL Conventional Tablets	**PANADOL ADVANCE & PROVAS NOVO 500 mg Tablet**
1) Marketing Authorization Status:	
Panadol 500mg is marketed by GlaxoSmithKline Consumer Healthcare (UK) Trading Limited bearing **Marketing authorization number(s)** PL 44673/0081 **Reference attached** https://www.medicines.org.uk/emc/product/6474/smpc#gref	Panadol advance 500mg is marketed by GlaxoSmithKline Consumer Healthcare (UK) Trading Limited bearing **Marketing authorization number(s)** PL 44673/0080 **Reference attached** https://www.medicines.org.uk/emc/product/6512/smpc#gref
2) Pharmacokinetics	
-	• Human scintigraphy data demonstrate that Panadol Advance 500 mg Tablets generally start to disintegrate by 5 minutes post dose in the stomach • 37% faster compared to standard paracetamol tablets • It dissolves in 5 minutes and start to relieve pain within 15 minutes **Reference attached** https://www.medicines.org.uk/emc/product/6512/smpc#gref
3) Disintegration time	
Disintegration Time: within 15minutes	**Disintegration Time:** within 10minutes
Dissolution	
Dissolution Test: NLT 80% (Q) in 30minutes	**Dissolution Test: NLT 80% (Q)** in 10minutes
4) Technology/Formulation	
Standard Paracetamol tablet formulated using conventional wet granulation process	Optizorb technology is used to provide rapid onset of action and allows it to dissolve in 5minutes and start to relive pain with in 15minutes
5) Excipients	
-	• Contain a unique disintegrant system which consist on following three excipients: ▪ **Alginic acid** which draws fluid from the stomach into the tablet causing it to swell and break apart ▪ **Calcium Carbonate** works together with Alginic Acid to boost disintegration of the tablet

Crospovidone acts as a super-disintegrate due to its ability to dissolve well in water

Decision of 321st meeting: The Board discussed that the applicant already have the registration of formulation containing Paracetamol 500mg as immediate release tablet whereas the firm has applied for the same formulation having different excipients and there is no change in strength, dosage form, salt form, drug delivery system etc. Considering the fact that different excipients are used in the applied product and already approved formulation, the Board deferred the case for clarification from applicant and then further deliberation.

Firm's response:

- Keeping in line with the International developments for new & innovative drug therapies in Pain Management, and as per DRAP's Vision to ensure access to safe, quality assured and efficacious therapeutic drugs in line with the national laws and international best practices, we have developed this formulation

- Paracetamol is considered as a safe and efficacious drug from the time of its first introduction in 1950. Since then, in order to improve over its limitations while providing innovative therapies to healthcare professionals as well as the patients, the innovator / Research Company, M/s. GSK introduced a new and improved formulation under the name of PANADOL ADVANCE (with Optizorb Formulation)

  Panadol Optizorb 500 mg tablet (new formula) is a fast-dissolving paracetamol tablet which has been formulated to have an improved tablet dissolution rate compared to standard paracetamol tablets. It contains a disintegrant system which improves early drug absorption compared to a standard paracetamol tablet, as demonstrated start to disintegrate by 5 minutes post dose and early expose to paracetamol have been detected on plasma by 10 minutes in fasted and fed states.
  (Reference enclosed: European Union Member State Public Assessment Report 2014)

  This formulation, besides Conventional Paracetamol, is available in many countries worldwide as detailed below:

Reference Regulatory Authority (RRA) /PICs Member States	**Conventional formulation**	**Advance formulation**
EMA	Yes	Yes
United Kingdom	Yes	Yes
Australia	Yes	Yes
Ireland	Yes	Yes
Belgium	Yes	Yes
Malaysia	Yes	Yes
United Arab Emirates	Yes	Yes

Reference pages from respective RRA are enclosed

- Comparison of various parameters between "Conventional Paracetamol Tablets" viz. a viz. newly applied ADVANCE formulation is mentioned as under; our applied formulation is comparable with the Innovator brand – PANADOL ADVANCE

Parameters	**Conventional Panadol / Provas Tablets**	**PANADOL ADVANCE / PROVAS NOVO**
Disintegration	Within 15 minutes	Within 10 minutes

Absorption	Paracetamol is poorly absorbed in the stomach but well absorbed in the small intestine due to the greater surface area and absorptive capacity. Conventional Paracetamol tablets have no such ingredient(s) to increase the rate of absorption	Human scintigraphy data demonstrates that the tablets generally start to disintegrate by 5 minutes post dose in the stomach The advanced technology disperses up to five times faster than standard paracetamol tablets
Dissolution	NLT 80% (Q) in 30 minutes	NLT 80% (Q) in 10 minutes
Gastric safety	-	The absorption of Paracetamol occurs in the small intestine and as such is dependent on the rate of emptying of stomach contents into the small intestine and is therefore not associated with gastric irritation. The technology used in PROVAS NOVO 500mg Tablets increases gastric emptying time of the drug
Onset of action	Onset of action is slow, as peak plasma concentrations occur about 30 minutes to 2 hours after ingestion	**The unique disintegrant system is used to provide rapid onset of action and allows it to dissolve in 5 minutes and start to relieve pain within 15 minutes**. Human pharmacokinetic data demonstrate that the time taken to reach plasma paracetamol therapeutic threshold is at least 37% faster as compared to standard paracetamol tablets
Other attributes	Round conventional shape Uncoated tablets and hence a bitter taste	Capsular shape makes it easy to swallow Bitter taste of Paracetamol is masked through film coating Stomach friendly
Formulation detail	Each tablet contains: Paracetamol Maize starch Povidone Potassium sorbate Soluble starch Purified talc Stearic acid	Each film coated tablet contains : Paracetamol Pregelatinized Starch Polyvinylpyrrolidone K-30 Calcium Carbonate Alginic Acid Crospovidone Type A Silicon Dioxide Fumed Magnesium Stearate Hydroxypropylmethyl cellulose ES Polyethylene Glycol 6000 Titanium dioxide Polysorbate 80

Above references taken from SmPC & Official website of PANADOL ADVANCE are enclosed

- Conventional Paracetamol Tablet is available in Pharmacopeia, whereas under applied PROVAS NOVO having different specifications which is more stringent than the Pharmacopeal specifications, for which we have already submitted our revised Finished Product specifications, vide our letter dated 22-08-2022, complying with that of the Innovator brand

• While considering the difference in various parameters between the two formulations i.e. Conventional Paracetamol & PROVAS NOVO Tablets and its availability in many RRA countries besides conventional Paracetamol Tablets, we hope you will find the above explanation in order and grant us registration of this novel formulation		
Decision of 329th meeting: Registration Board deferred the case for further dliberation.		
9.	Name, address of Applicant / Marketing Authorization Holder	M/s PDH Laboratories (pvt) Limited 9.5 Km Sheikhupura road, Lahore.
	Name, address of Manufacturing site.	M/s PDH Laboratories (pvt) Limited 9.5 Km Sheikhupura road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26230 dated 16/09/2022
	Details of fee submitted	PKR 30,000/-: dated 05/04/2022
	The proposed proprietary name / brand name	**Ketis Syrup 1mg/5Ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5mL contains: Ketotifen as Hydrogen Fumarate……..1mg
	Pharmaceutical form of applied drug	Clear colorless solution with apricot flavor
	Pharmacotherapeutic Group of (API)	Anti-Histamine
	Reference to Finished product specifications	Manufacturer's specifications
	Proposed Pack size	1's (60mL)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zaditen Oral Solution 1mg/5mL, HPRA Ireland Approved.
	For generic drugs (me-too status)	Zatofen Syrup 1mg/5mL by Novartis Phram.
	GMP status of the Finished product manufacturer	Inspection report dated 03/01/2022 & 04/01/2022 is submitted. The panel recommended renewal of DML.
	Section approval	Oral Liquid Section (General) vide letter no.F.1-1/86-Lic(Vol-V) dated 7th June, 2022.
	Name and address of API manufacturer.	M/s Suzhou Homesun Pharmaceutical Co., Ltd., No. 12 West Xiexin road, Taicang Port Development Zone, Taicang City, Jiangsu Province China. Copy of GMP certificate no. JS20170699 valid till 03/09/2022 issued by Jiangsu Food and Drug Administration.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification,

		reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, residual solvents, specifications, analytical procedures and its complete validation studies, batch analysis and justification of specification, details of reference standards, container closure system and stability studies of drug substance.
	Stability studies	• Real time: 30˚C ± 2˚C / 75% ± 5%RH for 24 months (KETIII/00319 (24 months, KETIII/00420 (12 months, KETIII/00520, KETIII/00620) • Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (KETIII/00718, KETIII/00818, KETIII/00918)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	The firm has submitted pharmaceutical equivalence against Zatofen Syrup 60mL Mfg by M/s Novarits by performing quality tests. Batch number: JLRAAH
	Analytical method validation/verification of product	Method validation / verification studies have submitted including accuracy/recovery, precision, specificity, , system suitability etc for drug substance and drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Suzhou Homesun Pharmaceutical Co., Ltd., No. 12 West Xiexin road, Taicang Port Development Zone, Taicang City, Jiangsu Province China.
API Lot No.	20201005
Description of Pack (Container closure system)	Amber colored glass bottle
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	T001	T002	T003
Batch Size	50bottles	50bottles	50bottles
Manufacturing Date	18/02/2021	18/02/2021	18/02/2021
Date of Initiation	18/02/2021	18/02/2021	18/02/2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No response is submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate no. JS20170699 valid till 03/09/2022 issued by Jiangsu Food and Drug Administration.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of invoice number 01005SLT2012401-2 dated 08/01/2021 cleared vide diary number 1439/2021-DRAP dated 26/01/2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	**N/A**
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator-I:

Sr. No.	Observations	Response
1	As per Section 1.6.5 the drug substance manufacturer is M/s Suzhou Homesun Pharmaceutical Co., Ltd., while as per Module II and III and as per the submitted documents the manufacturer is M/s Fleming Laboratories Limited, India, Please clarify. Moreover, provide GMP certificate of drug substance manufacturer along with the correct name and address of drug substance manufacturer in-lined with the name and address mentioned in GMP certificate.	The manufacturer of API is M/s Suzhou Homesun Pharmaceutical Co., Ltd., No. 12 West Xiexin road, Taicang Port Development Zone, Taicang City, Jiangsu Province China. The firm has provided relevant documents including GMP certificate. Stability study of API is submitted already with the initial application. Copy of GMP certificate no. JS20170699 valid till 03/09/2022 issued by Jiangsu Food and Drug Administration
2	Please provide detail of specifications of the drug substance along with the submission of detail of analytical procedures.	Submitted.
3	Please provide detail of reference standard along with the COAs in relevant section since the information is not provide din the submitted dossier.	Submitted. Batch number: 20201105
4	Provide analytical method verification studies including accuracy, specificity and precision for drug substance performed by drug product manufacturer.	The firm has submitted analytical method verification studies including specificity, accuracy and precision from drug product manufacturer long with the protocol.

5	Detail of container closure system for the drug substance.	Submitted.
5	Provide Pharmaceutical Equivalence studies against reference / innovator's product by performing all the quality tests.	The firm has submitted pharmaceutical equivalence against Zatofen Syrup 60mL Mfg by M/s Novarits by performing quality tests. Batch number: JLRAAH
6	Provide COA of relevant batch used for the product development of the applied product from drug substance as well as from the drug product manufacturer.	COA is submitted from drug product manufacturer and drug substance manufacturer. Batch number: 20201005
7	The excipients used in the applied formulation are different from the excipients used by the innovator, therefore, you are required to submit compatibility studies of excipients with the drug substance.	Drug-excipient compatibility studies have been submitted.
8	UV method has been developed for analysis of the drug product instead of HPLC method, please justify.	*The product is developed according to In-House specifications. At the time of product development phase, we have developed the analytical method of Ketis Syrup on UV spectrophotometer for performance of assay test along with the performance of analytical method validation studies.*
9	Please provide detail of reference standard along with the relevant COAs.	Submitted.
10	Stability summary sheets for batch number T002 for 3rd month time point of accelerated stability studies are not provided.	The firm has submitted stability summary sheets for batch number T002 for 3rd month time point of accelerated stability studies.
11	Provide documents for the procurement of API with approval from DRAP (in case of import).	Copy of invoice number 01005SLT2012401-2 dated 08/01/2021 cleared vide diary number 1439/2021-DRAP dated 26/01/2021.
12	Provide complete batch manufacturing record.	Submitted.
13	Justification is required since the trial batches have been manufactured before the grant of "Oral Liquid Section (General)'.	*Please be informed that all trial batches are developed in R&D lab.*

Decision of 323rd meeting: Registration Board deferred the case for submission of complete testing including Assay test using HPLC method on the next time point of long term stability studies along with analytical method validation studies.

Firm's response: Firm has submitted long term stability studies data at next time point for Trial 001 (24th month), Trial 002 (24th month) & Trial 003 (18th month) wherein Assay testing has been performed as per HPLC method. Firm has submitted relevant HPLC chromatograms and raw data sheets along with analytical method validation studies for the HPLC method.
Fee shall be submitted for revision of drug product analytical procedure.

Decision: Registration Board while considering the case noted the fact that firm has manufactured the trial batches without formal approval of the manufacturing facility and even before the panel inspection for the approval of "Oral Liquid Section (General)", hence Board decided that the submitted stability data of these trial batches could not be considered.
Registration Board further decided that firm shall formulate new trial batches and submit its stability data for both accelerated and long term conditions along with full fee of registration i.e., Rs. 30,000/- for correction/pre-approval change in stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
The Board further advised PE&R Division to prepare guidance document on the matter.

10.	**Name and address of manufacturer / Applicant**	**M/s Pacific Pharmaceuticals Limited 30 Km, Multan road Lahore**
	Brand Name +Dosage Form + Strength	Dexlan 30mg Capsule

	Composition	Each Capsules contains: Dexlansoprazol delayed release pellets eq t Dexlanzoprazol.....…30mg
	Diary No. Date of R& I & fee	Dy. No 36634 dated 06-11-2018 Rs.20,000 /- Dated 06-11-2018
	Pharmacological Group	Proton Pump inhibitor
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	2 x 7's, 4 x 7's :As per SRO
	Approval status of product in Reference Regulator Authorities	Dexilant Delayed Release Capsule 30mg of USFDA approved
	Me-too status	Lansodex Capsule 30mg of M/S Getz Pharma
	GMP status	Last inspection conducted on 22/02/2018 and concludes that "In the light of the inspection conducted by the panel and based on the people met, documents reviewed and findings during inspection, M/s pacific pharma ltd Multan road Lahore, was considered to be operating at good level of GMP compliance at the time of inspection. Therefore, the panel of inspectors recommends considering the firm for grant of GMP certificate for export purposes." "GMP Certificate Issued on 05-03-2018."
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Dexlan 30mg Capsule		
Name of Manufacturer	M/s Pacific Pharmaceuticals Limited 30 Km, multan road lahore		
Manufacturer of API	M/S Vision Pharmaceuticals (Pvt)., Ltd is submitted. **M/S Al Wajar Pharmaceuticals Industry LLC**		
API Lot No.	**PDLB19003, PDLB19002 & PDLB19001** DLP 376		
Description of Pack (Container closure system)	PVC-PVDC blisters		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated:6 months		
Frequency	Accelerated:0,1,2,3,4,5,6 (month) Real Time: 0,3,6, (month)		
Batch No.	TDX00101P	TDX00201P	TDX00301P
Batch Size	5000 Capsules	5000 Capsules	5000 Capsules
Manufacturing Date	10-2019	10-2019	10-2019
Date of Initiation	05-02-2020	05-02-2020	05-02-2020
No. of Batches	03		
Date of Submission	27-08-2020 (21606)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status

1.	Reference of previous approval of applications with stability study data of the firm.	• Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	**Copy of COA of Dex-Lansoprazole DDR pellets 22.5% (Batch# PDLB19003, PDLB19002 & PDLB19001) from M/S Al Wajar Pharmaceuticals Industry LLC is submitted.** Copy of COA [Batch# DLP 376)from M/S Vision Pharmaceuticals (Pvt) Ltd is submitted. Copy of COA (Batch# DLP 376) from M/S Pacific Pharmaceuticals is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Yes
4.	Stability study data of API from API manufacturer	Yes
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Certificate of Good manufacturing practice Based on inspection conducted on 11-02-2019
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not valid
7.	Protocols followed for conduction of stability study	Yes
8.	Method used for analysis of FPP	No
9.	Drug-excipients compatibility studies (where applicable)	Not valid
10.	Complete batch manufacturing record of three stability batches.	No
11.	Record of comparative dissolution data.	No
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	No
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Yes
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Yes

Remarks of Evaluator

S.No	Shortcomings Communicated	Reply
1.	Data has not been provided as per guidelines approved by registration board in 293rd meeting nor arranged in order.	Submitted
2.	Stability data of 30mg and 60mg shall be submitted separately.	Submitted
3.	Submit differential fee of RS: 80000/- in case of imported pellets.	**Now source mentioned is vision pharmaceuticals**

4.	Submit Certificate of Analysis of API from Finished Product manufacturer	Submitted
5.	Submit Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Submitted
6.	Submit Stability study data of API from API manufacturer	Submitted
7.	Submit Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin	Submitted
8.	Submit AD attested invoice of pellets.	Not valid
9.	Protocols followed for conduction of stability study prepared after initiation of stability studies. Clarify	Submitted
10.	Data of 03 batches will be supported by attested respective documents like, Raw data sheets, COA, summary data sheets etc.	Not Submitted
2nd letter 24th November 2021		
1.	In initial submitted data source of pellets was M/S Al-Wajar Pharmaceuticals Industry LLC while in reply source of pellets is changed to vision Pharmaceuticals. Clarification is required in this regard.	• The Vision Pharmaceuticals has provided complete data, while no supporting documents are provided by M/s Al Wajar Pharmaceuticals, That's why, pallets are locally purchased and source is changed to Vision Pharmaceuticals. • Firm has also submitted copy of commercial invoice from M.s Vision Pharmaceuticals for the Dexlansoprazole pellets dated 28-12-2018.
2.	Method used for analysis of FPP.	Firm has submitted drug product analytical procedure.
3.	Reference of previous approval of applications with stability study data of the firm.	Firm has referred to previous onsite inspection report of their product Esmelin tablet 15mg dated 10-08-2020 on the basis of which Registration Board in its 313th meeting decided to approve the registration of Esmelin 15mg tablet. The report shows that: • The HPLC software is 21 CFR compliant and Log of data was available in the HPLCs. The data was also checked through hard copies of chromatograms. • Adequate monitoring and control were available for stability chamber. The firm was advised to improve the alarm system.
4.	Record of comparative dissolution data.	Firm has submitted comparative dissolution profile studies against the Delanzo 30mg capsule of M/s Sami Pharmaceutical with acceptable value of f2 value.
5.	Complete batch manufacturing record of three stability batches.	Firm has submitted BMR of three trial batches.
6.	Data of 03 batches will be supported by attested respective documents like, Raw data sheets, COA, summary data sheets etc.	Submitted.
Decision of 324th meeting: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.		

Firm's response:

Sr.#	Observations	Firm's response
1.	In initial submitted data source of pellets was M/S Al-Wajar Pharmaceuticals Industry LLC while in reply source of pellets is changed to vision Pharmaceuticals. Clarification is required in this regard.	• The Vision Pharmaceuticals has provided complete data, while no supporting documents are provided by M/s Al Wajar Pharmaceuticals, That's why, pallets are locally purchased and source is changed to Vision Pharmaceuticals. • Firm has also submitted copy of commercial invoice from M.s Vision Pharmaceuticals for the Dexlansoprazole pellets dated 28-12-2018.
2.	Method used for analysis of FPP.	Firm has submitted drug product analytical procedure.
3.	Reference of previous approval of applications with stability study data of the firm.	Firm has referred to previous onsite inspection report of their product Esmelin tablet 15mg dated 10-08-2020 on the basis of which Registration Board in its 313th meeting decided to approve the registration of Esmelin 15mg tablet. The report shows that: • The HPLC software is 21 CFR compliant and Log of data was available in the HPLCs. The data was also checked through hard copies of chromatograms. • Adequate monitoring and control were available for stability chamber. The firm was advised to improve the alarm system.
4.	Record of comparative dissolution data.	Firm has submitted comparative dissolution profile studies against the Delanzo 30mg capsule of M/s Sami Pharmaceutical with acceptable value of f2 value.
5.	Complete batch manufacturing record of three stability batches.	Firm has submitted BMR of three trial batches.
6.	Data of 03 batches will be supported by attested respective documents like, Raw data sheets, COA, summary data sheets etc.	Submitted.

Decision: Approved with Innovator's specification. Registration letter shall be issued after submission of fee Rs. 30,000/- for revision of source of drug substance, as per Notification No. 7-11/2012-B&A dated 07.05.2021.
Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

11.	**Name and address of manufacturer / Applicant**	**M/s Pacific Pharmaceuticals Limited** **30 Km, multan road lahore**
	Brand Name +Dosage Form + Strength	Dexlan 60mg Capsule
	Composition	Each Capsules contains: Dexlansoprazol delayed release pellets eq. to Dexlanzoprazol .....… 60mg

	Diary No. Date of R& I & fee	Dy.No 36635 dated 06-11-2018 Rs.20,000 /- Dated 06-11-2018
	Pharmacological Group	Proton Pump inhibitor
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	2 x 7's, 4 x 7's :As per SRO
	Approval status of product in Reference Regulator Authorities	Dexilant Delayed Release Capsule 60mg of USFDA approved
	Me-too status	Lansodex Capsule 60mg of M/S Getz Pharma
	GMP status	Last inspection conducted on 22/02/2018 and concludes that "In the light of the inspection conducted by the panel and based on the people met, documents reviewed and findings during inspection, M/s pacific pharma ltd Multan road Lahore, was considered to be operating at good level of GMP compliance at the time of inspection. Therefore, the panel of inspectors recommends considering the firm for grant of GMP certificate for export purposes." "GMP Certificate Issued on 05-03-2018."
	Remarks of the Evaluator	

STABILITY STUDY DATA

Drug	Dexlan 60mg Capsule		
Name of Manufacturer	M/s Pacific Pharmaceuticals Limited 30 Km, multan road lahore		
Manufacturer of API	M/S Vision Pharmaceuticals (Pvt)., Ltd is submitted. **M/S Al Wajar Pharmaceuticals Industry LLC**		
API Lot No.	**PDLB19003, PDLB19002 & PDLB19001** DLP 376		
Description of Pack (Container closure system)	PVC-PVDC blisters		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated:6 months		
Frequency	Accelerated:0,1,2,3,4,5,6(month) Real Time: 0,3,6, (month)		
Batch No.	TDL00101P	TDL00201P	TDL00301P
Batch Size	4500 Capsules	4500 Capsules	4500 Capsules

Manufacturing Date	10-2019	10-2019	10-2019
Date of Initiation	05-02-2020	05-02-2020	05-02-2020
No. of Batches	03		
Date of Submission	27-08-2020 (21606)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	• Not submitted
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	**Copy of COA of Dex-Lansoprazole DDR pellets 22.5% (Batch# PDLB19003, PDLB19002 & PDLB19001) from M/S Al Wajar Pharmaceuticals Industry LLC is submitted.** Copy of COA [Batch# DLP 376) from M/S Vision Pharmaceuticals (Pvt) Ltd is submitted. Copy of COA (Batch# DLP 376) from M/S Pacific Pharmaceuticals is submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Yes
4.	Stability study data of API from API manufacturer	Yes
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Certificate of Good manufacturing practice Based on inspection conducted on 11-02-2019
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Not valid
7.	Protocols followed for conduction of stability study	Yes
8.	Method used for analysis of FPP	No
9.	Drug-excipients compatibility studies (where applicable)	Not valid
10.	Complete batch manufacturing record of three stability batches.	No
11.	Record of comparative dissolution data (where applicable)	No
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	No
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Yes

14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Yes

Remarks of Evaluator

S.No	Shortcomings Communicated	Reply
1.	Data has not been provided as per guidelines approved by registration board in 293rd meeting nor arranged in order.	Submitted
2.	Stability data of 30mg and 60mg shall be submitted separately.	Submitted
3.	Submit differential fee of RS: 80000/- in case of imported pellets.	**Now source mentioned is vision pharmaceuticals**
4.	Submit Certificate of Analysis of API from Finished Product manufacturer	Submitted
5.	Submit Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Submitted
6.	Submit Stability study data of API from API manufacturer	Submitted
7.	Submit Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin	Submitted
8.	Submit AD attested invoice of pellets.	Not valid
9.	Protocols followed for conduction of stability study prepared after initiation of stability studies. Clarify	Submitted
10.	Data of 03 batches will be supported by attested respective documents like, Raw data sheets, COA, summary data sheets etc.	Not Submitted
2nd letter 24th November 2021		
1.	In initial submitted data source of pellets was M/S Al Wajar Pharmaceuticals Industry LLC while in reply source of pellets is changed to vision Pharmaceuticals. Clarification is required in this regard.	
2.	Method used for analysis of FPP	
3.	Reference of previous approval of applications with stability study data of the firm.	
4.	Record of comparative dissolution data.	
5.	Complete batch manufacturing record of three stability batches.	
6.	Data of 03 batches will be supported by attested respective documents like, Raw data sheets, COA, summary data sheets etc.	

Decision of 324th meeting: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Firm's response:

Sr.#	Observations	Firm's response
1.	In initial submitted data source of pellets was M/S Al-Wajar Pharmaceuticals Industry LLC while in reply source of pellets is changed to vision Pharmaceuticals. Clarification is required in this regard.	• The Vision Pharmaceuticals has provided complete data, while no supporting documents are provided by M/s Al Wajar Pharmaceuticals, That's why, pallets are locally purchased and source is changed to Vision Pharmaceuticals. • Firm has also submitted copy of commercial invoice from M.s Vision Pharmaceuticals for the Dexlansoprazole pellets dated 28-12-2018.
2.	Method used for analysis of FPP.	Firm has submitted drug product analytical procedure.
3.	Reference of previous approval of applications with stability study data of the firm.	Firm has referred to previous onsite inspection report of their product Esmelin tablet 15mg dated 10-08-2020 on the basis of which Registration Board in its 313th meeting decided to approve the registration of Esmelin 15mg tablet. The report shows that: • The HPLC software is 21 CFR compliant and Log of data was available in the HPLCs. The data was also checked through hard copies of chromatograms. • Adequate monitoring and control were available for stability chamber. The firm was advised to improve the alarm system.
4.	Record of comparative dissolution data.	Firm has submitted comparative dissolution profile studies against the Delanzo 60mg capsule of M/s Sami Pharmaceutical with acceptable value of f2 value.
5.	Complete batch manufacturing record of three stability batches.	Firm has submitted BMR of three trial batches.
6.	Data of 03 batches will be supported by attested respective documents like, Raw data sheets, COA, summary data sheets etc.	Submitted.

Decision: Approved with Innovator's specification. Registration letter shall be issued after submission of fee Rs. 30,000/- for revision of source of drug substance, as per Notification No. 7-11/2012-B&A dated 07.05.2021.

Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

12.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s PDH Laboratories Pvt Ltd. 9.5 km, Sheikhupura Road, Lahore, Pakistan**

	Name, address of Manufacturing site.	M/s PDH Laboratories Pvt Ltd. 9.5 km, Sheikhupura Road, Lahore, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Evidence of Manufacturing facility	Issuance of additional section vide letter no. F.1-1/86-Lic (Vol-V) dated 07-06-2022 for Oral liquid section (General)
	Dy. No. and date of submission	Dy. No 27453 dated 28-09-2022
	Details of fee submitted	Rs.30,000/- dated 05-04-2022
	The proposed proprietary name / brand name	**PD-Fen Syrup 0.25mg/5ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Pizotifen Malate…….0.25mg
	Pharmaceutical form of applied drug	Liquid Syrup
	Pharmacotherapeutic Group of (API)	Other antimigraine preparations
	Reference to Finished product specifications	Manufacturer's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved by AEMPS of Spain
	For generic drugs (me-too status)	Mosegar syrup by M/s Novartis Pharma Reg. No. 006282
	GMP status of the Finished product manufacturer	Panel inspection dated 03-1-2022 recommends renewal of DML
	Name and address of API manufacturer.	M/s Suzhou Homesun Pharmaceutical Co., Ltd No. 12 Xiexing West Roas, taicang City, Jiangsu province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Mosegor syrup by M/s Novartis Pharma.
	Analytical method validation/verification of product	Method validation studies have been submitted.

STABILITY STUDY DATA

Manufacturer of API	M/s Suzhou Homesun Pharmaceutical Co., Ltd No. 12 Xiexing West Roas, taicang City, Jiangsu province, China.		
API Lot No.	20201026		
Description of Pack (Container closure system)	Amber colour Glass bottle		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 03 months Accelerated: 03 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial 003	Trial 004	Trial 005
Batch Size	40 bottles	40 bottles	40 bottles
Manufacturing Date	11-2021	11-2021	11-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate# HA20180047 issued by CFDA valid till 21-08-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice no. 0105SLT2012401-2 attested by AD I&E DRAP dated 26-01-2021 for import of 24gm of Pizotifen malate.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).	Submitted

Remarks of Evaluator[II]:

Section#	Observations	Firm's response
1.5.3	Submit the strength/concentration of applied formulation as per innovator product in terms of mg/ml and considering the equivalency factor for hydrogen malate along with submission of fee for correction/pre-approval change in label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	Firm has submitted revised label claim: "Each 5ml contains: Pizotifen as hydrogen malate ……. 0.25mg"
3.2. S.4.3	Drug Substance Analytical Method Verification Studies shall include performance of specificity and accuracy parameter.	Submitted.
3.2.P.1	Justify the prosed quantity of Pizotifen malate per unit considering equivalency factor for hydrogen malate	Firm has submitted justification based upon the theoretical factor for the malate salt form calculated on basis of molecular weight.
3.2.P.5.2	Submit drug product analytical procedure.	Submitted.
3.2.P.5.4	Submit signed batch analysis certificates for the trial batches.	Submitted.
3.2.P.5.6	Justification/reference shall be submitted for the limits of test of pH and viscosity.	It is submitted that during the product development phase, we have developed the testing specifications of PD-Fen (Pizotifen) Syrup by comparing it with Competitor product (Mosegor (Pizotifen) Syrup), manufactured by Novartis Pharmaceuticals. The test limits of pH and viscosity are established by keeping in view the nature of the excipients and also with respect to the competitor product, available in the market. The pharmaceutical equivalence is submitted.
3.2.P.8	• Submitted invoice is of different batch no. of drug substance from that submitted in section 3.2. S.4.4. • Submit batch manufacturing record for stability batches. • Justification shall be submitted for applying UV spectrophotometric method for the performance of Assay test. • Justification shall be submitted for the production of trial batches before the grant of "Oral liquid section."	• Firm has submitted commercial invoice of relevant batch#20201026 attested by AD I&E DRAP Lahore dated 26-01-2021. • Firm has submitted trial batch manufacturing record for three stability batches. • It is submitted that the product is developed on In-house specifications. At the time of product development phase, we have developed the analytical method of PD-Fen Syrup 0.25mg/5ml on UV spectrophotometer for the performance of assay test. The compliance of this method is ensured through analytical method validation (provided with the dossier). The developed method has been validated

statistically for their specificity, linearity, accuracy and precision as per guidelines.
- Please be informed that all trial batches are developed in R&D Lab (Batch size: 2.40 Liters).

Decision of 323rd meeting: Deferred for following:

- Revision of drug product analytical procedure for assay test on basis of HPLC method and submission of performance of next time point of long term stability studies as per revised HPLC method along with analytical method validation studies.
- Evidence of approval of R&D lab from CLB.

Firm's response:

Observations	Firm's response
Revision of drug product analytical procedure for assay test on basis of HPLC method and submission of performance of next time point of long term stability studies as per revised HPLC method along with analytical method validation studies.	Firm has submitted revised drug product analytical method for Assay test based on HPLC method along with method validation studies and long term stability studies of next time point with Assay test as per HPLC method.
Evidence of approval of R&D lab from CLB.	It is submitted that our syrup section was ready for inspection in October 2019 as intimated by us to I Licensing Division vide letter no. PDHL/D&RA/19/0828 (copy attached) while the final approval was granted in July 2022 (Copy attached). Since we had the requisite manufacturing equipment available in our newly developed section so we developed R&D trial batches in said facility in November 2021 to avoid delay in product development and stability studies.

Decision: Registration Board while considering the case noted the fact that firm has manufactured the trial batches without formal approval of the manufacturing facility and even before the panel inspection for the approval of "Oral Liquid Section (General)", hence Board decided that the submitted stability data of these trial batches could not be considered.

Registration Board further decided that firm shall formulate new trial batches and submit its stability data for both accelerated and long term conditions along with full fee of registration i.e., Rs. 30,000/- for correction/pre-approval change in stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

13.	**Name and address of manufacturer / Applicant**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan** contract manufacturing by **M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore**
	Brand Name + Dosage Form + Strength	Noriday 5mg Tablet
	Composition	Each Tablet Contains: Norethisterone Acetate ……. 5mg
	Diary No. Date of R& I & fee	R&I Dy.No 41482 dated 07-12-2018 verified by R&I Incharge, Rs.50,000/- dated 07-12-2018
	Pharmacological Group	Progestogen
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHR of UK

	Me-too status (with strength and dosage form)	Postpon-M Tablet by M/s OBS, (Reg# 073532)
	GMP status	Dyson: GMP inspection dated 11-01-2019, concluded satisfactory level of GMP compliance.
	Evaluation by PEC: M/s Dyson Research Laboratories has Tablet hormone section.	
	Decision of 321st meeting: Deferred for further deliberation regarding requirement of manufacturing facility for applied formulation.	
	Firm's response: Firm has copy of letter no. F.1-7/2003-Lic(Vol-IV) dated 22nd February, 2023 issued by name of M/s Dyson Research laboratories (Pvt.) Ltd., Lahore wherein grant of Tablet (Steroidal Hormone) section is approved.	
	Decision: Approved.	
14.	**Name and address of manufacturer / Applicant**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan** contract manufacturing by **M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore**
	Brand Name + Dosage Form + Strength	Tibogen 2.5mg Tablet
	Composition	Each Tablet Contains: Tibolone…….2.5mg
	Diary No. Date of R& I & fee	R&I Dy.No 41484 dated 07-12-2018 verified by R&I Incharge, Rs.50,000/- dated 07-12-2018
	Pharmacological Group	Estrogens
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Livial 2.5 mg tablets of MHRA approved
	Me-too status (with strength and dosage form)	Tibopause Tablets 2.5mg by M/s Zafa Pharmaceuticals (Reg# 024213)
	GMP status	Dyson: GMP inspection dated 11-01-2019, concluded satisfactory level of GMP compliance.
	Evaluation by PEC: M/s Dyson Research Laboratories has Tablet hormone section.	
	Decision of 321st meeting: Deferred for further deliberation regarding requirement of manufacturing facility for applied formulation.	
	Firm's response: Firm has copy of letter no. F.1-7/2003-Lic(Vol-IV) dated 22nd February, 2023 issued by name of M/s Dyson Research laboratories (Pvt.) Ltd., Lahore wherein grant of Tablet (Steroidal Hormone) section is approved.	
	Decision: Approved.	
15.	**Name and address of manufacturer / Applicant**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan** contract manufacturing by **M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore**
	Brand Name + Dosage Form + Strength	Mestif 25mg Tablet
	Composition	Each Tablet Contains: Mesterolone…….25mg
	Diary No. Date of R& I & fee	R&I Dy.No 41485 dated 07-12-2018 verified by R&I Incharge, Rs.50,000/- dated 07-12-2018
	Pharmacological Group	Androgen (5-androstanon (3) derivative)
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Pro-viron of MHRA approved
	Me-too status (with strength and dosage form)	Androviron 25mg Tablets by M/s Global (Reg# 030471)

	GMP status	Dyson: GMP inspection dated 11-01-2019, concluded satisfactory level of GMP compliance.
	Evaluation by PEC: M/s Dyson Research Laboratories has Tablet hormone section.	
	Decision of 321st meeting: Deferred for further deliberation regarding requirement of manufacturing facility for applied formulation.	
	Firm's response: Firm has copy of letter no. F.1-7/2003-Lic(Vol-IV) dated 22nd February, 2023 issued by name of M/s Dyson Research laboratories (Pvt.) Ltd., Lahore wherein grant of Tablet (Steroidal Hormone) section is approved.	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
16.	**Name and address of manufacturer / Applicant**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan** contract manufacturing by **M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore**
	Brand Name + Dosage Form + Strength	Lynest 500mcg Tablet
	Composition	Each Tablet Contains: Lynestrenol …….500mcg
	Diary No. Date of R& I & fee	R&I Dy.No 41487 dated 07-12-2018 verified by R&I Incharge, Rs.50,000/- dated 07-12-2018
	Pharmacological Group	Androgen (5-androstanon (3) derivative)
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Pro-viron of MHRA approved
	Me-too status (with strength and dosage form)	Androviron 25mg Tablets by M/s Global (Reg# 030471)
	GMP status	Dyson: GMP inspection dated 11-01-2019, concluded satisfactory level of GMP compliance.
	Evaluation by PEC: M/s Dyson Research Laboratories has Tablet hormone section.	
	Decision of 321st meeting: Deferred for further deliberation regarding requirement of manufacturing facility for applied formulation.	
	Firm's response: Firm has copy of letter no. F.1-7/2003-Lic(Vol-IV) dated 22nd February, 2023 issued by name of M/s Dyson Research laboratories (Pvt.) Ltd., Lahore wherein grant of Tablet (Steroidal Hormone) section is approved.	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
17.	**Name and address of manufacturer / Applicant**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan** contract manufacturing by **M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore**
	Brand Name + Dosage Form + Strength	C-Ethin 2mg/35mcg Tablet
	Composition	Each Film Coated Tablet Contains: Cyproterone as Acetate…2mg Ethinyloestradiol……..35mcg
	Diary No. Date of R& I & fee	R&I Dy.No 41486 dated 07-12-2018 verified by R&I Incharge, Rs.50,000/- dated 07-12-2018
	Pharmacological Group	Anti-androgen/estrogen
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Dermapil film coated tablet, TGA Approved.
	Me-too status (with strength and dosage form)	DIANE-35 by Bayer Health care (Reg. No. 011467), Eva-35 tablet by M/s Hansel (Reg#064796)
	GMP status	Dyson: GMP inspection dated 11-01-2019, concluded satisfactory level of GMP compliance.
	Evaluation by PEC: M/s Dyson Research Laboratories has Tablet hormone section.	
	Decision of 321st meeting: Deferred for further deliberation regarding requirement of manufacturing facility for applied formulation.	
	Firm's response: Firm has copy of letter no. F.1-7/2003-Lic(Vol-IV) dated 22nd February, 2023 issued by name of M/s Dyson Research laboratories (Pvt.) Ltd., Lahore wherein grant of Tablet (Steroidal Hormone) section is approved.	
	Decision: Approved with BP specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
18.	**Name and address of manufacturer / Applicant**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan** contract manufacturing by **M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore**
	Brand Name + Dosage Form + Strength	C-Ethin 2mg/35mcg Tablet
	Composition	Each Film Coated Tablet Contains: Cyproterone as Acetate…2mg Ethinyloestradiol……..35mcg
	Diary No. Date of R& I & fee	R&I Dy.No 41486 dated 07-12-2018 verified by R&I Incharge, Rs.50,000/- dated 07-12-2018
	Pharmacological Group	Anti-androgen/estrogen
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Dermapil film coated tablet, TGA Approved.
	Me-too status (with strength and dosage form)	DIANE-35 by Bayer Health care (Reg. No. 011467), Eva-35 tablet by M/s Hansel (Reg#064796)
	GMP status	Dyson: GMP inspection dated 11-01-2019, concluded satisfactory level of GMP compliance.
	Evaluation by PEC: M/s Dyson Research Laboratories has Tablet hormone section.	
	Decision of 321st meeting: Deferred for further deliberation regarding requirement of manufacturing facility for applied formulation.	
	Firm's response: Firm has copy of letter no. F.1-7/2003-Lic(Vol-IV) dated 22nd February, 2023 issued by name of M/s Dyson Research laboratories (Pvt.) Ltd., Lahore wherein grant of Tablet (Steroidal Hormone) section is approved.	
	Decision: Approved with BP specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
19.	**Deleted due to repetition**	
20.	**Name and address of manufacturer / Applicant**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan** contract manufacturing by **M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore**
	Brand Name + Dosage Form + Strength	Etges 0.02mg/0.075mg tablet
	Composition	Each Film Coated Tablet Contains: Ethiynlestradiol ……. 0.2mg Gestodene ……. 0.075mg

	Diary No. Date of R& I & fee	R&I Dy.No 41483 dated 07-12-2018 verified by R&I Incharge, Rs.50,000/- dated 07-12-2018
	Pharmacological Group	Hormonal contraceptives for systemic use (Progestogens and estrogens, fixed Combinations)
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Aidulan 20/75 microgram film-coated tablets of MHRA approved
	Me-too status (with strength and dosage form)	Meliane Tablets of M/s Medipharm Reg# 024076
	GMP status	Dyson: GMP inspection dated 11-01-2019, concluded satisfactory level of GMP compliance.
	Evaluation by PEC: M/s Dyson Research Laboratories has Tablet hormone section.	
	Decision of 321st meeting: Deferred for further deliberation regarding requirement of manufacturing facility for applied formulation.	
	Firm's response: Firm has copy of letter no. F.1-7/2003-Lic(Vol-IV) dated 22nd February, 2023 issued by name of M/s Dyson Research laboratories (Pvt.) Ltd., Lahore wherein grant of Tablet (Steroidal Hormone) section is approved.	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
21.	**Name and address of manufacturer / Applicant**	**Bio-Mark Pharmaceuticals.** 527-Sunder Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	**LAXATIVE Syrup 10g/15ml**
	Diary No. Date of R& I & fee	Diary No: 6166, 14/06/2017, Rs: 20,000/-
	Composition	Each 15ml contains: Lactitol as monohydrate…10gm.
	Pharmacological Group	Osmotically acting laxative
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specifications.
	Pack size & Demanded Price	120ml / As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Importal Syrup by M/s Novartis (Swissmedica)
	Me-too status	Lacasil 10g/15ml syrup by M/s Sami Pharmaceuticals Pvt. Limited. (Reg#070552)
	GMP status	NEW LICENCE.
	Remarks of the Evaluator.	• Confirmation of availability of RI detector.
	Decision of 272nd meeting: Deferred for confirmation of availability of RI detector.	
	Firm's response: Firm has submitted IQ & OQ reports of the HPLC equipped with RI Detector along with commercial invoice for the RI detector.	
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	

Case no. 04 Registration Applications of priority on basis of NCE:

22.	**Name, address of Applicant / Importer**	**M/s AJM Pharma (Pvt.) Ltd., 1st Floor, Shafi Court, Merewether Road, Civil Lines, Karachi. Pakistan.**
	Details of Drug Sale License of importer	**License No: 064** **Address:** 1st Floor, Shafi Court, Civil Lines, Merewether Road, Karachi, Pakistan. **Address of Godown:** Plot No.44, Sector27, orangei Industrial Area, Karachi

		Validity: 23.02.2023. **Status:** License to sell drugs as distributor **Renewal:**
	Name and address of marketing authorization holder (abroad)	Chia Tai Tianqing Pharmaceutical Group Co., Ltd. No. 369 South Yuzhou Road, Haizhou District, Lianyungang,Jiangsu Province, China,
	Name, address of manufacturer(s)	Chia Tai Tianqing Pharmaceutical Group Co., Ltd. No. 369 South Yuzhou Road, Haizhou District, Lianyungang,Jiangsu Province, China,
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP certificate (No.JS20220116) valid up to 31-03-2024 issued by Jiangsu Drug Administration, China the Applied product is available for free sale in exporting country. The facilities and operations conform WHO-GMP as per CoPP as well as GMP status of the manufacturing site through periodic inspection every year.
	Details of letter of authorization / sole agency agreement	Copy of Letter of Authorization is attached. Chia Tai Tianqing Pharmaceutical Group Co., Ltd. No. 369 South Yuzhou Road, Haizhou District, Lianyungang,Jiangsu Province China, authorizes M/s AJM Pharma (Pvt) Ltd., 1st Floor Shafi Court, Merewether Road , Civil Lines Karachi to register, Import & Distribute Fosaprepitant Dimeglumine 150mg Injection. The authorization letter is valid till 19,2027.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy.No 13563 dated 03-06-2022
	Details of fee submitted	PKR 75,000/-: 23-05-2022
	The proposed proprietary name / brand name	**FOSATANT 150mg Powder for Solution For Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Fosaprepitant as Dimeglumine ……. 150 mg
	Pharmaceutical form of applied drug	Powder for solution for infusion
	Pharmacotherapeutic Group of (API)	Anti-emetics and antinauseants Pharmacological Class: P/neurokinin 1 (NK1) receptor antagonist.
	Reference to Finished product specifications	As per In-house Specs.
	Proposed Pack size	**1 Vial / Unit Pack**

	Proposed unit price	As Per Current SRO
	The status in reference regulatory authorities	IVEMEND® with marketing authorization holder of Merck Sharp & Dohme Ltd, United Kingdom, the marketing authorization was granted on 11 January, 2008 in EU with an MA (EU) Number of EU/1/07/437/003.
	For generic drugs (me-too status)	NA
	Module-II (Quality Overall Summary)	Submitted
	Name, address of drug substance manufacturer	M Lianyungang Runzhong Pharmaceutical Co., Ltd.. No. 16 Jinqiao Road, Dapu Industrial Park, Lianyungang, Jiangsu 222069, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at -20 °C ± 5 °C. The stability study data is till 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence performed against RMP (IVEMEND®, Lot: M036007) by Merck Sharp & Dohme Ltd.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Injection vials made of neutral borosilicate glass tubing Transparent, Rubber closures, Caps made of aluminum-plastic combination.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 25°C±2°C /60%RH±5%RH for 6 months. The real time stability study data is conducted at 5°C±3°C. The real time stability study data of 3 batches is for 36 months.
Evaluation by PEC[II]: Firm has submitted label claim is not as per reference product wherein the declared strength is in terms of the base whereas section 3.2.P.1 and COPP declares the strength as per Innovator product i.e. Each vial contains Fosaprepitant Dimeglumine eq. to Fosaprepitant ……. 150 mg		
Decision: Approved with Innovator's specifications as per policy of inspections of manufacturer abroad. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.		

Case no. 05 Registration Applications of New DML (Human):

CLB in its 282nd meeting held on 31st August 2021 has considered and approved the grant of Drug Manufacturing License by way of formulation with following six (06) sections to M/s Swera Pharmaceuticals Plot 27, Street S-4, Industrial Area Rawat Islamabad

1	Tablet(General)	4	Cream/ Gel (General)
2	Capsule (General)	5	Lotion Section (General)
3	Sachet (General)	6	Dry Powder Injection (General)

23.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Swera Pharmaceuticals Plot 27, Street S-4, Industrial Area Rawat Islamabad**
	Name, address of Manufacturing site.	M/s Swera Pharmaceuticals Plot 27, Street S-4, Industrial Area Rawat Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 6022 dated 03/03/2023
	Details of fee submitted	PKR 30,000/-: dated 03/03/2023
	The proposed proprietary name / brand name	**Swedol 500mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet contains: Paracetamol …….500mg
	Pharmaceutical form of applied drug	White to off white rounded compressed tablets packed in PVC blister
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	BP specs
	Proposed Pack size	1×100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Name of the drug; **Paracetamol 500mg Tablets** approved by MHRA of UK
	For generic drugs (me-too status)	Mylenol 500mg Tablets by M/s Dr Raza Pharma 44-C industrial state Hayat Abad Peshawar
	GMP status of the Finished product manufacturer	New license granted on 14/09/2021 Tablet (General) section approved.
	Name and address of API manufacturer.	**Pharmagen Limited** Kot Nabi, Bukswala, 34km Ferozepur Road Lahore Pakistan www.pharmagen.com.pk
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 72 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches:(LE00510911/001/2016, LE00510911/002/2016, LE00510911/003/2016)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Innovator that is Panadol 500mg Tablets by GlaxoSmithKline by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same innovator that is Panadol 500mg Tablets by GlaxoSmithKline in pH 1.2, 4.5 and 6.8 media The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	**Pharmagen Limited** Address: Kot Nabi, Bukswala, 34km Ferozepur Road Lahore Pakistan www.pharmagen.com.pk		
API Lot No.	00510911/083/2022		
Description of Pack (Container closure system)	PVC blister packed in unit carton (1×100's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD-T013	RD-T014	RD-T015
Batch Size	1000 tab	1000 tab	1000 tab

Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	21-06-2022	22-06-2022	23-06-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 204/2022-DRAP(AD/159531263130-536) issued by DRAP valid till 18/11/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	NA
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	N/A
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	N/A
Remarks of Evaluator:		
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

M/s Pacific Pharmaceuticals Ltd. Ravi lane, Plot No., 384, Sundar industrial Estate, Raiwind Road, Lahore.

The Central Licensing Board in its 270th meeting held on 23rd May, 2019 has considered and approved the grant of Drug Manufacturing License to M/s Pacific Pharmaceuticals Ltd. Ravi lane, Plot No., 384, Sundar industrial Estate, Raiwind Road, Lahore by way of Formulation vide approval letter No. F. 1-56/2011 Lic dated 24th June, 2019 with following (03) sections.

S No.	Name of Section
1.	LVP (General) Section
2.	SVP (General) Section
3.	Ophthalmic General) Section

24.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pacific Pharmaceuticals Ltd. Plot No. 384, Sunder Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Pacific Pharmaceuticals Ltd. Plot No. 384, Sunder Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate issued on 17-07-2020

	Evidence of approval of manufacturing facility	Firm has submitted copy of section approval letter dated 24-06-2019 which specifies Ophthalmic general section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 789 dated 10-01-2022
	Details of fee submitted	Rs.30,000/- Dated: 06-12-2021
	The proposed proprietary name / brand name	**OptiFine Eye drops**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 10ml Contains: Hypromellose ..…… 0.3%
	Pharmaceutical form of applied drug	Eye Drops, Solution
	Pharmacotherapeutic Group of (API)	Hypromellose: Ophthalmic lubricants and irrigations ATC code: SO1X A20
	Reference to Finished product specifications	BP specification
	Proposed Pack size	1 x 10 ml
	Proposed unit price	--
	The status in reference regulatory authorities	USFDA Hypromellose Eye Drops BP FDC International Ltd UK PL 15872/0005
	For generic drugs (me-too status)	Tearkool Eye drops by Remington Pharmaceuticals (Me too Status) Pack size: 10 ml
	Name and address of API manufacturer.	M/s Anhui Sunhere Pharmaceuticals Excipients Co., Ltd. Address: Economic and technological developing zone, Huainan City, Anhui Province, P.R. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions duration of Stability studies)	**Hypromellose** Long-term stability studies were performed at a storage temperature of 30°C±2°C/65%±5% RH for 36 months. Accelerated stability studies were performed at a temperature of 40±2°C/75%±5% RH for 6 months.

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence Studies against the reference product of "Tearkool sterile ophthalmic Solution" by Remington pharmaceuticals Ltd. Pakistan.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions.

STABILITY STUDY DATA

Manufacturer of APIs	**Hypromellose** Anhui Sunhere Pharmaceuticals Expicients Co., Ltd. Address: Economic and technological developing zone, Huainan City, Anhui Province, P.R. China		
API Lot No.	210344		
Description of Pack (Container closure system)	Low density polyethylene (LDPE) vial with an insert cap assembly, comprising of white coloured HDPE screw cap over a LDPE nozzle with tamper-evident LDPE dust cover sealing the vial cap.		
Stability Storage Condition	Real time: 30ºC ± 2ºC / 35% HR ±5% Accelerated: 40ºC ± 2ºC / NMT 25% HR		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PDCM0012021	PDCM0022021	PDCM0032021
Batch Size	5 liter	5 liter	5 liter
Manufacturing Date	05/2021	05/2021	05/2021

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	**Documents To Be Provided**	**Status**
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Hypromellose** Copy of DML certificate in the name of Anhui Sunhere Pharmaceuticals Expicients Co., Ltd. Address: Economic and technological developing zone, Huainan City, Anhui Province, P.R. China by Anhui Drug Administration.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice attested by AD I&E DRAP, Lahore, has been submitted. **Batch No.** — **Quantity Imported** — **Date of approval by DRAP** 210344 — 250 g — 30-04-2021

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches along with batch manufacturing record and analytical record.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports on product testing.
6.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator:

Section no.	Observations	Firm's response
3.2.P.8.3	Submit both accelerated and long term stability studies data till 6th month time point for all the stability batches.	Firm has submitted accelerated and long term stability studies of 6th month time point.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Case No. 03 Registration applications of Form-5 cases

a) New cases

25.	**Name and address of manufacturer / Applicant**	**M/s Webrose Pharmaceuticals. Plot # 1, Street # 10, National Industrial Zone, Rawat, Pakistan**
	Brand Name +Dosage Form + Strength	Weloxicam 7.5mg Tablet
	Composition	Each Tablet Contains: Meloxicam…7.5mg
	Diary No. Date of R& I & fee	Dy No. 15036: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Melor Tablet by Sami
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
26.	**Name and address of manufacturer / Applicant**	**M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan**
	Brand Name +Dosage Form + Strength	U Lamer 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Sevelamer HCl…400mg
	Diary No. Date of R& I & fee	Dy No. 14431: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Drugs for treatment of hyperkalemia and hyperphosphatemia
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Renavel Tablets by Genome Pharmaceuticals
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.

	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
27.	**Name and address of manufacturer / Applicant**	**M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan**
	Brand Name +Dosage Form + Strength	U Lamer 800mg Tablet
	Composition	Each Film Coated Tablet Contains: Sevelamer HCl…800mg
	Diary No. Date of R& I & fee	Dy No. 14432: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Drugs for treatment of hyperkalemia and hyperphosphatemia
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Renavel Tablets by Genome Pharmaceuticals
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
28.	**Name and address of manufacturer / Applicant**	**M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan**
	Brand Name +Dosage Form + Strength	Awa Modil 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Modafinil…100mg
	Diary No. Date of R& I & fee	Dy No. 14425: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Folic acid analogs
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Modagil 100mg Tablet by Rotex Pharma
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with following label claim: **Each Tablet Contains:**	

	Modafinil…100mg • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of formulation from film coated tablet to uncoated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
29.	**Name and address of manufacturer / Applicant**	**M/s Usawa Pharmaceuticals 146 S.I.Z. Risalpur, KPK, Pakistan**
	Brand Name +Dosage Form + Strength	Awa Modil 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Modafinil…200mg
	Diary No. Date of R& I & fee	Dy No. 14426: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Folic acid analogs
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Modagil 200mg Tablet by Rotex Pharma
	GMP status	Firm was inspected on 08.01.2019, wherein satisfactory level of GMP was reported
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with following label claim: **Each Tablet Contains:** **Modafinil…200mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** **Firm shall submit 7,500/- fee for revision of formulation from film coated tablet to uncoated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
30.	**Name and address of manufacturer / Applicant**	**M/s Trison Research Laboratories Pvt Ltd. 27-A, Punjab Small Industries Estate, Sargodha**
	Brand Name +Dosage Form + Strength	Trinoxin 8mg Tablets
	Composition	Each Film Coated Tablet Contains: Lornoxicam…8mg
	Diary No. Date of R& I & fee	Dy No. 13632: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Xefo 8mg Film-Coated Tablet, Takeda Austria GmbH, Austria approved.
	Me-too status	Zafon Tablets by Getz
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with Innovator's specifications.	

	• **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
31.	**Name and address of manufacturer / Applicant**	**M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi**
	Brand Name +Dosage Form + Strength	Rocycl Injection
	Composition	Each 2ml Ampoule Contains: Procyclidine HCl…10mg
	Diary No. Date of R& I & fee	Dy No. 16847: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Anti-Parkinson Drugs
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Xprodine Injeciton 10mg by Mass Pharma
	GMP status	GMP certificate issued on basis of inspection conducted on 18-03-2022.
	Remarks of the Evaluator[3].	• Firm has liquid injectable (SVP) (General) section. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
32.	**Name and address of manufacturer / Applicant**	**M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Hepcon 5g Sachet
	Composition	Each Sachet Contains: L-Ornithine L-Aspartate…3g
	Diary No. Date of R& I & fee	Dy No. 13437: 07-03-2019 PKR 20,000/-: 05-03-2019
	Pharmacological Group	Amino Acid (Hepato Protective Lipotropic)
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Hepa-Merz 3g Granules by Austria Approved
	Me-too status	Hepa Merz Sachet by Brookes
	GMP status	Panel inspection conducted on 18-02-2020 wherein the panel recommended the renewal of DML.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.

		• Clarification is required since brand name is 5g sachet, while the applied composition specifies 3g.
	Decision: Deferred for clarification since the applied brand name is 5g sachet, while the applied composition specifies 3g strength. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
33.	**Name and address of manufacturer / Applicant**	**M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 KM Adyala Raod Post Office Daghal, Rawalpindi**
	Brand Name +Dosage Form + Strength	Tromelac 10 Injection
	Composition	Each 1ml Amoule Contains Ketorolac Tromethamine…10mg
	Diary No. Date of R& I & fee	Dy No. 15197: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Anti-inflammatory and anti-rheumatic products
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Tromit Injection 10mg/ml by Standpharm
	GMP status	GMP certificate issued to the firm on 28-12-2021 based on inspection conducted on 04-11-2021.
	Remarks of the Evaluator[3].	• Firm has sterile liquid injectable general section as per the submitted GMP certificate. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
34.	**Name and address of manufacturer / Applicant**	**M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 KM Adyala Raod Post Office Daghal, Rawalpindi**
	Brand Name +Dosage Form + Strength	Tromelac 30 Injection
	Composition	Each 1ml Amoule Contains Ketorolac Tromethamine…30mg
	Diary No. Date of R& I & fee	Dy No. 15196: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Anti-inflammatory and anti-rheumatic products
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1x1 ampoule: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ketorolac Tromethamine Injection 30mg/ml by M/s Hospira Pharmaceuticals, **USFDA** approved.
	Me-too status	Toralac Injection 30mg/ml by M/s Vision Pharmaceuticals
	GMP status	GMP certificate issued to the firm on 28-12-2021 based on inspection conducted on 04-11-2021.

	Remarks of the Evaluator[3].	• Firm has sterile liquid injectable general section as per the submitted GMP certificate.
	Decision: Approved.	
35.	**Name and address of manufacturer / Applicant**	**M/s Shaigan Pharmaceuticals (Pvt) Ltd. 14 KM Adyala Raod Post Office Daghal, Rawalpindi**
	Brand Name +Dosage Form + Strength	Taclorex Ointment 0.05mg/0.5mg
	Composition	Each Gram Contains: Calcipotriol as Monohydrate…0.05mg Batamethasone as Dipropionate Eq To Batamethasone…0.5mg
	Diary No. Date of R& I & fee	Dy No. 15206: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antipsoriatics for topical use in combination
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Caliros Ointment by Panacea Pharma
	GMP status	GMP certificate issued to the firm on 28-12-2021 based on inspection conducted on 04-11-2021.
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Revise your formulation as per the reference product along with submission of full fee of registration.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
36.	**Name and address of manufacturer / Applicant**	**M/s Sante Pvt Ltd A-97, S.I.T.E Super Highway, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Nasomet 50mcg Nasal Suspension
	Composition	Each Spray Contains: Mometasone Furoate…50mcg
	Diary No. Date of R& I & fee	Dy No. 16945: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Corticosteroids
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Hivate Nasal Spray of Saffron
	GMP status	Firm has submitted copy of GMP certificate of M/s Sante (Pvt) Ltd. dated 08-03-2022 issued on the basis of inspection dated 07-03-2022.

	Remarks of the Evaluator[3].	• The same product is already registered in the name of the firm M/s Sante Pvt Ltd, A-97, S.I.T.E II, Superhighway, Karachi vide Registration # 108661. The firm has applied for Change in Registration Status of Products From M/s Elko Organization (Pvt) Ltd., Karachi To M/s. Sante (Pvt) Ltd., Karachi and the case was considered and approved by the Board in its 297th meeting.
	Decision: Registration Board decided to reject the application since the applied formulation is already registered in the name of the firm.	
37.	**Name and address of manufacturer / Applicant**	**M/s Remington Pharmaceuticals Industries Pvt Ltd. 18 km, Multan Road, Lahore**
	Brand Name +Dosage Form + Strength	Alagar Oral Suspension
	Composition	Each ml Contains: Sodium Bicarbonate…133.5mg Sodium Alginate…250mg Calcium Carbonate…80mg
	Diary No. Date of R& I & fee	Dy No. 16458: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antacid
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	GMP inspection report dated 30th Sep 2021 and panel recommends considering the firm for grant of cGMP certificate in respect of all manufacturing sections.
	Remarks of the Evaluator[3].	• Firm has oral liquid section (General). • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	
38.	**Name and address of manufacturer / Applicant**	**M/s Remington Pharmaceuticals Industries Pvt Ltd. 18 km, Multan Road, Lahore**
	Brand Name +Dosage Form + Strength	Aquatral Sachet
	Composition	Each Sachet Contains: Sodium Citrate…2.9Gm Sodium Chloride…2.6Gm Potassium Chloride…1.5Gm Anhydrous Glucose…13.5Gm Orange Flavour…0.05Gm
	Diary No. Date of R& I & fee	Dy No. 16457: 07-03-2019 PKR 20,000/-: 07-03-2019

	Pharmacological Group	Antacid
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	GMP inspection report dated 30th Sep 2021 and panel recommends considering the firm for grant of cGMP certificate in respect of all manufacturing sections.
	Remarks of the Evaluator[3].	• Firm has sachet (general) section. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. **Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.**	
39.	**Name and address of manufacturer / Applicant**	**M/s Reliance Pharma. Plot No 8, Street No. S-8, Industrial Estate, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Reli Mirt 15mg Tablet
	Composition	Each Film Coated Tablet Contains: Mirtazapine…15mg
	Diary No. Date of R& I & fee	Dy No. 16171: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Mirtazapine tablet by Actavis (**MHRA** Approved)
	Me-too status	Elaxine tablet by Standpharm
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
40.	**Name and address of manufacturer / Applicant**	**M/s Reliance Pharma. Plot No 8, Street No. S-8, Industrial Estate, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Reli Mirt 30mg Tablet
	Composition	Each Film Coated Tablet Contains: Mirtazapine…30mg

	Diary No. Date of R& I & fee	Dy No. 16172: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Mirtazapine tablet by Actavis (**MHRA** Approved)
	Me-too status	Elaxine tablet by Standpharm
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
41.	**Name and address of manufacturer / Applicant**	**M/s Reliance Pharma. Plot No 8, Street No. S-8, Industrial Estate, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Relimod 200mg Tablet
	Composition	Each Tablet Contains: Modafinil…200mg
	Diary No. Date of R& I & fee	Dy No. 16173: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Folic acid analogs
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Modagil 200mg Tablet by Rotex Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
42.	**Name and address of manufacturer / Applicant**	**M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan**
	Brand Name +Dosage Form + Strength	Rakalor 4mg Tablet
	Composition	Each Film Coated Tablet Contains: Lornoxicam…4mg
	Diary No. Date of R& I & fee	Dy No. 16244: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	Xefo 4mg Film-Coated Tablet, Austria approved.
	Me-too status	Zafon Tablet by Getz
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
43.	**Name and address of manufacturer / Applicant**	**M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan**
	Brand Name +Dosage Form + Strength	Zonamide 50mg Capsule
	Composition	Each Capsule Contains: Zonisamide…50mg
	Diary No. Date of R& I & fee	Dy No. 16257: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Nisazon Capsule by Genetics
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
44.	**Name and address of manufacturer / Applicant**	**M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan**
	Brand Name +Dosage Form + Strength	Rizine 5mg Capsule
	Composition	Each Capsule Contains: Flunarizine HCl…5mg
	Diary No. Date of R& I & fee	Dy No. 16259: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Anti vertigo preparation
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Health Canada Approved
	Me-too status	Migram 5mg Capsule of Wilshire Laboratories
	GMP status	

	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Capsule Contains: Flunarizine as HCl…5mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Capsule Contains:** **Flunarizine as HCl…5mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
45.	**Name and address of manufacturer / Applicant**	**M/s Rakaposhi Pharmaceuticals Pvt Ltd. 97-K, Industrial Estate, Hayatabad, Peshawar, Pakistan**
	Brand Name +Dosage Form + Strength	Rofulvin Tablets 500mg
	Composition	Each Film Coated Tablet Contains: Griseofulvin…500mg
	Diary No. Date of R& I & fee	Dy No. 16251: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antifungals for systemic use
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Genovin Tablets 500 mg by Genome
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
46.	**Name and address of manufacturer / Applicant**	**M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Ropiron 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Eplerenone…50mg
	Diary No. Date of R& I & fee	Dy No. 16086: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Diuretics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications while monograph is available in JP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Epliron Tablet by Highnoon
	GMP status	Inspection dated 12-10-2018, the panel recommended renewal of DML
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with JP specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
47.	**Name and address of manufacturer / Applicant**	**M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Repro 100mg Tablet
	Composition	Each Tablet Contains: Metoprolol Tartarate…100mg
	Diary No. Date of R& I & fee	Dy No. 16088: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA Approved
	Me-too status	Simnex 10mg Tablet by Nexus Pharma
	GMP status	Inspection dated 12-10-2018, the panel recommended renewal of DML
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Metoprolol Tartarate…100mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Metoprolol Tartarate…100mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
48.	**Name and address of manufacturer / Applicant**	**M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Rycotil 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Mycophenolate Mofetil…500mg
	Diary No. Date of R& I & fee	Dy No. 16089: 07-03-2019 PKR 20,000/-: 07-03-2019

	Pharmacological Group	Immunosuppressant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Mycophenol 500mg Tablets of Wellborne
	GMP status	Inspection dated 12-10-2018, the panel recommended renewal of DML
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
49.	**Name and address of manufacturer / Applicant**	**M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Restyl Plus Tablet
	Composition	Each Film Coated Tablet Contains: Gestodene…0.075mg Ethinylestradiol…0.02mg
	Diary No. Date of R& I & fee	Dy No. 16105: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Hormonal contraceptives for systemic use
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Aidulan 20/75 microgram film-coated tablets, MHRA approved.
	Me-too status	Meliane Tablets by Medipharm
	GMP status	Inspection dated 12-10-2018, the panel recommended renewal of DML
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of required manufacturing facility / section approval letter from Licensing Division.
	Decision: Registration Board decided to reject the application since the firm does not have approval of requisite manufacturing facility i.e., "Tablet (Hormone) section" from Licensing Division of DRAP.	
50.	**Name and address of manufacturer / Applicant**	**M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Rabrin 2.5mg Tablet
	Composition	Each Tablet Contains: Terbutaline Sulphate…2.5mg
	Diary No. Date of R& I & fee	Dy No. 16112: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Selective beta-2-adrenoreceptor agonists
	Type of Form	Form 5

	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Respair 2.5mg Tablet by Zanctok Pharmaceutical
	GMP status	Inspection dated 12-10-2018, the panel recommended renewal of DML
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
51.	**Name and address of manufacturer / Applicant**	**M/s Radiant Pharma Pvt Ltd. 43-E, Sundar Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Roldi 1mg Tablet
	Composition	Each Film Coated Tablet Contains: Tolterodine Tartrate…1mg
	Diary No. Date of R& I & fee	Dy No. 16110: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Urinary antispasmodics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications while monograph is available in BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Neuterod Tablet by Neutro Pharma
	GMP status	Inspection dated 12-10-2018, the panel recommended renewal of DML
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with BP specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
52.	**Name and address of manufacturer / Applicant**	**M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Megate Tablets 40mg
	Composition	Each Film Coated Tablet Contains: Megestrol Acetate…40mg
	Diary No. Date of R& I & fee	Dy No. 13630: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Progestogens L02AB
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification while monograph is available in USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Mestrol Tablets by Pharmedic
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
53.	**Name and address of manufacturer / Applicant**	**M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Megate Tablets 160mg
	Composition	Each Film Coated Tablet Contains: Megestrol Acetate…160mg
	Diary No. Date of R& I & fee	Dy No. 13630: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Progestogens L02AB
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification while monograph is available in USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved b yMHRA of UK
	Me-too status	Progace Tablets 160mg by Medinet
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. Registration letter will be issued upon submission of latest GMP inspection report conducted within last three years.	
54.	**Name and address of manufacturer / Applicant**	**M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Rebamid Tablet 100mg
	Composition	Each Film Coated Tablet Contains: Rebamipide…100mg
	Diary No. Date of R& I & fee	Dy No. 16343: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other drugs for peptic ulcer and gastro-oesophageal reflux disease
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification while monograph is available in JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed

	Me-too status	Mucosta Tablet 100mg by Otsuka (Approved in 237th RB meeting)
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
55.	**Name and address of manufacturer / Applicant**	**M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Somin Tablet 2mg
	Composition	Each Extended Release Tablet Contains: Melatonin…2mg
	Diary No. Date of R& I & fee	Dy No. 16341: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Hypnotics And Sedatives
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	
56.	**Name and address of manufacturer / Applicant**	**M/s Pharma Health Pakistan Pvt Ltd. 17-Km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	E Dol 2mg Tablet
	Composition	Each Gram Contains: Estradiol Valerate…2mg
	Diary No. Date of R& I & fee	Dy No. 17253: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Estrogens
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Clarification is required since on some pages of Form 5, tablet dosage form is written while the label claim specifies that it is a topical dosage form. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. **Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.**	
57.	**Name and address of manufacturer / Applicant**	**M/s Pharma Health Pakistan Pvt Ltd. 17-Km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Just N 200mg/ml Injection
	Composition	Each ml Contains: Norethisterone Enanthate…200mg
	Diary No. Date of R& I & fee	Dy No. 17252: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Hormonal contraceptives for systemic use
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification while monograph is available in international pharmacopoeia
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Noristerat 200mg by Bayer Health (**MHRA** Approved)
	Me-too status	Norigest by Bayer Health Care
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of required manufacturing facility / section approval letter from Licensing Division is verified.
	Decision: Approved with InternationalPharmacopoeia specifcations. Registration letter will beissued upon submission of fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, alongwith latest GMP inspection report conducted within last three years	
58.	**Name and address of manufacturer / Applicant**	**M/s Medisearch Pharma Pvt Ltd** **5-Km, Raiwind Manga Road, Lahore**
	Brand Name +Dosage Form + Strength	Fenrate Capsule 67mg
	Composition	Each Capsule Contains Fenofibrate…67mg

	Diary No. Date of R& I & fee	Dy No. 13826: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Lipid modifying agents
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Lebirat capsule by Fynk Pharma
	GMP status	The firm is granted GMP certificate based on inspection conducted on 22-02-2021.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
59.	**Name and address of manufacturer / Applicant**	**M/s Zeta Pharmaceuticals. Plot # 494-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Zesyl 2mg Tablet
	Composition	Each Tablet Contains: Perindopril As Tert-butylamine…2mg
	Diary No. Date of R& I & fee	Dy No. 15997: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	ACE Inhibitor
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification while monograph is available in USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Erbpril Tablet by Mass pharma
	GMP status	GMP certificate has been submitted on the basis of evaluation conducted on 25-10-2019
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Perindopril Tert-butylamine and Perindopril erbumine are synonyms. • Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Tablet Contains: Perindopril Tert-butylamine…2mg
	Decision: Approved with USP specifications and with following label claim: Each Tablet Contains: Perindopril Tert-butylamine…2mg • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
60.	**Name and address of manufacturer / Applicant**	**M/s Zeta Pharmaceuticals. Plot # 494-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Zesyl 4mg Tablet

	Composition	Each Tablet Contains: Perindopril As Tert-butylamine…4mg
	Diary No. Date of R& I & fee	Dy No. 15988: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	ACE Inhibitor
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification while monograph is available in USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Erbpril Tablet by Mass pharma
	GMP status	GMP certificate has been submitted on the basis of evaluation conducted on 25-10-2019
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Perindopril Tert-butylamine and Perindopril erbumine are synonyms. • Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Tablet Contains: Perindopril Tert-butylamine…4mg
	Decision: Approved with USP specifications and with following label claim: **Each Tablet Contains:** **Perindopril Tert-butylamine…4mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
61.	**Name and address of manufacturer / Applicant**	**M/s Zeta Pharmaceuticals.** **Plot # 494-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Zesyl 8mg Tablet
	Composition	Each Tablet Contains: Perindopril As Tert-butylamine…8mg
	Diary No. Date of R& I & fee	Dy No. 15999: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	ACE Inhibitor
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification while monograph is available in USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Erbpril Tablet by Mass pharma
	GMP status	GMP certificate has been submitted on the basis of evaluation conducted on 25-10-2019
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Perindopril Tert-butylamine and Perindopril erbumine are synonyms.

		• Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Tablet Contains: Perindopril Tert-butylamine…8mg
	Decision: Approved with USP specifications and with following label claim: **Each Tablet Contains:** **Perindopril Tert-butylamine…8mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
62.	**Name and address of manufacturer / Applicant**	**M/s Paramount Pharmaceuticals Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Remigal Tablet 4mg
	Composition	Each Tablet Contains: Galantamine Hydrobromide…4mg
	Diary No. Date of R& I & fee	Dy No. 16298: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Acetylcholinesterase inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Dementio Tablet by Reko Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Galantamine (as Hydrobromide)…4mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Galantamine (as Hydrobromide)…4mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
63.	**Name and address of manufacturer / Applicant**	**M/s Paramount Pharmaceuticals Plot No. 36, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Remigal Tablet 8mg
	Composition	Each Tablet Contains: Galantamine Hydrobromide…8mg
	Diary No. Date of R& I & fee	Dy No. 16295: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Acetylcholinesterase inhibitor
	Type of Form	Form 5

	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Dementio Tablet by Reko Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Galantamine (as Hydrobromide)…8mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Galantamine (as Hydrobromide)…8mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
64.	**Name and address of manufacturer / Applicant**	**M/s Pakheim International Pharma Pvt Ltd. 28 Km, Feroze Pur Road, Lahore**
	Brand Name +Dosage Form + Strength	Lefomide 10mg Tablet
	Composition	Each Tablet Contains: Leflunomide…10mg
	Diary No. Date of R& I & fee	Dy No. 13657: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Selective immunosuppressants (L04AA)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Leflomid Tablet by Pharmatec
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Leflunomide…10mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Film Coated Tablet Contains:** **Leflunomide…10mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	

65.	**Name and address of manufacturer / Applicant**	**M/s Obsons Pharmaceuticals. 209-S, Quaid e Azam Industrial Estate, Kotlakhpat, Lahore, Pakistan**
	Brand Name +Dosage Form + Strength	Obfan Syrup 12.5mg/ml
	Composition	Each 5ml of Syrup Contains: Dimemorfan Phospate…12.5mg
	Diary No. Date of R& I & fee	Dy No. 16083: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antitussive-cough suppressant
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	PMDA japan approved
	Me-too status	Inventive Syrup by Amson vaccines & Pharma
	GMP status	GMP certificate issued on dated 07-03-2022 based on inspection conducted on 22-02-2022
	Remarks of the Evaluator[3].	•
	Decision: Registration Board deferred the case till verification of validity of DML status of the applicant, from the Licensing Division.	
66.	**Name and address of manufacturer / Applicant**	**M/s Obsons Pharmaceuticals. 209-S, Quaid e Azam Industrial Estate, Kotlakhpat, Lahore, Pakistan**
	Brand Name +Dosage Form + Strength	Obispro Tablet 2.5mg
	Composition	Each Film Coated Tablet Contains: Bisoprolol Fumarate…2.5mg
	Diary No. Date of R& I & fee	Dy No. 16081: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Actim Tablet by Sami
	GMP status	GMP certificate issued on dated 07-03-2022 based on inspection conducted on 22-02-2022
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Bisoprolol Fumarate…2.5mg
	Decision: Registration Board deferred the case till the decision by CLB regarding change of management and site for the DML of M/s Obsons Pharmaceuticals.	
67.	**Name and address of manufacturer / Applicant**	**M/s Obsons Pharmaceuticals. 209-S, Quaid e Azam Industrial Estate, Kotlakhpat, Lahore, Pakistan**
	Brand Name +Dosage Form + Strength	Obispro Tablet 5mg
	Composition	Each Film Coated Tablet Contains: Bisoprolol Fumarate…5mg

	Diary No. Date of R& I & fee	Dy No. 16082: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Actim Tablet by Sami
	GMP status	GMP certificate issued on dated 07-03-2022 based on inspection conducted on 22-02-2022
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Tablet Contains: Bisoprolol Fumarate…5mg
	Decision: Registration Board deferred the case till the decision by CLB regarding change of management and site for the DML of M/s Obsons Pharmaceuticals.	
68.	**Name and address of manufacturer / Applicant**	**M/s Obsons Pharmaceuticals. 209-S, Quaid e Azam Industrial Estate, Kotlakhpat, Lahore, Pakistan**
	Brand Name +Dosage Form + Strength	Obizipine Syrup 30mg/5ml
	Composition	Each 5ml Of Syrup Contains: Levodropropizine…30mg
	Diary No. Date of R& I & fee	Dy No. 16074: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Levodropropizine
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Glopizine 30mg/5ml Syrup by Global Pharma
	GMP status	GMP certificate issued on dated 07-03-2022 based on inspection conducted on 22-02-2022
	Remarks of the Evaluator[3].	•
	Decision: Registration Board deferred the case till the decision by CLB regarding change of management and site for the DML of M/s Obsons Pharmaceuticals.	
69.	**Name and address of manufacturer / Applicant**	**M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Ofene Tablet 50mg
	Composition	Each Tablet Contains: Clomiphene Citrate…50mg
	Diary No. Date of R& I & fee	Dy No. 16154: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Ovulation stimulants, synthetic
	Type of Form	Form 5
	Finished Product Specification	BP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Vogi Tablet by Genix Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection conducted on 06/08/2021.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
70.	**Name and address of manufacturer / Applicant**	**M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Defaxine ER 50mg Tablet
	Composition	Each Extended Release Tablet Contains: Desvenlafaxine As Succinate…50mg
	Diary No. Date of R& I & fee	Dy No. 16153: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidepressants
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	Desven XR Tablet by PharmEvo
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection conducted on 06/08/2021.
	Remarks of the Evaluator[3].	• Firm has revised the label claim along with submission of 7500 fee (741646875037 dated 02-06-2023) as per the innovator's product as per following: Each Extended Release Film Coated Tablet Contains: Desvenlafaxine As Succinate…50mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Extended Release Film Coated Tablet Contains:** **Desvenlafaxine as Succinate…50mg**	
71.	**Name and address of manufacturer / Applicant**	**M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	D Spa Injection 40mg
	Composition	Each 2ml Ampoule Contains: Drotaverine As Hcl…40mg
	Diary No. Date of R& I & fee	Dy No. 16155: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Anti-spasmodic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	1. NO-SPA 40 mg solution for injection by Sanofi Aventis (OGYEI Hungary Approved) 2. NO-SPA 40 mg / 2 ml solution for injection by Sanofi Romania (NAMMD Romania Approved)

		3. No-Spa 20 mg/ml solution for injection by Chinoin Pharmaceutical and Chemical Works Co. Ltd (Executive Agency For Medicinal Products, Bulgaria Approved)
	Me-too status	Dytra Injection by Tabros
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection conducted on 06/08/2021.
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Firm has revised the label claim along with submission of 30,000/- fee (67412701552 dated 02-06-2023) as per the innovator's product as per following: Each 2ml ampoule Contains: Drotaverine HCl…40mg
	Decision: Registration Board deliberated the matter in detail and observed that the applied formulation is approved by three European Union countries i.e., Hungary, Romania & Bulgaria and the applied formulation is also already approved by DRAP, The Board therefore decided to approved the product with with Innovator's specifications and with following label claim: **Each 2ml ampoule Contains:** **Drotaverine HCl…40mg**	
72.	**Name and address of manufacturer / Applicant**	**M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	D Spa Tablet 40mg
	Composition	Each Film Coated Tablet Contains: Drotaverine Hcl…40mg
	Diary No. Date of R& I & fee	Dy No. 15221: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Anti-spasmodic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Applied formulation is present in different European Economic Area (EEA) states like Poland, Hungary, Lithuania & Latvia (both as un-coated and coated tablets).
	Me-too status	No-Spa Tablet by Sanofi Aventis
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection conducted on 06/08/2021.
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Firm has revised the label claim along with submission of 7500 fee (213834769 dated 02-06-2023) as per the innovator's product as per following: Each Tablet Contains: Drotaverine HCl…40mg
	Decision: Registration Board deliberated the matter in detail and observed that the applied formulation is approved by three European Union countries i.e., Poland, Hungary, Lithuania & Latvia and the applied formulation is also already approved by DRAP, The Board therefore decided to approved the product with with Innovator's specifications and with following label claim: **Each Tablet Contains:** **Drotaverine HCl…40mg**	

73.	**Name and address of manufacturer / Applicant**	**M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Flozed Capsule 20mg
	Composition	Each Capsule Contains: Fluoxetine HCl…20mg
	Diary No. Date of R& I & fee	Dy No. 15220: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Selective Serotonin Reuptake Inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Wintin capsule by Winlet Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection conducted on 06/08/2021.
	Remarks of the Evaluator[3].	• Firm has revised the label claim along with submission of 30,000 fee (76737273 dated 02-06-2023) as per the innovator's product as per following: Each Capsule Contains: Fluoxetine (as HCl)…20mg
	Decision: Approved with following label claim: **Each Capsule Contains:** **Fluoxetine (as HCl)…20mg**	
74.	**Name and address of manufacturer / Applicant**	**M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Lepsi Injection 100mg
	Composition	Each ml Contains: Levetiracetam…100mg
	Diary No. Date of R& I & fee	Dy No. 15177: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	1's: 5ml Vial, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Levetiracetam 100 mg / mL Concentrate for solution for infusion (MHRA Approved)
	Me-too status	Lumark Injection by Searle
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection conducted on 06/08/2021.
	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
75.	**Name and address of manufacturer / Applicant**	**M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Mafic Tablet 500mg

	Composition	Each Tablet Contains: Mefenamic Acid…500mg
	Diary No. Date of R& I & fee	Dy No. 16151: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ponstan Forte Tablet by Pfizer
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection conducted on 06/08/2021.
	Remarks of the Evaluator[3].	• Firm has revised the label claim along with submission of 7500 fee (47987616873 dated 02-06-2023) as per the innovator's product as per following: Each Film Coated Tablet Contains: Mefenamic Acid…500mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Mefenamic Acid…500mg**	
76.	**Name and address of manufacturer / Applicant**	**M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Migrin Plus Tablet 85/500mg
	Composition	Each Film Coated Tablet Contains: Sumatriptan Succinate Eq To Sumatriptan…85mg Naproxen Sodium…500mg
	Diary No. Date of R& I & fee	Dy No. 16152: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	NSAID and Selective serotonin (5HT1) agonists
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Sumanex Tablet by High-Q
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection conducted on 06/08/2021.
	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
77.	**Name and address of manufacturer / Applicant**	**M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Tovivax Tablet 300mg
	Composition	Each Film Coated Tablet Contains: Tenofovir Disoproxil Fumarate…300mg

	Diary No. Date of R& I & fee	Dy No. 16150: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Anti viral
	Type of Form	Form 5
	Finished Product Specification	International Pharmacopoeia
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Viread by Gilead Pharma (**USFDA** Approved)
	Me-too status	Tenovir by Pharmix
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection conducted on 06/08/2021.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
78.	**Name and address of manufacturer / Applicant**	**M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Hemotran Capsule 250mg
	Composition	Each Capsule Contains: Tranexamic Acid…250mg
	Diary No. Date of R& I & fee	Dy No. 15218: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antifibrinolytics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications but available in JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	PMDA Japan Approved
	Me-too status	Btrol Capsule by Bosch pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection conducted on 06/08/2021.
	Remarks of the Evaluator[3].	•
	Decision: Approved with JP specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
79.	**Name and address of manufacturer / Applicant**	**M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Traxenamic Acid 500mg
	Composition	Each Capsule Contains: Traxenamic Acid…500mg
	Diary No. Date of R& I & fee	Dy No. 15219: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antifibrinolytics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications but available in JP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	PMDA Japan Approved
	Me-too status	Btrol Capsule by Bosch pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection conducted on 06/08/2021.
	Remarks of the Evaluator[3].	•
	Decision: Approved with JP specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
80.	**Name and address of manufacturer / Applicant**	**M/s Nawan Laboratories (Pvt) Ltd 136 sector 15 Korangi Industrial Area Karachi.**
	Brand Name +Dosage Form + Strength	Tinazeen 2mg Tablet
	Composition	Each Tablet Contains: Tizanidine As Hcl…2mg
	Diary No. Date of R& I & fee	Dy No. 16873: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Movax Tablet by Sami
	GMP status	Last GMP inspection is conducted on 25-01-2022 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Tizanidine (as HCl)…2mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Tizanidine (as HCl)…2mg** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
81.	**Name and address of manufacturer / Applicant**	**M/s Nawan Laboratories (Pvt) Ltd 136 sector 15 Korangi Industrial Area Karachi.**
	Brand Name +Dosage Form + Strength	Tinazeen 4mg Tablet
	Composition	Each Tablet Contains: Tizanidine As Hcl…4mg
	Diary No. Date of R& I & fee	Dy No. 16874: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Movax Tablet by Sami
	GMP status	Last GMP inspection is conducted on 25-01-2022 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Tizanidine (as HCl)…4mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Tizanidine (as HCl)…4mg** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
82.	**Name and address of manufacturer / Applicant**	**M/s Nabiqasim Industries Pvt Ltd 17/24, Korangi Industrial Area, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Deslumfort-D 2.5/120 mg Tablet
	Composition	Each Film Coated Tablet Contains: Desloratadine…2.5mg Pseudoephedine Sulphate…120mg
	Diary No. Date of R& I & fee	Dy No. 16216: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antiallergic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Desrhin Tablet by Atco
	GMP status	Firm has submitted copy of GMP certificate dated 28-05-2022 issued based on inspection dated 27-05-2022.
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
83.	**Name and address of manufacturer / Applicant**	**M/s Nabiqasim Industries Pvt Ltd 17/24, Korangi Industrial Area, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Lumfort-D 5/120 mg Tablet
	Composition	Each Film Coated Tablet Contains: Loratadine…5mg Pseudoephedrine Sulphate…120mg
	Diary No. Date of R& I & fee	Dy No. 16218: 07-03-2019 PKR 20,000/-: 07-03-2019

	Pharmacological Group	Antiallergic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Softin-P Tablets by Werrick Pharmaceuticals
	GMP status	Firm has submitted copy of GMP certificate dated 28-05-2022 issued based on inspection dated 27-05-2022.
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
84.	**Name and address of manufacturer / Applicant**	**M/s Nabiqasim Industries Pvt Ltd 17/24, Korangi Industrial Area, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Deslumfort-D 5/240 mg Tablet
	Composition	Each Film Coated Tablet Contains: Desloratadine…5mg Pseudoephedine Sulphate…240mg
	Diary No. Date of R& I & fee	Dy No. 16127: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antiallergic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Desrhin Tablet by Atco
	GMP status	Firm has submitted copy of GMP certificate dated 28-05-2022 issued based on inspection dated 27-05-2022.
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
85.	**Name and address of manufacturer / Applicant**	**M/s Nabiqasim Industries Pvt Ltd 17/24, Korangi Industrial Area, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Lumfort-D 10/240 mg Tablet
	Composition	Each Film Coated Tablet Contains:

		Loratadine…10mg Pseudoephedrine Sulphate…240mg
	Diary No. Date of R& I & fee	Dy No. 16129: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antiallergic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	Firm has submitted copy of GMP certificate dated 28-05-2022 issued based on inspection dated 27-05-2022.
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	
86.	**Name and address of manufacturer / Applicant**	**M/s MTI Medical Pvt Ltd 586-587, Sundar Industrial Estate, Lahore, Pakistan**
	Brand Name +Dosage Form + Strength	Eazo 10mg Tablet
	Composition	Each Tablet Contains: Loratadine…10mg
	Diary No. Date of R& I & fee	Dy No. 15217: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antiallergic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Smartec Tablet by Hilton Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
87.	**Name and address of manufacturer / Applicant**	**M/s MTI Medical Pvt Ltd 586-587, Sundar Industrial Estate, Lahore, Pakistan**
	Brand Name +Dosage Form + Strength	Eazo 5mg/5ml Syrup

	Composition	Each 5ml Contains: Loratadine…5mg
	Diary No. Date of R& I & fee	Dy No. 15216: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antiallergic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Salmorat 5mg/5ml Syrup by Fedro Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Firm has oal liquid (General) section
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
88.	**Name and address of manufacturer / Applicant**	**M/s MTI Medical Pvt Ltd 586-587, Sundar Industrial Estate, Lahore, Pakistan**
	Brand Name +Dosage Form + Strength	Predex Injection 200mcg/2ml vial
	Composition	Each Vial 2ml Contains: Dexmedetomidine As Hcl…200mcg
	Diary No. Date of R& I & fee	Dy No. 15214: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other hypnotics and sedatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Precidex Injection by Brookes
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of required manufacturing facility / section approval letter from Licensing Division. • Submission of stability study data of three batches of drug product as per the guidelines and checklist approved by Registration Board in its 293rd meeting.
	Decision: Registration Board decided to reject the application since the firm has not submitted stability study data of 3 batches of the drug product before the lapse of deadline decided by DRAP Authority i.e. till 31st December 2022.	
89.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Alomor Capsule 6.25mg
	Composition	Each Capsule Contains: Alogliptin…6.25mg

	Diary No. Date of R& I & fee	Dy No. 14244: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	
90.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Alomor Capsule 12.5mg
	Composition	Each Capsule Contains: Alogliptin…12.5mg
	Diary No. Date of R& I & fee	Dy No. 14243: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.

	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	
91.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Alomor Capsule 25mg
	Composition	Each Capsule Contains: Alogliptin …25mg
	Diary No. Date of R& I & fee	Dy No. 14242: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	
92.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Alomor-P 12.5/15 mg Capsule
	Composition	Each Capsule Contains: Alogliptin…12.5mg Pioglitazone…15mg
	Diary No. Date of R& I & fee	Dy No. 14238: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed

	Me-too status	Could not be confirmed
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	
93.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Alomor P Capsule 25mg/15mg
	Composition	Each Capsule Contains: Alogliptin …25mg Pioglitazone…15mg
	Diary No. Date of R& I & fee	Dy No. 14241: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	
94.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Alomor P Capsule 12.5mg/30mg
	Composition	Each Capsule Contains: Alogliptin …12.5mg

		Pioglitazone…30mg
	Diary No. Date of R& I & fee	Dy No. 14237: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	
95.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Alomor-P 25/30 mg Tablet
	Composition	Each Capsule Contains: Alogliptin…25mg Pioglitazone…30mg
	Diary No. Date of R& I & fee	Dy No. 14240: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.

		• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	
96.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Alomor P Capsule 12.5mg/45mg
	Composition	Each Capsule Contains: Alogliptin …12.5mg Pioglitazone…45mg
	Diary No. Date of R& I & fee	Dy No. 14236: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	
97.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Alomor P Capsule 25mg/45mg
	Composition	Each Capsule Contains: Alogliptin …25mg Pioglitazone…45mg
	Diary No. Date of R& I & fee	Dy No. 14239: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	
98.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Flotec Capsule 100mg
	Composition	Each Capsule Contains: Diclofenac Sodium…100mg
	Diary No. Date of R& I & fee	Dy No. 14211: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Arthonil Capsule by Batala Pharma
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets). • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Capsule Contains: Diclofenac sodium (as SR pellets)…100mg
	Decision: Approved with following label claim: **Each Capsule Contains:** **Diclofenac sodium (as SR pellets)…100mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in**	

	product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter. • **Firm shall submit source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets) before issuance of registration letter.**	
99.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Ivarid Capsule 5mg
	Composition	Each Capsule Contains: Ivabradine …5mg
	Diary No. Date of R& I & fee	Dy No. 14218: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other cardiac preparations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	
100.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Ivarid Capsule 7.5mg
	Composition	Each Capsule Contains: Ivabradine …7.5mg
	Diary No. Date of R& I & fee	Dy No. 14217: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other cardiac preparations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed

	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	
101.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Olmitan 5mg Capsule
	Composition	Each Capsule Contains: Olmesartan Medoximil…5mg
	Diary No. Date of R& I & fee	Dy No. 14226: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	
102.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Olmitan 10mg Capsule
	Composition	Each Capsule Contains: Olmesartan Medoximil…10mg
	Diary No. Date of R& I & fee	Dy No. 14229: 07-03-2019 PKR 20,000/-: 06-03-2019

	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	
103.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Olmitan 20mg Capsule
	Composition	Each Capsule Contains: Olmesartan Medoximil…20mg
	Diary No. Date of R& I & fee	Dy No. 14228: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board.	

	Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	
104.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Olmitan 40mg Capsule
	Composition	Each Capsule Contains: Olmesartan Medoximil…40mg
	Diary No. Date of R& I & fee	Dy No. 14227: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	
105.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Olmitan Hct 20/12.5 mg Tablet
	Composition	Each Capsule Contains: Olmesartan…20mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee	Dy No. 14208: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.

	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	
106.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Olmitan Hct 40/12.5mg
	Composition	Each Capsule Contains: Olmesartan Medoxomil…40mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee	Dy No. 14206: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	
107.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Olmitan Hct 20/25mg
	Composition	Each Capsule Contains: Olmesartan Medoximil…20mg Hydrochlorothizide…25mg
	Diary No. Date of R& I & fee	Dy No. 14207: 07-03-2019 PKR 20,000/-: 06-03-2019

	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	
108.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Olmitan Hct 40/25 mg Tablet
	Composition	Each Capsule Contains: Olmesartan…40mg Hydrochlorothiazide…25mg
	Diary No. Date of R& I & fee	Dy No. 14205: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.

	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	
109.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Brio Capsule
	Composition	Each Capsule Contains: Absorbic Acid…500mg Calciferol…400IU Calcium Carbonate…670mg Pyridoxime…10mg
	Diary No. Date of R& I & fee	Dy No. 14213: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Vitamins and minerals
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	
110.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Verve Capsule
	Composition	Each Capsule Contains: Calcium Lactate Glucose…1000mg Calcium Carbonate…327mg Vitamin C…500mg Vitamin D3…400Iu Vitamin B2…10Gm
	Diary No. Date of R& I & fee	Dy No. 14212: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Vitamins and minerals
	Type of Form	Form 5

	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	
111.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Gabafit 50mg Capsule
	Composition	Each Capsule Contains: Pregabalin…50mg
	Diary No. Date of R& I & fee	Dy No. 14209: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Anticonvulsant
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications while available in BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved
	Me-too status	Gabica Capsule by Getz
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with BP specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
112.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Gabafit 100mg Capsule
	Composition	Each Capsule Contains: Pregabalin…100mg

	Diary No. Date of R& I & fee	Dy No. 14210: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Anticonvulsant
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications while available in BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved
	Me-too status	Gabica Capsule by Getz
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with BP specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
113.	**Name and address of manufacturer / Applicant**	**M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Detral Tablets 4mg
	Composition	Each Capsule Contains: Tolterodine…4mg
	Diary No. Date of R& I & fee	Dy No. 14214: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Urinary antispasmodics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm is granted GMP certificate based on inspection conducted on 30-5-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	
114.	**Name and address of manufacturer / Applicant**	**M/s Medpharm Research Lab 28 km, Ferozepur Road, Lahore**

	Brand Name +Dosage Form + Strength	Amsar 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine Besylate…5mg
	Diary No. Date of R& I & fee	Dy No. 15654: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Calcium channel blockers
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Norvasc Tablet by Pfizer
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Tablet Contains: Amlodipine as Besylate…5mg
	Decision: Approved with following label claim: **Each Tablet Contains:** **Amlodipine as Besylate…5mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
115.	**Name and address of manufacturer / Applicant**	**M/s Medpharm Research Lab 28 km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Amsar 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine Besylate…10mg
	Diary No. Date of R& I & fee	Dy No. 15653: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Calcium channel blockers
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Norvasc Tablet by Pfizer
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Tablet Contains: Amlodipine as Besylate…10mg

	Decision: Approved with following label claim: **Each Tablet Contains:** **Amlodipine as Besylate…10mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
116.	**Name and address of manufacturer / Applicant**	**M/s Medpharm Research Lab 28 km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Amsar 5/160mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine Besylate…5mg Valsartan…80mg
	Diary No. Date of R& I & fee	Dy No. 15655: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Exforge Tablet by Novartis
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Clarification is required since on some pages 5/80mg strength is mentioned while on other pages 5/160mg strength is mentioned.
	Decision: Deferred for clarification regarding the applied strength since, the brand name specifies 5/160mg strength while the composition is provided for 5/80mg strength. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
117.	**Name and address of manufacturer / Applicant**	**M/s Medpharm Research Lab 28 km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Medzine 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Cetirizine …….10mg
	Diary No. Date of R& I & fee	Dy No. 15652: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Piperazine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Baydal Tablet by Bayer

	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Cetirizine Dihydrochloride…10mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Cetirizine Dihydrochloride…10mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
118.	**Name and address of manufacturer / Applicant**	**M/s Medpharm Research Lab 28 km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Mednac 75mg Tablet
	Composition	Each Enteric Coated Tablet Contains: Diclofenac as Sodium…75mg
	Diary No. Date of R& I & fee	Dy No. 15660: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Ayanac Tablet by Healthcare Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revision of formulation as per the reference product along with submission of full fee of registration. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
119.	**Name and address of manufacturer / Applicant**	**M/s Medpharm Research Lab 28 km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Medomycin 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Clarithromycin …250mg
	Diary No. Date of R& I & fee	Dy No. 15656: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Macrolides
	Type of Form	Form 5

	Finished Product Specification	Firm has claimed in house specifications while monograph is available in USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Claritek Tablet by Getz
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with USP specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
120.	**Name and address of manufacturer / Applicant**	**M/s Medpharm Research Lab 28 km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Medomycin 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Clarithromycin …500mg
	Diary No. Date of R& I & fee	Dy No. 15657: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications while monograph is available in USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Claritek Tablet by Getz
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with USP specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
121.	**Name and address of manufacturer / Applicant**	**M/s Medpharm Research Lab 28 km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Medaxamil 550mg Tablet
	Composition	Each Tablet Contains: Rifaximin…550mg
	Diary No. Date of R& I & fee	Dy No. 15666: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Axibol Tablet by Genetics Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Rifaximin…550mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Rifaximin…550mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
122.	**Name and address of manufacturer / Applicant**	**M/s Medpharm Research Lab 28 km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Meddone Tablet 1mg
	Composition	Each Tablet Contains: Risperidone…1mg
	Diary No. Date of R& I & fee	Dy No. 15661: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antipsychotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Neo-Risp Tablet by Wilshire
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Risperidone…1mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Risperidone…1mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
123.	**Name and address of manufacturer / Applicant**	**M/s Medpharm Research Lab 28 km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Medline 50mg Tablet

	Composition	Each Film Coated Tablet Contains: Sertraline Hcl…50mg
	Diary No. Date of R& I & fee	Dy No. 15659: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Seralin Tablet by Bosch
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Sertraline (as HCl)…50mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Sertraline (as HCl)…50mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
124.	**Name and address of manufacturer / Applicant**	**M/s Medpharm Research Lab 28 km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Medline 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Sertraline Hcl…100mg
	Diary No. Date of R& I & fee	Dy No. 15658: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Seralin Tablet by Bosch
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Sertraline (as HCl)…100mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:**	

	Sertraline (as HCl)…100mg • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
125.	**Name and address of manufacturer / Applicant**	**M/s Medpharm Research Lab 28 km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Sitamet 50/500 mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin Phospate Monohydrate.…50mg Metformin HCl…500mg
	Diary No. Date of R& I & fee	Dy No. 15663: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Treivamet Tablet by Getz
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Sitagliptin as Phospate Monohydrate.…50mg Metformin HCl…500mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Sitagliptin as Phospate Monohydrate.…50mg** **Metformin HCl…500mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
126.	**Name and address of manufacturer / Applicant**	**M/s Medpharm Research Lab 28 km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Sitamet DS plus Tablet 50/1000mg
	Composition	Each Film Coated Tablet Contains: Sitagliptin Phospate Monohydrate …50mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Dy No. 15662: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Treivamet Tablet by Getz
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Sitagliptin as Phospate Monohydrate.…50mg Metformin HCl…1000mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Sitagliptin as Phospate Monohydrate.…50mg** **Metformin HCl…1000mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
127.	**Name and address of manufacturer / Applicant**	**M/s Medpharm Research Lab 28 km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Meddine 4mg Tablet
	Composition	Each Tablet Contains: Tizanidine Hcl…4mg
	Diary No. Date of R& I & fee	Dy No. 15664: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Movax Tablet by Sami
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Tizanidine (as HCl)…4mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Tizanidine (as HCl)…4mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	

128.	**Name and address of manufacturer / Applicant**	**M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt**
	Brand Name +Dosage Form + Strength	Levta 100mg/5ml
	Composition	Each 5ml Contains: Levetiracetam…100mg
	Diary No. Date of R& I & fee	Dy No. 16785: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of required manufacturing facility / section approval letter from Licensing Division. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Registration Board deferred the case on basis of following information received from the Licesning Division: **"The CLB in its 289th meeting held on 23rd January, 2023 considerd the case of renewal of DML of M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt and decided a sunder:** **"The Board considerd and deferred the application for grant of renewal ofor inspection by all three members of the panel of inspectors."**	
129.	**Name and address of manufacturer / Applicant**	**M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt**
	Brand Name +Dosage Form + Strength	Ondron Syrup 4mg/5ml
	Composition	Each 5ml Contains: Ondansetron Hcl …4mg
	Diary No. Date of R& I & fee	Dy No. 16786: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antiemetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ondasave oral solution by Medisave
	GMP status	

	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each 5ml Contains: Ondansetron (as hydrochloride dehydrate)..…4mg
	Decision: Registration Board deferred till the decision of CLB regarding renewal of DML of M/s Medley Pharmaceuticals 41-A, PSIE Jhang Bahatar Road, Wah Cantt	
130.	**Name and address of manufacturer / Applicant**	**M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karchi, Pakistan**
	Brand Name +Dosage Form + Strength	Medirica 25mg Capsule
	Composition	Each Capsule Contains: Pregabalin…25mg
	Diary No. Date of R& I & fee	Dy No. 16928: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Anticonvulsant
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications while available in BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved
	Me-too status	Gabica Capsule by Getz
	GMP status	Last Inspection Report 17-12-2021 (Acceptable Level of Compliance)
	Remarks of the Evaluator[3].	•
	Decision: Approved with BP specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
131.	**Name and address of manufacturer / Applicant**	**M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura**
	Brand Name +Dosage Form + Strength	Cefmash 50mg Dry Suspension
	Composition	Each 5ml of Reconstituted Suspension Contains: Cefpodoxime as Proxetil…50mg
	Diary No. Date of R& I & fee	Dy No. 16144: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Ipod Suspension by Genome
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.

	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
132.	**Name and address of manufacturer / Applicant**	**M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura**
	Brand Name +Dosage Form + Strength	Cefmash 100mg Dry Suspension
	Composition	Each 5ml of Reconstituted suspension Contains: Cefpodoxime as Proxetil…100mg
	Diary No. Date of R& I & fee	Dy No. 16145: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Ipod Suspension by Genome
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
133.	**Name and address of manufacturer / Applicant**	**M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura**
	Brand Name +Dosage Form + Strength	Mosacit 2.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Mosapride Citrate…2.5mg
	Diary No. Date of R& I & fee	Dy No. 16148: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Propulsives
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications while monograph is available in JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	PMDA Japan Approved
	Me-too status	SAP Tablet by Tabros Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Mosapride Citrate Hydrate eq to Mosapride Citrate…2.5mg
	Decision: Approved with JP specifications and with following label claim: **Each Film Coated Tablet Contains:** **Mosapride Citrate Hydrate eq to Mosapride Citrate…2.5mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	

	• **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
134.	**Name and address of manufacturer / Applicant**	**M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura**
	Brand Name +Dosage Form + Strength	Mosacit 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Mosapride Citrate…5mg
	Diary No. Date of R& I & fee	Dy No. 16142: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Propulsives
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications while monograph is available in JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	PMDA Japan Approved
	Me-too status	SAP Tablet by Tabros Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Mosapride Citrate Hydrate eq to Mosapride Citrate…5mg
	Decision: Approved with JP specifications and with following label claim: **Each Film Coated Tablet Contains:** **Mosapride Citrate Hydrate eq to Mosapride Citrate…2.5mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
135.	**Name and address of manufacturer / Applicant**	**M/s Kanel Pharma. Plot # 6, St # SS-3, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Kancox Tablet 60mg
	Composition	Each Tablet Contains: Etoricoxib …60mg
	Diary No. Date of R& I & fee	Dy No. 15041: 07-03-2019 PKR 20,000/-: 05-03-2019
	Pharmacological Group	Antiinflammatory and Antirheumatic Products, Non-Steroids
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Etoxib Tablet by Hiranis
	GMP status	

	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Etoricoxib.….60mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Film Coated Tablet Contains:** **Etoricoxib..…60mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
136.	**Name and address of manufacturer / Applicant**	**M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi**
	Brand Name +Dosage Form + Strength	Ranalaz 375mg Tablet
	Composition	Each Film Coated Tablet Cotains: Ranolazine…375mg
	Diary No. Date of R& I & fee	Dy No. 16868: 07-03-2019 PKR 20,000/-: 05-03-2019
	Pharmacological Group	Other cardiac preparations
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved (as prolonged releae tablet)
	Me-too status	Could not be confirmed
	GMP status	GMP inspection report dated 11-08-2020 concluded that overall GMP compliance of the firm with respect to building, facilities and procedures demonstrated was satisfactory at the time of inspection.
	Remarks of the Evaluator[3].	• Revise your formulation as per the reference product along with submission of full fee of registration. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Proceedings of the Board: Registration Board was apprised that the firm has submitted stability study data of drug product before 31-12-2022. **Decision: Deferred for considered on its turn on the basis of the date of submission of stability study data.**	
137.	**Name and address of manufacturer / Applicant**	**M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi**
	Brand Name +Dosage Form + Strength	Ranalaz 500mg Tablet
	Composition	Each Film Coated Tablet Cotains: Ranolazine…500mg
	Diary No. Date of R& I & fee	Dy No. 16870: 07-03-2019 PKR 20,000/-: 05-03-2019
	Pharmacological Group	Other cardiac preparations
	Type of Form	Form 5
	Finished Product Specification	BP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved (as prolonged releae tablet)
	Me-too status	Razine ER 500mg Tablet by CCL
	GMP status	GMP inspection report dated 11-08-2020 concluded that overall GMP compliance of the firm with respect to building, facilities and procedures demonstrated was satisfactory at the time of inspection.
	Remarks of the Evaluator[3].	• Revise your formulation as per the reference product along with submission of full fee of registration.
	Proceedings of the Board: Registration Board was apprised that the firm has submitted stability study data of drug product before 31-12-2022. **Decision: Deferred for considered on its turn on the basis of the date of submission of stability study data.**	
138.	**Name and address of manufacturer / Applicant**	**M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi**
	Brand Name +Dosage Form + Strength	Ranalaz 750mg Tablet
	Composition	Each Film Coated Tablet Cotains: Ranolazine…750mg
	Diary No. Date of R& I & fee	Dy No. 16869: 07-03-2019 PKR 20,000/-: 05-03-2019
	Pharmacological Group	Other cardiac preparations
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved (as prolonged releae tablet)
	Me-too status	Could not be confirmed
	GMP status	GMP inspection report dated 11-08-2020 concluded that overall GMP compliance of the firm with respect to building, facilities and procedures demonstrated was satisfactory at the time of inspection.
	Remarks of the Evaluator[3].	• Revise your formulation as per the reference product along with submission of full fee of registration. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Proceedings of the Board: Registration Board was apprised that the firm has submitted stability study data of drug product before 31-12-2022. **Decision: Deferred for considered on its turn on the basis of the date of submission of stability study data.**	
139.	**Name and address of manufacturer / Applicant**	**M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura**
	Brand Name +Dosage Form + Strength	Perijen Tablet 10mg
	Composition	Each Tablet Contains: Domperidone…10mg
	Diary No. Date of R& I & fee	Dy No. 15699: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Propulsives

	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Domel Tablet by Barrett Hodgson
	GMP status	The firm was inspected on 23-12-2020 and conclusion of inspection was: Keeping in view the findings of inspection, and commitment of the management for future improvement, the members of the panel are of the opinion to recommend the grant of renewal of Drug Manufacturing License (000823) by way of formulation to M/s Jenner Pharma. 26 Km Lahore Shariqpur Road, District Sheikhupura.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Tablet Contains: Domperidone Maleate Eq To Domperidone…10mg
	Decision: Approved with following label claim: **Each Tablet Contains:** **Domperidone Maleate Eq To Domperidone…10mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
140.	**Name and address of manufacturer / Applicant**	**M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura**
	Brand Name +Dosage Form + Strength	Cetrijen Tablets 5mg
	Composition	Each Film Coated Tablet Contains: Levocetirizine Dihydrochloride…5mg
	Diary No. Date of R& I & fee	Dy No. 15703: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antihistaminic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	BELAIR 5mg Tablet by BAYER
	GMP status	The firm was inspected on 23-12-2020 and conclusion of inspection was: Keeping in view the findings of inspection, and commitment of the management for future improvement, the members of the panel are of the opinion to recommend the grant of renewal of Drug Manufacturing License (000823) by way of formulation to M/s Jenner Pharma. 26 Km Lahore Shariqpur Road, District Sheikhupura.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
141.	**Name and address of manufacturer / Applicant**	**M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura**

	Brand Name +Dosage Form + Strength	Jencholic 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Obetichlolic Acid…10mg
	Diary No. Date of R& I & fee	Dy No. 15705: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Bile acids and derivatives
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Obliva Tablet by Hilton
	GMP status	The firm was inspected on 23-12-2020 and conclusion of inspection was: Keeping in view the findings of inspection, and commitment of the management for future improvement, the members of the panel are of the opinion to recommend the grant of renewal of Drug Manufacturing License (000823) by way of formulation to M/s Jenner Pharma. 26 Km Lahore Shariqpur Road, District Sheikhupura.
	Remarks of the Evaluator[3].	• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting.
	Proceedings of the Board: Registration Board was apprised that the firm has submitted stability study data of drug product before 31-12-2022. **Decision: Deferred for considered on its turn on the basis of the date of submission of stability study data.**	
142.	**Name and address of manufacturer / Applicant**	**M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura**
	Brand Name +Dosage Form + Strength	Symbyjen Capsule 3/25mg
	Composition	Each Capsule Contains: Olanzapine…3mg Fluoxetine As Hcl…25mg
	Diary No. Date of R& I & fee	Dy No. 15701: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Atypical antipsychotic and a selective serotonin reuptake inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Byflanz capsule by martin dow
	GMP status	The firm was inspected on 23-12-2020 and conclusion of inspection was: Keeping in view the findings of inspection, and commitment of the management for future improvement, the members of the panel are of the opinion to recommend the grant of renewal of Drug Manufacturing License (000823) by way of

		formulation to M/s Jenner Pharma. 26 Km Lahore Shariqpur Road, District Sheikhupura.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
143.	**Name and address of manufacturer / Applicant**	**M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura**
	Brand Name +Dosage Form + Strength	Symbyjen Capsule 6/25mg
	Composition	Each Capsule Contains: Olanzapine…6mg Fluoxetine As Hcl…25mg
	Diary No. Date of R& I & fee	Dy No. 15702: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Atypical antipsychotic and a selective serotonin reuptake inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Byflanz capsule by martin dow
	GMP status	The firm was inspected on 23-12-2020 and conclusion of inspection was: Keeping in view the findings of inspection, and commitment of the management for future improvement, the members of the panel are of the opinion to recommend the grant of renewal of Drug Manufacturing License (000823) by way of formulation to M/s Jenner Pharma. 26 Km Lahore Shariqpur Road, District Sheikhupura.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
144.	**Name and address of manufacturer / Applicant**	**M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura**
	Brand Name +Dosage Form + Strength	Symbyjen Capsule 12/25mg
	Composition	Each Capsule Contains: Olanzapine…12mg Fluoxetine As Hcl…25mg
	Diary No. Date of R& I & fee	Dy No. 15700: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Atypical antipsychotic and a selective serotonin reuptake inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Byflanz capsule by martin dow
	GMP status	The firm was inspected on 23-12-2020 and conclusion of inspection was: Keeping in view the findings of inspection, and commitment of the management for future improvement, the

		members of the panel are of the opinion to recommend the grant of renewal of Drug Manufacturing License (000823) by way of formulation to M/s Jenner Pharma. 26 Km Lahore Shariqpur Road, District Sheikhupura.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
145.	**Name and address of manufacturer / Applicant**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Brand Name +Dosage Form + Strength	Profam 800/26.6mg Tablet
	Composition	Each Film Coated Tablet Contains: Ibuprofen…800mg Famotidine…26.6mg
	Diary No. Date of R& I & fee	Dy No. 16581: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	NSAID with H2 receptor antagonist
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Could not be confirmed
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of required manufacturing facility / section approval letter from Licensing Division. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Revision of formulation as per the innovator's product along with submission of full fee of registration
	Decision: Registration Board decided to reject the application since the firm has not submitted stability study data of 3 batches of the drug product before the lapse of deadline decided by DRAP Authority i.e. till 31st December 2022.	
146.	**Name and address of manufacturer / Applicant**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Brand Name +Dosage Form + Strength	Spirozone 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Eplerenone…25mg
	Diary No. Date of R& I & fee	Dy No. 16579: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Diuretics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications while monograph is available in JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Epliron Tablet by Highnoon

	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with JP specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
147.	**Name and address of manufacturer / Applicant**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Brand Name +Dosage Form + Strength	Spirozone 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Eplerenone…50mg
	Diary No. Date of R& I & fee	Dy No. 16580: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Diuretics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications while monograph is available in JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Epliron Tablet by Highnoon
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with JP specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
148.	**Name and address of manufacturer / Applicant**	**M/s Heal Pharmaceuticals Pvt Ltd. W-33, Industrial Area, Hayatabad Peshawar**
	Brand Name +Dosage Form + Strength	Loratad D 0.5mg/ml Syrup
	Composition	Each ml Contains: Desloratadine…0.5mg
	Diary No. Date of R& I & fee	Dy No. 13616: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other antihistamines for systemic use
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Dezika Syrup by Islam Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Firm has Liquid / Syrup (General) section

	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
149.	**Name and address of manufacturer / Applicant**	**M/s Heal Pharmaceuticals Pvt Ltd. W-33, Industrial Area, Hayatabad Peshawar**
	Brand Name +Dosage Form + Strength	Loratad D 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Desloratadine…5mg
	Diary No. Date of R& I & fee	Dy No. 13615: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other antihistamines for systemic use
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Destina Tablet by Hilton
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
150.	**Name and address of manufacturer / Applicant**	**M/s Heal Pharmaceuticals Pvt Ltd. W-33, Industrial Area, Hayatabad Peshawar**
	Brand Name +Dosage Form + Strength	Fusion Cream 20/10mg
	Composition	Each Gram Contains: Fusidic Acid…20mg Hydrocortisone As Acetate…10mg
	Diary No. Date of R& I & fee	Dy No. 13617: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antibacterial Agent/Anti-inflammatory
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fucidin H Cream by Leo Laboratories Limited (**MHRA** Approved)
	Me-too status	Fosic H cream by Metro Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Firm has Cream, Ointment (General) section • Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Gram of Cream Contains: Fusidic Acid…20mg

		Hydrocortisone Acetate…10mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Gram of Cream Contains:** **Fusidic Acid…20mg** **Hydrocortisone Acetate…10mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
151.	**Name and address of manufacturer / Applicant**	**M/s Heal Pharmaceuticals Pvt Ltd. W-33, Industrial Area, Hayatabad Peshawar**
	Brand Name +Dosage Form + Strength	Levsicon Syrup
	Composition	Each 5ml Contains: Calcium Carbonate…80mg Sodium Alginate…250mg Sodium Bicarbonate…133.5mg
	Diary No. Date of R& I & fee	Dy No. 13613: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antacid/ Reflux suppressant
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications while monograph is available in BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA Australia Approved
	Me-too status	Permach oral liquid by Perfect Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Firm has Liquid / Syrup (General) section
	Decision: Approved with BP specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
152.	**Name and address of manufacturer / Applicant**	**M/s GMP Pharmaceuticals 28-Km Sheikhupura Road, Lahore**
	Brand Name +Dosage Form + Strength	Cefocaine Injection 1% 20mg/2ml
	Composition	Each 2ml ampoule Contains: Lignocaine HCl…20mg
	Diary No. Date of R& I & fee	Dy No. 14021: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Local anesthetics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved

	Me-too status	Lycas Injection by Pharmedic Laboratories
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. •
	Decision: Approved.	
153.	**Name and address of manufacturer / Applicant**	**M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Hemoflan 500mg Tablet
	Composition	Each Film Coated Tablet Conatains: Diosmin…450mg Hesperidin…50mg
	Diary No. Date of R& I & fee	Dy No. 16403: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Capillary stabilizing agents
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Daflon 500mg Tablet ANSM France Approved
	Me-too status	Hemorif Tablet 450mg/50mg by Genome Pharma
	GMP status	The firm is granted GMP certificate based on inspection conducted on 03-01-2022 and it is valid till 02-10-2024.
	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
154.	**Name and address of manufacturer / Applicant**	**M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Glovir tablet 450mg
	Composition	Each Film Coated Tablet Contains: Valganciclovir…450mg
	Diary No. Date of R& I & fee	Dy No. 16405: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Direct Acting Antivirals.
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Zacval 450mg Tablet by Genix
	GMP status	The firm is granted GMP certificate based on inspection conducted on 03-01-2022 and it is valid till 02-10-2024.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Valganciclovir (as HCl)…450mg
	Decision: Approved with following label claim:	

	Each Film Coated Tablet Contains: **Valganciclovir (as HCl)…450mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
155.	**Name and address of manufacturer / Applicant**	**M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Mosid 5mg tablet
	Composition	Each Film Coated Tabled Contains: Mosapride…5mg
	Diary No. Date of R& I & fee	Dy No. 16404: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Propulsives
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications while monograph is available in JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	PMDA Japan Approved
	Me-too status	SAP 5mg Tablet by Tabros Pharma
	GMP status	The firm is granted GMP certificate based on inspection conducted on 03-01-2022 and it is valid till 02-10-2024.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Mosapride Citrate Hydrate eq to Mosapride Citrate…5mg
	Decision: Approved with JP Specifications and with following label claim: **Each Film Coated Tablet Contains:** **Mosapride Citrate Hydrate eq to Mosapride Citrate…5mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
156.	**Name and address of manufacturer / Applicant**	**M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Vigarin 500mg tablet
	Composition	Each Film Coated Tablet Contains: Vagabatrin…500mg
	Diary No. Date of R& I & fee	Dy No. 16400: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Brizga 500mg film-coated tablet by Martin Dow
	GMP status	The firm is granted GMP certificate based on inspection conducted on 03-01-2022 and it is valid till 02-10-2024.
	Remarks of the Evaluator[3].	•

	Decision: Approved.	
157.	**Name and address of manufacturer / Applicant**	**M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Doxiba 400mg tablets
	Composition	Each Tablet Contains: Doxofylline…400mg
	Diary No. Date of R& I & fee	Dy No. 16402: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Other Systemic Drugs For Obstructive Airway Diseases
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	AIFA Italy Approved
	Me-too status	Xofi Tablet by Hilton
	GMP status	The firm is granted GMP certificate based on inspection conducted on 03-01-2022 and it is valid till 02-10-2024.
	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
158.	**Name and address of manufacturer / Applicant**	**M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Otilon 40mg tablet
	Composition	Each Tablet Contains: Otilomium Bromide…40mg
	Diary No. Date of R& I & fee	Dy No. 16401: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Anticholinergic, quaternary ammonium compounds
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	(Spain Approved)
	Me-too status	Spasmomen tablet 40mg of Pharmatech
	GMP status	The firm is granted GMP certificate based on inspection conducted on 03-01-2022 and it is valid till 02-10-2024.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Otilomium Bromide…40mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Film Coated Tablet Contains:** **Otilomium Bromide…40mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	

159.	**Name and address of manufacturer / Applicant**	**M/s Glitz Pharma Plot No 265. Industrial Triangle. Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Aliska 150mg Tablet
	Composition	Each Film Coated Tablet Contains: Aliskiren Hemifumarate Eq To Aliskiren…150mg
	Diary No. Date of R& I & fee	Dy No. 16038: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Renin inhibitor
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Stay Tablet by Wilson Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
160.	**Name and address of manufacturer / Applicant**	**M/s Glitz Pharma Plot No 265. Industrial Triangle. Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Aliska 300mg Tablet
	Composition	Each Film Coated Tablet Contains: Aliskiren Hemifumarate Eq. To Aliskiren…300mg
	Diary No. Date of R& I & fee	Dy No. 16037: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Renin inhibitor
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Stay Tablet by Wilson Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
161.	**Name and address of manufacturer / Applicant**	**M/s Glitz Pharma Plot No 265. Industrial Triangle. Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Arostein 225mg Sachet

	Composition	Each Sachet Contains Erdostetine…225mg
	Diary No. Date of R& I & fee	Dy No. 16040: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Mucodox 225mg Sachet by Vision Pharma
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of required manufacturing facility / section approval letter from Licensing Division. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting along with evidence of approval of required manufacturing facility/section from CLB. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
162.	**Name and address of manufacturer / Applicant**	**M/s Glitz Pharma Plot No 265. Industrial Triangle. Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Ozip 2.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Olanzapine…2.5mg
	Diary No. Date of R& I & fee	Dy No. 16024: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Olpine Tablet by Fynk Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
163.	**Name and address of manufacturer / Applicant**	**M/s Glitz Pharma Plot No 265. Industrial Triangle. Kahuta Road, Islamabad**

	Brand Name +Dosage Form + Strength	Ozip 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Olanzapine…20mg
	Diary No. Date of R& I & fee	Dy No. 16025: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Could not be confirmed
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
164.	**Name and address of manufacturer / Applicant**	**M/s Ferroza International Pharmaceuticals Pvt. Ltd. 33 Km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Feroxib 60mg Tablet
	Composition	Each Tablet Contains: Etoricoxib…60mg
	Diary No. Date of R& I & fee	Dy No. 17338: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antiinflammatory and Antirheumatic Products, Non-Steroids
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Etoxib Tablet by Hiranis
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Etoricoxib.…60mg
	Decision: Approved with Innovator's specifications and with following label claim: Each Film Coated Tablet Contains: Etoricoxib.…60mg	

	• **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
165.	**Name and address of manufacturer / Applicant**	**M/s Ferroza International Pharmaceuticals Pvt. Ltd. 33 Km, Ferozepur Road, Lahore**
	Brand Name +Dosage Form + Strength	Relaxfer 2mg Tablet
	Composition	Each Tablet Contains: Tizanidine Hydrochloride…2mg
	Diary No. Date of R& I & fee	Dy No. 17343: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Movax Tablet by Sami
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Tablet Contains: Tizanidine (as HCl).…2mg
	Decision: Approved with Innovator's specifications and with following label claim: Each Tablet Contains: Tizanidine (as HCl).…2mg • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
166.	**Name and address of manufacturer / Applicant**	**M/s Farmaceutics International F-1-A3, S.I.T.E, Karachi**
	Brand Name +Dosage Form + Strength	Alledra 30mg/5ml suspension
	Composition	Each 5ml Contains: Fexofenadine HCl…30mg
	Diary No. Date of R& I & fee	Dy No. 13597: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	H1 Receptor antagonist
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As Per SRO
	Approval status of product in Reference Regulatory Authorities.	(**USFDA** Approved)
	Me-too status	Fexofast by Platinum Pharma

	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
167.	**Name and address of manufacturer / Applicant**	**M/s Farmaceutics International F-1-A3, S.I.T.E, Karachi**
	Brand Name +Dosage Form + Strength	Levofer 125mg/5ml Suspension
	Composition	Each 5ml Contains: Levofloxacin…125mg
	Diary No. Date of R& I & fee	Dy No. 13594: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Levocure 125 Dry Suspension by Hygeia Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
168.	**Name and address of manufacturer / Applicant**	**M/s Farmaceutics International F-1-A3, S.I.T.E, Karachi**
	Brand Name +Dosage Form + Strength	Levofer 250mg/5ml Suspension
	Composition	Each 5ml Contains: Levofloxacin…250mg
	Diary No. Date of R& I & fee	Dy No. 13595: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Lazer 250mg Dry Suspension by Genome Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.

		• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
169.	**Name and address of manufacturer / Applicant**	**M/s Fahmir Pharma Pvt Ltd. 26 km, Lahore Jaranwala Road, Main Stop Mandianwala, Sharaqpur, Distt. Sheikhupura**
	Brand Name +Dosage Form + Strength	Aspiclo 75/75 mg Tablet
	Composition	Each Film Coated Tablet Contains: Clopidogrel…75mg Aspirin…75mg
	Diary No. Date of R& I & fee	Dy No. 14456: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antiplatelet agent
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As Per SRO
	Approval status of product in Reference Regulatory Authorities.	DUOPALVIN by Sanofi (**ANSM** France Approved)
	Me-too status	Ascard Plus by Atco
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of Bilayer Tablet machine • Revision of formulation and label claim as per the innovator's product along with submission of full fee of registration.
	Decision: Deferred for following submissions: • **Evidence of Bilayer Tablet machine** • **Revision of formulation and label claim as per the innovator's product along with submission of full fee of registration.** • **Latest GMP inspection report conducted within a period of last three years.**	
170.	**Name and address of manufacturer / Applicant**	**M/s Fahmir Pharma Pvt Ltd. 26 km, Lahore Jaranwala Road, Main Stop Mandianwala, Sharaqpur, Distt. Sheikhupura**
	Brand Name +Dosage Form + Strength	Escita 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Escitalopram Oxalate Eq. To Escitalopram…5mg
	Diary No. Date of R& I & fee	Dy No. 14462: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Citanew Tablet by Hilton
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
171.	**Name and address of manufacturer / Applicant**	**M/s Fahmir Pharma Pvt Ltd. 26 km, Lahore Jaranwala Road, Main Stop Mandianwala, Sharaqpur, Distt. Sheikhupura**
	Brand Name +Dosage Form + Strength	Escita 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Escitalopram Oxalate Eq. To Escitalopram…10mg
	Diary No. Date of R& I & fee	Dy No. 14461: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Citanew Tablet by Hilton
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
172.	**Name and address of manufacturer / Applicant**	**M/s Fahmir Pharma Pvt Ltd. 26 km, Lahore Jaranwala Road, Main Stop Mandianwala, Sharaqpur, Distt. Sheikhupura**
	Brand Name +Dosage Form + Strength	Ferromir 100/0.35 mg Tablet
	Composition	Each Film Coated Tablet Contains: Iron III Hydroxide Polymaltose Complex Eq. To Elemental Iron…100mg Folic Acid…0.35mg
	Diary No. Date of R& I & fee	Dy No. 14460: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Hematinic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Crocytic-F Tablet 100/0.35mg of Parkar Pharma

	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Approved. Registration letter will be issued after submission of updated GMP inspection report by the firm.	
173.	**Name and address of manufacturer / Applicant**	**M/s Fahmir Pharma Pvt Ltd. 26 km, Lahore Jaranwala Road, Main Stop Mandianwala, Sharaqpur, Distt. Sheikhupura**
	Brand Name +Dosage Form + Strength	MF-1gm Tablet
	safeComposition	Each Film Coated Tablet Contains: Metformin HCl…1000mg
	Diary No. Date of R& I & fee	Dy No. 14459: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Biguanides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Glucophage Tablet by Martin Dow
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
174.	**Name and address of manufacturer / Applicant**	**M/s Fahmir Pharma Pvt Ltd. 26 km, Lahore Jaranwala Road, Main Stop Mandianwala, Sharaqpur, Distt. Sheikhupura**
	Brand Name +Dosage Form + Strength	Rosufim 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Rosuvastatin Calcium Eq. To Rosuvastatin…5mg
	Diary No. Date of R& I & fee	Dy No. 14457: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Crestat Tablet by CCL
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved.	

	• **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
175.	**Name and address of manufacturer / Applicant**	**M/s Fahmir Pharma Pvt Ltd. 26 km, Lahore Jaranwala Road, Main Stop Mandianwala, Sharaqpur, Distt. Sheikhupura**
	Brand Name +Dosage Form + Strength	Rosufim 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Rosuvastatin Calcium Eq. To Rosuvastatin…10mg
	Diary No. Date of R& I & fee	Dy No. 14458: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Crestat Tablet by CCL
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
176.	**Name and address of manufacturer / Applicant**	**M/s Evolution Pharmaceuticals Pvt Ltd. Plot # 25 & 26, Street S-3, RCCI, National Industrial Zone, Rawat, Islamabad, Pakistan**
	Brand Name +Dosage Form + Strength	Zonex 20mg Sachet
	Composition	Each Sachet Contains: Esomeprazole Magnesium Trihydrate Eq. To Esomeprazole…20mg
	Diary No. Date of R& I & fee	Dy No. 16423: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Espra Sachet by CCL
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets). • Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each sachet Contains:

		Esomeprazole as Magnesium Trihydrate (enteric coated pellets)…20mg
	Decision: Approved as per following label claim: **"Each sachet Contains:** **Esomeprazole as Magnesium Trihydrate (enteric coated pellets) …20mg"** **Firm shall submit following before issuance of registration letter:** • **Source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets).** • **Fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021** • **Latest GMP inspection report conducted within a period of last three years.**	
177.	**Name and address of manufacturer / Applicant**	**M/s Evolution Pharmaceuticals Pvt Ltd. Plot # 25 & 26, Street S-3, RCCI, National Industrial Zone, Rawat, Islamabad, Pakistan**
	Brand Name +Dosage Form + Strength	Zonex 40mg Granules for Oral Suspension
	Composition	Each Sachet Contains: Esomeprazole Magnesium Trihydrate Eq. To Esomeprazole…40mg
	Diary No. Date of R& I & fee	Dy No. 16424: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Espra Sachet by CCL
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets). • Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each sachet Contains: Esomeprazole as Magnesium Trihydrate (enteric coated pellets)…20mg
	Decision: Approved as per following label claim: **"Each sachet Contains:** **Esomeprazole as Magnesium Trihydrate (enteric coated pellets) …40mg"** **Firm shall submit following before issuance of registration letter:** • **Source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets).** • **Fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021** • **Latest GMP inspection report conducted within a period of last three years.**	

178.	**Name and address of manufacturer / Applicant**	**M/s Ethical Loboratories Pvt Ltd 14 KM, Multan Road, Lahore**
	Brand Name +Dosage Form + Strength	Ezy 20mg Capsule
	Composition	Each Capsule Contains: Esomeprazole As Esomeprazole Magnesium Trihydrate…20mg
	Diary No. Date of R& I & fee	Dy No. 16943: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Nexum capsule by Getz
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets). • Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Capsule Contains: Esomeprazole as Magnesium Trihydrate (enteric coated pellets)…20mg
	Decision: Approved with following label claim: **Each Capsule Contains:** **Esomeprazole as Magnesium Trihydrate (enteric coated pellets)…20mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.** • **Firm shall submit source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets) before issuance of registration letter.**	
179.	**Name and address of manufacturer / Applicant**	**M/s Ethical Loboratories Pvt Ltd 14 KM, Multan Road, Lahore**
	Brand Name +Dosage Form + Strength	Ezy 40mg Capsule
	Composition	Each Capsule Contains: Esomeprazole As Esomeprazole Magnesium Trihydrate…40mg
	Diary No. Date of R& I & fee	Dy No. 16944: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Nexum capsule by Getz
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets). • Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Capsule Contains: Esomeprazole as Magnesium Trihydrate (enteric coated pellets)…40mg
	Decision: Approved with following label claim: **Each Capsule Contains:** **Esomeprazole as Magnesium Trihydrate (enteric coated pellets)…40mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.** • **Firm shall submit source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets) before issuance of registration letter.**	
180.	**Name and address of manufacturer / Applicant**	**M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore**
	Brand Name +Dosage Form + Strength	Dyspro 0.3mg Tablet
	Composition	Each Film Coated Tablet Contains: Conjugated Oestrogen…0.3mg
	Diary No. Date of R& I & fee	Dy No. 15680: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Estrogens hormones
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Menorin 0.3Mg Tablet by Excel Healthcare
	GMP status	Firm has submitted GMP certificate based on evaluation conducted on 11-01-2019.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision:	
181.	**Name and address of manufacturer / Applicant**	**M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad**
	Brand Name +Dosage Form + Strength	Urisin D 0.5mg/0.4mg

	Composition	Each Capsule Contains: Dutasteride…0.5mg Tamsulosin Hcl…0.4mg
	Diary No. Date of R& I & fee	Dy No. 13041: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Alpha adrenoceptor antagonist 5 alpha reductase inhibitor
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	**USFDA** Approved
	Me-too status	Duodart capsule of GSK
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • The formulation is not as per innovator product approved by FDA • Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets).
	Decision: Deferred for following: • **Revision of formulation as per innovator product along with full fee of registration.** • **Source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets).** • **Evidence of approval of required required manufacturing facility of "Soft gel capsule (steroid) section or source of Dutasteride soft gel capsules, along with COA, stability study data of 3 batches, GMP certificate of soft gel capsule manufacturer and differential fee (in case of imported pellets** • **Evidence of availability of required manufacturing facility of "Capsule in Capsule filling machine".Latest GMP inspection report conducted within last three years.**	
182.	**Name and address of manufacturer / Applicant**	**M/s City Pharmaceutical Laboratories. Plot No. 12A, 1-5, Sector 5, New Survey No-276, Korangi Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Draxon Injection
	Composition	Each ml Ampoule Contains: Dexamethasone Sodium Phospate …4mg
	Diary No. Date of R& I & fee	Dy No. 17011: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Corticosteroids
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Merrysone 4mg Injection by Hygeia Pharma
	GMP status	Firm has submitted copy of inspection report dated 29-12-2021, in which the panel recommends renewal of DML.

	Remarks of the Evaluator[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division. • Specify the exact fill volume of the applied product. • Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each ml Ampoule Contains: Dexamethasone Sodium Phospate eq to dexamethasone phosphate …4mg
	Decision: Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Liquid Injection ampoule (Steroid) section" from CLB.	
183.	**Name and address of manufacturer / Applicant**	**M/s City Pharmaceutical Laboratories. Plot No. 12A, 1-5, Sector 5, New Survey No-276, Korangi Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Spastop Forte Tablet 80mg
	Composition	Each Tablet Contains: Drotaverine Hcl…80mg
	Diary No. Date of R& I & fee	Dy No. 17009: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Anti-spasmodic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Applied formulation is present in different European Economic Area (EEA) states like Poland, Hungary, Lithuania & Latvia (both as un-coated and coated tablets).
	Me-too status	No-Spa Tablet by Sanofi Aventis
	GMP status	Firm has submitted copy of inspection report dated 29-12-2021, in which the panel recommends renewal of DML.
	Remarks of the Evaluator[3].	•
	Decision: Registration Board deliberated the matter in detail and observed that the applied formulation is approved by three European Union countries i.e., Poland, Hungary, Lithuania & Latvia and the applied formulation is also already approved by DRAP, The Board therefore decided to approved the product with with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
184.	**Name and address of manufacturer / Applicant**	**M/s City Pharmaceutical Laboratories. Plot No. 12A, 1-5, Sector 5, New Survey No-276, Korangi Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Galmid 5mg Tablet
	Composition	Each Tablet Contains: Glibenclamide…5mg
	Diary No. Date of R& I & fee	Dy No. 17008: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Florazid Tablet 5mg by Zephyr Pharma
	GMP status	Firm has submitted copy of inspection report dated 29-12-2021, in which the panel recommends renewal of DML.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
185.	**Name and address of manufacturer / Applicant**	**M/s City Pharmaceutical Laboratories. Plot No. 12A, 1-5, Sector 5, New Survey No-276, Korangi Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Lincomycin 600mg/2ml Injection
	Composition	Each 2ml Contains: Lincomycin HCl Monohydrate…600mg
	Diary No. Date of R& I & fee	Dy No. 17010: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved (as 2ml vial) PMDA Japan Approved (as 1ml)
	Me-too status	Linkotrex Injection by Wimits Pharma
	GMP status	Firm has submitted copy of inspection report dated 29-12-2021, in which the panel recommends renewal of DML.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each 2ml Ampoule Contains: Lincomycin (as HCl Monohydrate)…600mg
	Decision: Approved as per following label claim: "Each 2ml Ampoule Contains: Lincomycin (as HCl Monohydrate) …….600mg" The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
186.	**Name and address of manufacturer / Applicant**	**M/s City Pharmaceutical Laboratories. Plot No. 12A, 1-5, Sector 5, New Survey No-276, Korangi Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Tricort Injection
	Composition	Each ml Ampoule Contains: Triamcinolone Acetonide…40mg
	Diary No. Date of R& I & fee	Dy No. 17007: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Glucocorticoid
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Novacort injection by Novex Pharma
	GMP status	Firm has submitted copy of inspection report dated 29-12-2021, in which the panel recommends renewal of DML.
	Remarks of the Evaluator[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division. • Specify the exact fill volume of the applied product.
	Decision: Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Liquid Injection ampoule (Steroid) section" from CLB.	
187.	**Name and address of manufacturer / Applicant**	**M/s Cibex Pvt Ltd. F-405, S.I.T.E, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Terbex 0.3mg/ml Syrup
	Composition	Each ml Contains: Terbutaline Sulphate…0.3mg
	Diary No. Date of R& I & fee	Dy No. 14998: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Selective beta-2-adrenoreceptor agonists
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Obtaline 0.3mg/ml Syrup by Obsons
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of required manufacturing facility / section approval letter from Licensing Division.
	Decision: Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Liquid Syrup section" from CLB.	
188.	**Name and address of manufacturer / Applicant**	**M/s Cibex Pvt Ltd. F-405, S.I.T.E, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Lactopic 5mg/5ml Solution
	Composition	Each 5ml Contains: Picosulphate…5mg
	Diary No. Date of R& I & fee	Dy No. 14003: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Contact laxatives
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Anzulax 5mg/5ml Oral Liquid by Bio-Mark
	GMP status	

	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of required manufacturing facility / section approval letter from Licensing Division. • Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each 5ml Contains: Sodium picosulphate…5mg
	Decision: Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Liquid Syrup section" from CLB.	
189.	**Name and address of manufacturer / Applicant**	**M/s Cibex Pvt Ltd. F-405, S.I.T.E, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Valepa 250mg Tablets
	Composition	Each Tablet Contains: Divalproex Sodium…250mg
	Diary No. Date of R& I & fee	Dy No. 14002: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Epival Tablet by Abbott
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Enteric Coated Tablet Contains: Valproate Semisodium eq to valproic acid…250mg
	Decision: Approved with following label claim: **Each Enteric Coated Tablet Contains:** **Valproate Semisodium eq to valproic acid…250mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
190.	**Name and address of manufacturer / Applicant**	**M/s Cibex Pvt Ltd. F-405, S.I.T.E, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Valepa 250mg/5ml Syrup
	Composition	Each 5ml Contains: Sodium Valproate…250mg
	Diary No. Date of R& I & fee	Dy No. 14001: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished Product Specification	BP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Fyporic 250mg/5ml Oral Solution by Fynk Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
191.	**Name and address of manufacturer / Applicant**	**M/s Cibex Pvt Ltd. F-405, S.I.T.E, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Vagtro 400mg Tablet
	Composition	Each Tablet Contains: Metronidazole…400mg
	Diary No. Date of R& I & fee	Dy No. 14006: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Imidazole derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Flagyl Tablet by Sanofi Aventis
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Metronidazole……400mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Metronidazole……400mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
192.	**Name and address of manufacturer / Applicant**	**M/s Cibex Pvt Ltd. F-405, S.I.T.E, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Vagtro 200mg/5ml Suspension
	Composition	Each 5ml Contains: Metronidazole…200mg
	Diary No. Date of R& I & fee	Dy No. 15007: 07-03-2019 PKR 20,000/-: 07-03-2019

	Pharmacological Group	Imidazole derivatives
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	News-Zol 200mg/5ml Suspension by News Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each 5ml Contains: Metronidazole benzoate eq to metronidazole…200mg
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
193.	**Name and address of manufacturer / Applicant**	**M/s Cibex Pvt Ltd. F-405, S.I.T.E, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Fandol Forte 500mg Tablet
	Composition	Each Tablet Contains: Mefenamic Acid…500mg
	Diary No. Date of R& I & fee	Dy No. 15005: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ponstan Forte Tablet by Pfizer
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Mefenamic Acid…500mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Mefenamic Acid…500mg** • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
194.	**Name and address of manufacturer / Applicant**	**M/s Cibex Pvt Ltd. F-405, S.I.T.E, Karachi, Pakistan**

	Brand Name +Dosage Form + Strength	Fandol 50mg/5ml Suspension
	Composition	Each 5ml Contains: Mefenamic Acid…50mg
	Diary No. Date of R& I & fee	Dy No. 14004: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ponstan suspension by Pfizer
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with innovator's specification. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three years, before issuance of registration letter.	
195.	**Name and address of manufacturer / Applicant**	**M/s Cibex Pvt Ltd. F-405, S.I.T.E, Karachi, Pakistan**
	Brand Name +Dosage Form + Strength	Ventbex 2mg Tablet
	Composition	Each Tablet Contains: Salbutamol Sulphate Eq. To Salbutamol…2mg
	Diary No. Date of R& I & fee	Dy No. 14997: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Selective beta-2-adrenoreceptor agonists
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ventolin Tablet by GSK
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
196.	**Name and address of manufacturer / Applicant**	**M/s Care Pharmaceuticals 8-Km, Thokar Raiwind Raod, Lahore**
	Brand Name +Dosage Form + Strength	Pirocare 0.5% w/w Gel
	Composition	Each Gm of gel Contains: Piroxicam…5mg
	Diary No. Date of R& I & fee	Dy No. 16431: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	NSAID

	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications while monograph is available in BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Feldene Gel by Pfizer
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of required manufacturing facility / section approval letter from Licensing Division.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Gel section" from CLB. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
197.	**Name and address of manufacturer / Applicant**	**M/s Care Pharmaceuticals 8-Km, Thokar Raiwind Raod, Lahore**
	Brand Name +Dosage Form + Strength	Gravicare 12.5mg/5ml Syrup
	Composition	Each 5ml Contains: Dimenhydrinate…12.5mg
	Diary No. Date of R& I & fee	Dy No. 16430: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of required manufacturing facility / section approval letter from Licensing Division. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	
198.	**Name and address of manufacturer / Applicant**	**M/s Care Pharmaceuticals 8-Km, Thokar Raiwind Raod, Lahore**

	Brand Name +Dosage Form + Strength	Nepcare 1mg Eye Drops
	Composition	Each ml of Suspension Contains: Nepafenac…1mg
	Diary No. Date of R& I & fee	Dy No. 16433: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Anti-Inflammatory
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Nepaphenac Ophthalmic Suspension 0.1% w/v by Ophth Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of required manufacturing facility / section approval letter from Licensing Division.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
199.	**Name and address of manufacturer / Applicant**	**M/s Care Pharmaceuticals. 8-Km, Thokar Raiwind Raod, Lahore**
	Brand Name +Dosage Form + Strength	Albendacare 200mg/5ml Suspension
	Composition	Each 5ml Contains: Albendazole…200mg
	Diary No. Date of R& I & fee	Dy No. 16432: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Anthelmintics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZENTEL 0.4 g/10 ml, oral suspension ANSM France Approved
	Me-too status	Vantor 100mg/5ml Suspension by Axis Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of required manufacturing facility / section approval letter from Licensing Division.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
200.	**Name and address of manufacturer / Applicant**	**M/s Care Pharmaceuticals. 8-Km, Thokar Raiwind Raod, Lahore**
	Brand Name +Dosage Form + Strength	Careprofen 2.5% w/w Gel
	Composition	Each gram of gel Contains: Ketoprofen……25mg (2.5% w/w)
	Diary No. Date of R& I & fee	Dy No. 16429: 07-03-2019 PKR 20,000/-: 06-03-2019

	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ketobon 2.5% Gel by Panacea Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of required manufacturing facility / section approval letter from Licensing Division.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Topical Gel section" from CLB. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
201.	**Name and address of manufacturer / Applicant**	**M/s Care Pharmaceuticals. 8-Km, Thokar Raiwind Raod, Lahore**
	Brand Name +Dosage Form + Strength	Paincare Gel
	Composition	Each gram of gel Contains: Ibuprofen……..50mg (5% w/w)
	Diary No. Date of R& I & fee	Dy No. 16434: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Febridex Gel by Evolution Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of required manufacturing facility / section approval letter from Licensing Division.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Topical Gel section" from CLB. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
202.	**Name and address of manufacturer / Applicant**	**M/s Brookes Pharma Pvt Ltd. 58 & 59, Sector 15, Korangi Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Bacomac Cream 20mg
	Composition	Each Gm Contains: Mupirocin…20mg
	Diary No. Date of R& I & fee	Dy No. 16181: 07-03-2019 PKR 20,000/-: 07-03-2019

	Pharmacological Group	Antibiotic for topical use
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Mupas 2% w/w Cream by Mass Pharma
	GMP status	Firm has submitted copy of inspection report dated 18-08-2020 which recommends renewal of DML.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each gm of cream Contains: Mupirocin calcium eq to mupirocin……20mg
	Decision: Approved as per following label claim: **"Each gm of cream Contains:** **Mupirocin calcium eq to mupirocin……20mg"** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
203.	**Name and address of manufacturer / Applicant**	**M/s Bloom Pharmaceuticals Pvt Ltd. Plot # 30, Phase I & II, Industrial Estate, Hattar, Pakistan**
	Brand Name +Dosage Form + Strength	Austasol Cream
	Composition	Each Gram Contains: Clobetasol As Propionate…0.5mg
	Diary No. Date of R& I & fee	Dy No. 16184: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Corticosteroids
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Maxivate cream by Maxitech
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 21-06-2022.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each gram of cream Contains: Clobetasol Propionate……0.05%w/w
	Decision: Approved as per following label claim: **Each gram of cream Contains:** **Clobetasol Propionate……0.05%w/w** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
204.	**Name and address of manufacturer / Applicant**	**M/s Bloom Pharmaceuticals Pvt Ltd. Plot # 30, Phase I & II, Industrial Estate, Hattar, Pakistan**
	Brand Name +Dosage Form + Strength	Blofax 100mg Tablet

	Composition	Each Film Coated Tablet Contains: Fluvoxamine Maleate…100mg
	Diary No. Date of R& I & fee	Dy No. 16185: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidepressants
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Fluvoxamine Tablet by Lisko Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 21-06-2022.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
205.	**Name and address of manufacturer / Applicant**	**M/s Bloom Pharmaceuticals Pvt Ltd. Plot # 30, Phase I & II, Industrial Estate, Hattar, Pakistan**
	Brand Name +Dosage Form + Strength	Austac Gel 1% / 5%
	Composition	Each Gram Gel Contains: Clindamycin as Phospate…1% Benzoyl Peroxide…5%
	Diary No. Date of R& I & fee	Dy No. 16183: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Anti-infective for topical use
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications while the monograph is available in BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Duac Gel by GSK
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 21-06-2022.
	Remarks of the Evaluator[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Topical Gel section" from CLB. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
206.	**Name and address of manufacturer / Applicant**	**M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Neocitabine 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Capecitabine…500mg
	Diary No. Date of R& I & fee	Dy No. 16315: 07-03-2019 PKR 20,000/-: 06-03- Linical evidence for the efficacy 2019
	Pharmacological Group	Antineoplastic Agents (L01)
	Type of Form	Form 5

	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Xeloda Tablets by Roche
	GMP status	Firm has submitted copy of GMP certificate dated 28-02-2022 issued on the basis of inspection dated 03-08-2021.
	Remarks of the Evaluator[3].	• Firm does not have Tablet (Anticancer) section
	Decision: Registration Board rejected the application since firm does not have approved manufacturing facility for "Tablet (Anticancer)" section.	
207.	**Name and address of manufacturer / Applicant**	**M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Bioflavate 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Flavoxate HCl…200mg
	Diary No. Date of R& I & fee	Dy No. 16320: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Anticholinergic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Flavus Tablets by PDH Pharmaceutical
	GMP status	Firm has submitted copy of GMP certificate dated 28-02-2022 issued on the basis of inspection dated 03-08-2021.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
208.	**Name and address of manufacturer / Applicant**	**M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Flucin 0.25mg Ointment
	Composition	Each gm Contains: Fluocinolone Acetonide…0.25mg
	Diary No. Date of R& I & fee	Dy No. 16314: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Corticosteroids
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Flucinate Ointment by Atco
	GMP status	Firm has submitted copy of GMP certificate dated 28-02-2022 issued on the basis of inspection dated 03-08-2021.
	Remarks of the Evaluator[3].	•

	Decision: Approved.	
209.	**Name and address of manufacturer / Applicant**	**M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Ranidine 50mg/2ml Injection
	Composition	Each 2ml Contains: Ranitidine (Hcl)…50mg
	Diary No. Date of R& I & fee	Dy No. 16313: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	H2 – receptor antagonist
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Zantac injection by GSK
	GMP status	Firm has submitted copy of GMP certificate dated 28-02-2022 issued on the basis of inspection dated 03-08-2021.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each 2ml Ampoule Contains: Ranitidine HCl eq to Ranitidine…50mg
	Decision: Registration Board deferred the application on basis of the decision of 294th meeting of Board wherein registrations of Ranitidine containing prouducts have been suspended following FDA / EMA alerts on detection of probable carcinogenic impurity.	
210.	**Name and address of manufacturer / Applicant**	**M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Teocam 20mg Tablet
	Composition	Each Tablet Contains: Tenoxicam…20mg
	Diary No. Date of R& I & fee	Dy No. 16321: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Tex-20 Tablet by Glitz
	GMP status	Firm has submitted copy of GMP certificate dated 28-02-2022 issued on the basis of inspection dated 03-08-2021.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
211.	**Name and address of manufacturer / Applicant**	**M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Zonimide 50mg Capsule
	Composition	Each Capsule Contains: Zonisamide…50mg

	Diary No. Date of R& I & fee	Dy No. 16319: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Nisazon Capsule by Genetics
	GMP status	Firm has submitted copy of GMP certificate dated 28-02-2022 issued on the basis of inspection dated 03-08-2021.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
212.	**Name and address of manufacturer / Applicant**	**M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad**
	Brand Name +Dosage Form + Strength	Zonimide 100mg Capsule
	Composition	Each Capsule Contains: Zonisamide…100mg
	Diary No. Date of R& I & fee	Dy No. 16317: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Nisazon Capsule by Genetics
	GMP status	Firm has submitted copy of GMP certificate dated 28-02-2022 issued on the basis of inspection dated 03-08-2021.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
213.	**Name and address of manufacturer / Applicant**	**M/s Baxter Pharmaceuticals A-1/A, Scheem No.33, Phase-1, S.I.T.E,Super Highway, Karachi**
	Brand Name +Dosage Form + Strength	Sposma 40mg Tablet
	Composition	Each Tablet Contains: Drotaverine…40mg
	Diary No. Date of R& I & fee	Dy No. 14674: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Anti-spasmodic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Applied formulation is present in different European Economic Area (EEA) states like Poland, Hungary, Lithuania & Latvia (both as un-coated and coated tablets).
	Me-too status	No-Spa Tablet by Sanofi Aventis

	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Tablet Contains: Drotaverine HCl…40mg
	Decision: Registration Board decided to defer the application till decision of CLB regarding renewal of DML of M/s Baxter Pharmaceuticals A-1/A, Scheem No.33, Phase-1, S.I.T.E,Super Highway, Karachi.	
214.	**Name and address of manufacturer / Applicant**	**M/s Baxter Pharmaceuticals A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi**
	Brand Name +Dosage Form + Strength	Nipine Capsule 5mg
	Composition	Each Tablet Contains: Nifedipine…….5mg
	Diary No. Date of R& I & fee	Dy No. 14811: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Calcium channel blocker
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Clarify the applied formulation, since on some pages capsule is mentioned while on other pages tablet is mentioned. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Registration Board decided to defer the application till decision of CLB regarding renewal of DML of M/s Baxter Pharmaceuticals A-1/A, Scheem No.33, Phase-1, S.I.T.E,Super Highway, Karachi.	
215.	**Name and address of manufacturer / Applicant**	**M/s Baxter Pharmaceuticals A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi**
	Brand Name +Dosage Form + Strength	Zolep 40mg Capsule
	Composition	Each Capsule Contains: Pantoprazole…40mg
	Diary No. Date of R& I & fee	Dy No. 14689: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Proton Pump Inhibitors
	Type of Form	Form 5

	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Registration Board decided to defer the application till decision of CLB regarding renewal of DML of M/s Baxter Pharmaceuticals A-1/A, Scheem No.33, Phase-1, S.I.T.E,Super Highway, Karachi.	
216.	**Name and address of manufacturer / Applicant**	**M/s Baxter Pharmaceuticals A-1/A, Scheem No.33,Phase-1,S.I.T.E,Super Highway, Karachi**
	Brand Name +Dosage Form + Strength	Cough Stop Syrup 125mg/5ml
	Composition	Each Syrup Contains: Acefylline Piperazine…125mg/5ml
	Diary No. Date of R& I & fee	Dy No. 14670: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Xanthines
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Acefyl syrup by Nabiqasim
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Registration Board decided to defer the application till decision of CLB regarding renewal of DML of M/s Baxter Pharmaceuticals A-1/A, Scheem No.33, Phase-1, S.I.T.E, Super Highway, Karachi.	
217.	**Name and address of manufacturer / Applicant**	**M/s Aventek Pharmaceuticals Pvt Ltd 44-c, Sunder Industrial Estate, lahore**
	Brand Name +Dosage Form + Strength	Trama Plus Tablet 325/37.5mg
	Composition	Each Film Coated Tablet Contains: Paracetamol…325mg Tramadol HCl…37.5mg
	Diary No. Date of R& I & fee	Dy No. 16374: 07-03-2019 PKR 20,000/-: 06-03-2019

	Pharmacological Group	Analgesic / Antipyretic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	(**MHRA** Approved)
	Me-too status	Tramal Plus Tablet by Searle
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
218.	**Name and address of manufacturer / Applicant**	**M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi**
	Brand Name +Dosage Form + Strength	Emestat Tablet
	Composition	Each Sugar Coated Tablet Contains: Caffeine Anhydrous…25mg Propyphenazone…175mg
	Diary No. Date of R& I & fee	Dy No. 13324: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other Analgesics and antipyretics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Spain approved
	Me-too status	Optalidon Tablets of Novartis
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
219.	**Name and address of manufacturer / Applicant**	**M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi**
	Brand Name +Dosage Form + Strength	Diacin 50mg Capsule
	Composition	Each Capsule Contains: Dimenhydrinate…50mg
	Diary No. Date of R& I & fee	Dy No. 13322: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antihistamine
	Type of Form	Form 5

	Finished Product Specification	Not submitted
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Clarify the applied formulation, since on some pages dimenhydrinate 50mg capsule is mentioned while on other pages diacerein 50mg capsule is mentioned.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board.	
220.	**Name and address of manufacturer / Applicant**	**M/s Regal Pharmaceuticals Plot # 2A St.# S-5, National Industrial Zone, Rawat,Islamabad**
	Brand Name +Dosage Form + Strength	Chlora 500mg/5ml Oral Syrup
	Composition	Each 5ml Contains: Chloral Hydrate…500mg
	Diary No. Date of R& I & fee	Dy No. 15079: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Sedatives and Hypnotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Health Canada Approved
	Me-too status	Cedate Syrup 500mg of Xenon Pharma
	GMP status	The firm have submitted cGMP certificate issued based on inspection conducted on 19-01-2022.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
221.	**Name and address of manufacturer / Applicant**	**M/s Regal Pharmaceuticals Plot # 2A St.# S-5, National Industrial Zone, Rawat,Islamabad**
	Brand Name +Dosage Form + Strength	Clozole 500mg Vaginal Tablets
	Composition	Each Uncoated Tablet Contains: Clotrimazole…500mg
	Diary No. Date of R& I & fee	Dy No. 15077: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antifungals for systemic use
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved

	Me-too status	Mizole 500mg Tablet by Pharmix
	GMP status	The firm have submitted cGMP certificate issued based on inspection conducted on 19-01-2022.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
222.	**Name and address of manufacturer / Applicant**	**M/s Regal Pharmaceuticals Plot # 2A St.# S-5, National Industrial Zone, Rawat,Islamabad**
	Brand Name +Dosage Form + Strength	Zipix 15mg Tablet
	Composition	Each Tablet Contains: Mirtazapine…15mg
	Diary No. Date of R& I & fee	Dy No. 15080: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Mirtazapine tablet by Actavis (**MHRA** Approved)
	Me-too status	Elaxine tablet by Standpharm
	GMP status	The firm have submitted cGMP certificate issued based on inspection conducted on 19-01-2022.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Mirtazapine…15mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Mirtazapine…15mg** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
223.	**Name and address of manufacturer / Applicant**	**M/s Regal Pharmaceuticals Plot # 2A St.# S-5, National Industrial Zone, Rawat,Islamabad**
	Brand Name +Dosage Form + Strength	Zipix 30mg Tablet
	Composition	Each Tablet Contains: Mirtazapine…30mg
	Diary No. Date of R& I & fee	Dy No. 15081: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Mirtazapine tablet by Actavis (**MHRA** Approved)
	Me-too status	Elaxine tablet by Standpharm
	GMP status	The firm have submitted cGMP certificate issued based on inspection conducted on 19-01-2022.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following:

		Each Film Coated Tablet Contains: Mirtazapine…30mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Mirtazapine…30mg** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
224.	**Name and address of manufacturer / Applicant**	**M/s Medicraft Pharmaceuticals Pvt Ltd. 126-B, Indstrial Estate, Hayatabad, Peshawar, Pakistan**
	Brand Name +Dosage Form + Strength	Medithiol Syrup 250mg/5ml
	Composition	Each 5ml Contains: Carbocysteine…250mg
	Diary No. Date of R& I & fee	Dy No. 16339: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Mucolytic agent
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Mucodyne syrup 250mg/5ml by Lexon (MHRA Approved)
	Me-too status	Carbonol 250mg/5ml Syrup by CCL
	GMP status	The firm have submitted cGMP certificate issued on 13-05- 2022 based on inspection conducted on 10-05-2022.
	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
225.	**Name and address of manufacturer / Applicant**	**M/s Medicraft Pharmaceuticals Pvt Ltd. 126-B, Indstrial Estate, Hayatabad, Peshawar, Pakistan**
	Brand Name +Dosage Form + Strength	Perison 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Eperisone Hcl…50mg
	Diary No. Date of R& I & fee	Dy No. 16334: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Eperisone Hydrochloride Tablets 50mg "TCK" PMDA Japan Approved (Sugar coated tablet)
	Me-too status	Eprisa Tablet by Fynk Pharma
	GMP status	The firm have submitted cGMP certificate issued on 13-05- 2022 based on inspection conducted on 10-05-2022.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Sugar coated Tablet Contains: Eperisone HCl…50mg
	Decision: Approved with Innovator's specifications and with following label claim:	

	Each Sugar coated Tablet Contains: **Eperisone HCl…50mg** • **Firm shall submit 7,500/- fee for revision of formulation from film coated tablet to sugar coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
226.	**Name and address of manufacturer / Applicant**	**M/s Medicraft Pharmaceuticals Pvt Ltd. 126-B, Indstrial Estate, Hayatabad, Peshawar, Pakistan**
	Brand Name +Dosage Form + Strength	Medinac Suspension
	Composition	Each 5ml Suspension Contains: Ibuprofen…100mg Pseudoephedrine HCl…15mg
	Diary No. Date of R& I & fee	Dy No. 16338: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Propionic acid derivatives combinations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Branfed 100/15mg Suspension by Bio-Mark
	GMP status	The firm have submitted cGMP certificate issued on 13-05- 2022 based on inspection conducted on 10-05-2022.
	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
227.	**Name and address of manufacturer / Applicant**	**M/s Medicraft Pharmaceuticals Pvt Ltd. 126-B, Indstrial Estate, Hayatabad, Peshawar, Pakistan**
	Brand Name +Dosage Form + Strength	Medinac Tablet 400/60mg
	Composition	Each Film Coated Tablet Contains: Ibuprofen…400mg Pseudoephedrine HCl…60mg
	Diary No. Date of R& I & fee	Dy No. 16337: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Propionic acid derivatives combinations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications while monograph is available in USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Cos-Forte Tablet 400/60mg by Martin Dow
	GMP status	The firm have submitted cGMP certificate issued on 13-05- 2022 based on inspection conducted on 10-05-2022.
	Remarks of the Evaluator[3].	•
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response	

	within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
228.	**Name and address of manufacturer / Applicant**	**M/s Medicraft Pharmaceuticals Pvt Ltd. 126-B, Indstrial Estate, Hayatabad, Peshawar, Pakistan**
	Brand Name +Dosage Form + Strength	Ozapine 7.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Olanzapine…7.5mg
	Diary No. Date of R& I & fee	Dy No. 16331: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	**MHRA** Approved
	Me-too status	Odozap Tablet by Akhai Pharma
	GMP status	The firm have submitted cGMP certificate issued on 13-05- 2022 based on inspection conducted on 10-05-2022.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
229.	**Name and address of manufacturer / Applicant**	**M/s Medicraft Pharmaceuticals Pvt Ltd. 126-B, Indstrial Estate, Hayatabad, Peshawar, Pakistan**
	Brand Name +Dosage Form + Strength	Trimcinol Tablet 80/80mg
	Composition	Each Sugar Coated Tablet Contains: Phloroglucinol…80mg Trimethylphloroglucinol…80mg
	Diary No. Date of R& I & fee	Dy No. 16335: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antispasmodic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Spasfon, coated tablet by M/s Teva Sante, ANSM France Approved.
	Me-too status	Gluwix Tablet by Wnsfield
	GMP status	The firm have submitted cGMP certificate issued on 13-05- 2022 based on inspection conducted on 10-05-2022.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Sugar Coated Tablet Contains: Phloroglucinol Hydrate…80mg Trimethylphloroglucinol…80mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Sugar Coated Tablet Contains:** **Phloroglucinol Hydrate…80mg** **Trimethylphloroglucinol…80mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-**	

	2021, before issuance of registration letter.	
230.	**Name and address of manufacturer / Applicant**	**M/s Medicraft Pharmaceuticals Pvt Ltd. 126-B, Indstrial Estate, Hayatabad, Peshawar, Pakistan**
	Brand Name +Dosage Form + Strength	Qutimed 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Quetiapine As Fumarate…100mg
	Diary No. Date of R& I & fee	Dy No. 16332: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Q-Par Tablet by Helix
	GMP status	The firm have submitted cGMP certificate issued on 13-05- 2022 based on inspection conducted on 10-05-2022.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
231.	**Name and address of manufacturer / Applicant**	**M/s Medicraft Pharmaceuticals Pvt Ltd. 126-B, Indstrial Estate, Hayatabad, Peshawar, Pakistan**
	Brand Name +Dosage Form + Strength	Qutimed 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Quetiapine As Fumarate…200mg
	Diary No. Date of R& I & fee	Dy No. 16333: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Q-Par Tablet by Helix
	GMP status	The firm have submitted cGMP certificate issued on 13-05- 2022 based on inspection conducted on 10-05-2022.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
232.	**Name and address of manufacturer / Applicant**	**M/s Medicraft Pharmaceuticals Pvt Ltd. 126-B, Indstrial Estate, Hayatabad, Peshawar, Pakistan**
	Brand Name +Dosage Form + Strength	Tamsomed 0.4mg Capsule
	Composition	Each Capsule Contains: Tamsulosin HCl Sustained Release Pellets…0.4mg
	Diary No. Date of R& I & fee	Dy No. 16336: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Alpha-adrenoreceptor antagonists
	Type of Form	Form 5

	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Maxflow Capsule by CCL
	GMP status	The firm have submitted cGMP certificate issued on 13-05- 2022 based on inspection conducted on 10-05-2022.
	Remarks of the Evaluator[3].	• Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets). • Revise your label claim as per the innovator's product as under along with submission of full fee of registration: Each Capsule Contains: Tamsulosin HCl Modified Release Pellets Eq To Tamsulosin……0.4mg
	Decision: Approved with following label claim: **Each Capsule Contains:** **Tamsulosin HCl Modified Release Pellets Eq To Tamsulosin……0.4mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.** • **Firm shall submit source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets) before issuance of registration letter.**	
233.	**Name and address of manufacturer / Applicant**	**M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan**
	Brand Name +Dosage Form + Strength	Angitrin SR 0.5mg tablet
	Composition	Each Tablet Contains: Glyceryl Trinitrate …0.5mg
	Diary No. Date of R& I & fee	Dy No. 17270: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Organic nitrates
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	ANG Tablet by Glitz Pharma
	GMP status	The firm have submitted cGMP certificate issued on 14-12- 2020 based on inspection conducted on 23-09-2020.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved.	
234.	**Name and address of manufacturer / Applicant**	**M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan**
	Brand Name +Dosage Form + Strength	Angitrin SR 2.6mg tablet
	Composition	Each Tablet Contains: Glyceryl Trinitrate …2.6mg

	Diary No. Date of R& I & fee	Dy No. 17267: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Organic nitrates
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Angitryl 2.6mg Tablet by Saffron Pharma
	GMP status	The firm have submitted cGMP certificate issued on 14-12- 2020 based on inspection conducted on 23-09-2020.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
235.	**Name and address of manufacturer / Applicant**	**M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan**
	Brand Name +Dosage Form + Strength	Angitrin SR 6.4mg tablet
	Composition	Each Tablet Contains: Glyceryl Trinitrate …6.4mg
	Diary No. Date of R& I & fee	Dy No. 17271: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Organic nitrates
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Niglys SR 6.4mg Tablets by Uni-Mark Pharma
	GMP status	The firm have submitted cGMP certificate issued on 14-12- 2020 based on inspection conducted on 23-09-2020.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
236.	**Name and address of manufacturer / Applicant**	**M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan**

	Brand Name +Dosage Form + Strength	Prednicort 0.1% w/w Cream
	Composition	Each Gram Contains: Methylprednisolone Aceponate…1mg/Gm
	Diary No. Date of R& I & fee	Dy No. 17269: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Corticosteroids
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Depomax Cream by shaigan Pharma
	GMP status	The firm have submitted cGMP certificate issued on 14-12- 2020 based on inspection conducted on 23-09-2020.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
237.	**Name and address of manufacturer / Applicant**	**M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan**
	Brand Name +Dosage Form + Strength	Prednicort 0.1% w/w Ointment
	Composition	Each Gram Contains: Methylprednisolone Aceponate…1mg/Gm
	Diary No. Date of R& I & fee	Dy No. 17264: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Corticosteroids
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Methlepred Ointment by Jaens Pharma
	GMP status	The firm have submitted cGMP certificate issued on 14-12- 2020 based on inspection conducted on 23-09-2020.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.

	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
238.	**Name and address of manufacturer / Applicant**	**M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan**
	Brand Name +Dosage Form + Strength	Seboderm 1.5% w/v Liquid
	Composition	Each Gram Contain: Ciclopirox Olamine…1.5%W/V
	Diary No. Date of R& I & fee	Dy No. 17266: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antifungal for topical use
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Stieprox Shampoo by GSK **(Health Canada Approved)**
	Me-too status	Stieprox liquid by GSK
	GMP status	The firm have submitted cGMP certificate issued on 14-12- 2020 based on inspection conducted on 23-09-2020.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of required manufacturing facility / section approval letter from Licensing Division.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Lotion section" from CLB. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
239.	**Name and address of manufacturer / Applicant**	**M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan**
	Brand Name +Dosage Form + Strength	Synaroid Forte ointment
	Composition	Each Gram Contains: Diflucortolone Valerate…0.3%W/W
	Diary No. Date of R& I & fee	Dy No. 17265: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Corticosteroid
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Nerisone Forte Ointment 0.3% by Medipharm
	GMP status	The firm have submitted cGMP certificate issued on 14-12- 2020 based on inspection conducted on 23-09-2020.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.

	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
240.	**Name and address of manufacturer / Applicant**	**M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan**
	Brand Name +Dosage Form + Strength	Synaroid 0.1% w/w ointment
	Composition	Each Gram Contains: Diflurocortolone Valerate…0.1% W/W
	Diary No. Date of R& I & fee	Dy No. 17261: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Corticosteroid
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Could not be confirmed
	GMP status	The firm have submitted cGMP certificate issued on 14-12- 2020 based on inspection conducted on 23-09-2020.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
241.	**Name and address of manufacturer / Applicant**	**M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan**
	Brand Name +Dosage Form + Strength	Synaroid Forte Fatty 0.3% w/w Ointment
	Composition	Each Gram Contains: Diflurocortolone Valerate…0.3% W/W
	Diary No. Date of R& I & fee	Dy No. 17260: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Corticosteroid
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Nerisone Forte Fatty Ointment 0.3% by Medipharm
	GMP status	The firm have submitted cGMP certificate issued on 14-12- 2020 based on inspection conducted on 23-09-2020.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	

	The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
242.	**Name and address of manufacturer / Applicant**	**M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan**
	Brand Name +Dosage Form + Strength	Synaroid 0.1% w/w Cream
	Composition	Each Gram Contains: Diflurocortolone Valerate…0.1% W/W
	Diary No. Date of R& I & fee	Dy No. 17258: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Corticosteroid
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Flucortum Cream 0.1%w/w by Nabiqasim
	GMP status	The firm have submitted cGMP certificate issued on 14-12- 2020 based on inspection conducted on 23-09-2020.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
243.	**Name and address of manufacturer / Applicant**	**M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan**
	Brand Name +Dosage Form + Strength	Arynoin Gel
	Composition	Each Gram Contains: Isotretinoin…0.5mg
	Diary No. Date of R& I & fee	Dy No. 17262: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Retinoids for treatment of acne
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Acutin Gel by Linta Pharma
	GMP status	The firm have submitted cGMP certificate issued on 14-12- 2020 based on inspection conducted on 23-09-2020.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
244.	**Name and address of manufacturer / Applicant**	**M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan**
	Brand Name +Dosage Form + Strength	Siglitn 25mg tablet
	Composition	Each Tablet Contain:

		Sitagliptin…25mg
	Diary No. Date of R& I & fee	Dy No. 17263: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Tagip tablets by Highnoon
	GMP status	The firm have submitted cGMP certificate issued on 14-12- 2020 based on inspection conducted on 23-09-2020.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Sitagliptin as Phospate Monohydrate…25mg
	Decision: Approved with following label claim: **Each Film Coated Tablet Contains:** **Sitagliptin as Phospate Monohydrate…25mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
245.	**Name and address of manufacturer / Applicant**	**M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan**
	Brand Name +Dosage Form + Strength	Herpivir 5% w/w Cream
	Composition	Each Gram of Cream Contains: Acyclovir …5% w/w
	Diary No. Date of R& I & fee	Dy No. 17268: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	Zovirax cream by GSK
	GMP status	The firm have submitted cGMP certificate issued on 14-12- 2020 based on inspection conducted on 23-09-2020.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
246.	**Name and address of manufacturer / Applicant**	**M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan**
	Brand Name +Dosage Form + Strength	Herpivir 5% w/w Ointment
	Composition	Each Gram of Ointment Contains: Acyclovir……5% w/w

	Diary No. Date of R& I & fee	Dy No. 17258: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	Acylex Ointment by Ferozesons
	GMP status	The firm have submitted cGMP certificate issued on 14-12- 2020 based on inspection conducted on 23-09-2020.
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
247.	**Name and address of manufacturer / Applicant**	**M/s Macquin's International Pharmaceuticals F-2/H, P.T.C Industrial Complex, S.I.T.E Karachi**
	Brand Name +Dosage Form + Strength	Apriz 10mg Tablets
	Composition	Each Film Coated Tablet Contains: Cetirizine Dihydrochloride…10mg
	Diary No. Date of R& I & fee	Dy No. 13350: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Piperazine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Baydal Tablet by Bayer
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**	
248.	**Name and address of manufacturer / Applicant**	**M/s Macquin's International Pharmaceuticals F-2/H, P.T.C Industrial Complex, S.I.T.E Karachi**
	Brand Name +Dosage Form + Strength	Diacin 50mg Capsule
	Composition	Each Capsule Contains: Diacerein…50mg
	Diary No. Date of R& I & fee	Dy No. 13332: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other antiinflammatory and antirheumatic agents, non-steroids
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Diacerein Biogaran 50 mg, capsule ANSM Approved.
	Me-too status	Diora Capsule by Getz
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of required manufacturing facility / section approval letter from Licensing Division.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Capsule (General) section" from CLB. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
249.	**Name and address of manufacturer / Applicant**	**M/s Macquin's International Pharmaceuticals F-2/H, P.T.C Industrial Complex, S.I.T.E Karachi**
	Brand Name +Dosage Form + Strength	Oscicare Tablet 400/500mg Tablet
	Composition	Each Tablet Contains: Glucosamine Sulphate…500mg Chondrotoin Sulphate…400mg
	Diary No. Date of R& I & fee	Dy No. 13330: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other antiinflammatory and antirheumatic agents, nonsteroids
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Gevolox Ch Tablets by Hilton Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
250.	**Name and address of manufacturer / Applicant**	**M/s Macquin's International Pharmaceuticals F-2/h, P.T.C Industrial Complex, S.I.T.E Karachi**
	Brand Name +Dosage Form + Strength	Aprezole 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Albendazole…200mg
	Diary No. Date of R& I & fee	Dy No. 13335: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Anthelmintics
	Type of Form	Form 5
	Finished Product Specification	USP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Zentel Tablet by GSK
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
251.	**Name and address of manufacturer / Applicant**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Brand Name +Dosage Form + Strength	Ciprosone 3/1 mg Ear Drops
	Composition	Each ml Contains: Ciprofloxacin as HCl…3mg Dexamethasone…1mg
	Diary No. Date of R& I & fee	Dy No. 16676: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Quinolone Antibiotic and Corticosteroid
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Invoflox-D Eye Drops by Invotek Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-10-2022
	Remarks of the Evaluator[3].	• Firm has eye drops section as per the submitted GMP certificate • Firm has provided formulation of ophthalmic solution while the FDA approved product is available as ophthalmic suspension
	Decision: Approved as ophthalmic suspension with following label claim: **Each ml of ophthalmic suspension Contains:** **Ciprofloxacin as HCl…3mg** **Dexamethasone…1mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
252.	**Name and address of manufacturer / Applicant**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Brand Name +Dosage Form + Strength	Ciprocaine 3/50 mg Ear Drops
	Composition	Each ml Contains: Ciprofloxacin as Hcl…3mg Lignocaine…50mg
	Diary No. Date of R& I & fee	Dy No. 16675: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Ophthalmic Antibiotic in combination
	Type of Form	Form 5

	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Lidocip Ear Drops by Hygeia Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-10-2022
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
253.	**Name and address of manufacturer / Applicant**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Brand Name +Dosage Form + Strength	Kytofino 0.25mg Ophthalmic solution
	Composition	Each ml Contains: Ketotifen As Fumarate…0.25mg
	Diary No. Date of R& I & fee	Dy No. 16671: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Other antiallergics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ketti Eye Drops by Aries Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-10-2022
	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
254.	**Name and address of manufacturer / Applicant**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Brand Name +Dosage Form + Strength	Lotracin 5/3 mg Opthalmic Suspension
	Composition	Each ml Contains: Loteprednol…5mg Tobramycin…3mg
	Diary No. Date of R& I & fee	Dy No. 16673: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Corticosteroid and aminoglycoside antibiotic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZYLET by bausch & lomb (**USFDA** Approved)
	Me-too status	LOTEPRED-T by Sante
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-10-2022
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each ml Contains: Loteprednol etabonate…5mg Tobramycin…3mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each ml Contains:** **Loteprednol etabonate…5mg** **Tobramycin…3mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
255.	**Name and address of manufacturer / Applicant**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Brand Name +Dosage Form + Strength	Moxodex 5/1 mg Eye Drops
	Composition	Each ml Contains: Moxifloxacin Hcl…5mg Dexamethasone…1mg
	Diary No. Date of R& I & fee	Dy No. 16669: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Anti-infective and corticosteroids
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Comox eye drops by Elko
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-10-2022
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
256.	**Name and address of manufacturer / Applicant**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Brand Name +Dosage Form + Strength	Natocin 50mg Eye Drops
	Composition	Each ml Contains: Natamycin…50mg

	Diary No. Date of R& I & fee	Dy No. 16672: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification while monograph is available in USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Kocin Ophthalmic Suspension by Remington
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-10-2022
	Remarks of the Evaluator[3].	• Firm has provided formulation of ophthalmic solution while the FDA approved product is available as ophthalmic suspension
	Decision: Approved as ophthalmic suspension with following label claim: **Each ml of ophthalmic suspension Contains:** **Natamycin…50mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
257.	**Name and address of manufacturer / Applicant**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Brand Name +Dosage Form + Strength	Polygloc Opthalmic Drops
	Composition	Each ml Contains: Polyethylene Glycol…4mg Propylene Glycol…3mg
	Diary No. Date of R& I & fee	Dy No. 16677: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Lubricant
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed, available in Dailymed database as Systane day and night value pack
	Me-too status	Corniwet Eye Solution by Medicaids
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-10-2022
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
258.	**Name and address of manufacturer / Applicant**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Brand Name +Dosage Form + Strength	Tobrasone 3mg/1mg Eye Ointment
	Composition	Each gm of ointment Contains: Tobramycin…3mg

		Dexamethasone…1mg
	Diary No. Date of R& I & fee	Dy No. 16676: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Corticosteroids and Aminoglycoside antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	EyeBradex Eye Ointment by Barret Hodgson
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 12-10-2022
	Remarks of the Evaluator[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Ophthalmic ointment section" from CLB. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
259.	**Name and address of manufacturer / Applicant**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar,**
	Brand Name +Dosage Form + Strength	Beflin 600mg Tablet
	Composition	Each Film Coated Tablet Contains: Bamifylline Hcl…600mg
	Diary No. Date of R& I & fee	Dy No. 16156: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Methylxanthine
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Miffy 600mg Tablet by Shrooq Pharma
	GMP status	The firm has submitted copy of GMP Certificate issued on the basis of inspection dated 30-03-2022.
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
260.	**Name and address of manufacturer / Applicant**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar,**
	Brand Name +Dosage Form + Strength	Barin 5mg Tablet
	Composition	Each Uncoated Tablet Contains:

		Buspirone HCl…5mg
	Diary No. Date of R& I & fee	Dy No. 16170: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications while monograph is available in USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Buspin Tablet by Medizan
	GMP status	The firm has submitted copy of GMP Certificate issued on the basis of inspection dated 30-03-2022.
	Remarks of the Evaluator[3].	
	Decision: Approved with USP specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
261.	**Name and address of manufacturer / Applicant**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar,**
	Brand Name +Dosage Form + Strength	Barin 10mg Tablet
	Composition	Each Uncoated Tablet Contains: Buspirone Hcl…10mg
	Diary No. Date of R& I & fee	Dy No. 16170: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications while monograph is available in USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Buspin Tablet by Medizan
	GMP status	The firm has submitted copy of GMP Certificate issued on the basis of inspection dated 30-03-2022.
	Remarks of the Evaluator[3].	
	Decision: Approved with USP specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
262.	**Name and address of manufacturer / Applicant**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar,**
	Brand Name +Dosage Form + Strength	Inmide 2.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Indapamide…2.5mg
	Diary No. Date of R& I & fee	Dy No. 16176: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Diuretics
	Type of Form	Form 5
	Finished Product Specification	USP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Inmide Tablet by Bio-Labs
	GMP status	The firm has submitted copy of GMP Certificate issued on the basis of inspection dated 30-03-2022.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Indapamide (as hemihydrate)…2.5mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Film Coated Tablet Contains:** **Indapamide (as hemihydrate)…2.5mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
263.	**Name and address of manufacturer / Applicant**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar,**
	Brand Name +Dosage Form + Strength	Simtibe 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Simvastatin…20mg
	Diary No. Date of R& I & fee	Dy No. 16161: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	HMG-CoA-reductase inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Simtat tablet by Bio-Labs
	GMP status	The firm has submitted copy of GMP Certificate issued on the basis of inspection dated 30-03-2022.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
264.	**Name and address of manufacturer / Applicant**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar,**
	Brand Name +Dosage Form + Strength	Tacroz 0.5mg Tablet
	Composition	Each Capsule Contains: Tacrolimus as Monohydrate…0.5mg
	Diary No. Date of R& I & fee	Dy No. 16659: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Immunosuppressant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	Prograf by Astellas (**USFDA** Approved)
	Me-too status	Inograf by Platinum
	GMP status	The firm has submitted copy of GMP Certificate issued on the basis of inspection dated 30-03-2022.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
265.	**Name and address of manufacturer / Applicant**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar,**
	Brand Name +Dosage Form + Strength	Tacroz 1mg Tablet
	Composition	Each Extended Relese Tablet Contains: Tacrolimus Hydrate…1mg
	Diary No. Date of R& I & fee	Dy No. 16660: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Immunosuppressant
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Could not be confirmed
	GMP status	The firm has submitted copy of GMP Certificate issued on the basis of inspection dated 30-03-2022.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Extended Relese Tablet Contains: Tacrolimus as Monohydrate …1mg • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5D along with differential fee and stability study data of three batches of drug product.
	Decision: Registration Board decided to reject the application since the applied product requires submission of stability study data for its consideration, and the firm has not submitted stability study data of 3 batches of the drug product before the lapse of agreed deadline decided by DRAP Authority i.e. till 31st December 2022.	
266.	**Name and address of manufacturer / Applicant**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar,**
	Brand Name +Dosage Form + Strength	Tedro 1mg Tablet
	Composition	Each Film Coated Tablet Contains: Tolterodine Tartarate…1mg
	Diary No. Date of R& I & fee	Dy No. 16163: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Urinary antispasmodics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications while monograph is available in BP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Neuterod Tablet by Neutro Pharma
	GMP status	The firm has submitted copy of GMP Certificate issued on the basis of inspection dated 30-03-2022.
	Remarks of the Evaluator[3].	
	Decision: Approved with BP specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
267.	**Name and address of manufacturer / Applicant**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar,**
	Brand Name +Dosage Form + Strength	Tedro 4mg Tablet
	Composition	Each Film Coated Tablet Contains: Tolterodine Tartarate…4mg
	Diary No. Date of R& I & fee	Dy No. 16177: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Urinary antispasmodics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications while monograph is available in BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Toltero Tablets by CCL
	GMP status	The firm has submitted copy of GMP Certificate issued on the basis of inspection dated 30-03-2022.
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
268.	**Name and address of manufacturer / Applicant**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar,**
	Brand Name +Dosage Form + Strength	Vaclo 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Valacyclovir as HCl…500mg
	Diary No. Date of R& I & fee	Dy No. 16657: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antivirals for systemic use
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Viro Tablet by CCL

	GMP status	The firm has submitted copy of GMP Certificate issued on the basis of inspection dated 30-03-2022.
	Remarks of the Evaluator[3].	
	Decision: Approved.	
269.	**Name and address of manufacturer / Applicant**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar,**
	Brand Name +Dosage Form + Strength	Z Kast 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Zafirlukast…10mg
	Diary No. Date of R& I & fee	Dy No. 16165: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Leukotriene receptor antagonists
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Zulf Tablet by Semos Pharma
	GMP status	The firm has submitted copy of GMP Certificate issued on the basis of inspection dated 30-03-2022.
	Remarks of the Evaluator[3].	
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
270.	**Name and address of manufacturer / Applicant**	**M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar,**
	Brand Name +Dosage Form + Strength	Z Kast 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Zafirlukast…20mg
	Diary No. Date of R& I & fee	Dy No. 16166: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Leukotriene receptor antagonists
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Zulf Tablet by Semos Pharma
	GMP status	The firm has submitted copy of GMP Certificate issued on the basis of inspection dated 30-03-2022.
	Remarks of the Evaluator[3].	
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
271.	**Name and address of manufacturer / Applicant**	**M/s Welwink Pharmaceuticals.Factory G.T. Road, Industrial Estate, Gujranwala Cantt.**
	Brand Name +Dosage Form + Strength	Zipsit 10mg Tablet

	Composition	Each Film Coated Tablet Contains: Zafirlukast…10mg
	Diary No. Date of R& I & fee	Dy No. 16963: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Leukotriene receptor antagonists
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Zulf Tablet by Semos Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-07-2022
	Remarks of the Evaluator[3].	
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
272.	**Name and address of manufacturer / Applicant**	**M/s Welwink Pharmaceuticals.Factory G.T. Road, Industrial Estate, Gujranwala Cantt.**
	Brand Name +Dosage Form + Strength	Zipsit 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Zafirlukast…20mg
	Diary No. Date of R& I & fee	Dy No. 16964: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Leukotriene receptor antagonists
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Zulf Tablet by Semos Pharma
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-07-2022
	Remarks of the Evaluator[3].	
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
273.	**Name and address of manufacturer / Applicant**	**M/s Welwink Pharmaceuticals.Factory G.T. Road, Industrial Estate, Gujranwala Cantt.**
	Brand Name +Dosage Form + Strength	Introgen 5mg Capsule
	Composition	Each Capsule Contains: Tropisetron as HCl…5mg
	Diary No. Date of R& I & fee	Dy No. 16962: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Serotonin (5HT3) antagonists
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Norway Approved
	Me-too status	Navoban 5mg Capsule by Sandoz
	GMP status	Firm has submitted copy of GMP certificate issued on the basis of inspection dated 28-07-2022
	Remarks of the Evaluator[3].	
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
274.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Betameth Cream 0.1%
	Composition	Each Gram of Cream Contains: Betamethasone Valerate…….0.1%
	Diary No. Date of R& I & fee	Dy No. 16216: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Corticosteroids
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Betnogen Cream by Biogen Life Sciences
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division. • Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Gram of Cream Contains: Betamethasone as Valerate…….0.1%
	Decision: Deferred for following: • **Submission of evidence of approval of required manufacturing facility of "Cream section" from CLB.** • **Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following:** **Each Gram of Cream Contains:** **Betamethasone as Valerate…….0.1%** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
275.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Betagen Cream 0.5/1mg
	Composition	Each Gram of cream Contains: Betamethasone as Dipropionate…0.5mg

		Gentamycin as Sulfate…1mg
	Diary No. Date of R& I & fee	Dy No. 16216: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Corticosteroids, Combinations With Antibiotics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications (JP Monograph for Betamethasone Valerate and Gentamicin Sulfate Cream)
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Mibetin 1 mg/g + 0.5 mg/g Cream (gentamicin sulfate, betamethasone dipropionate).
	Me-too status	Dimed-G Cream by Maxitech
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Cream section" from CLB. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
276.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Betagen Cream 1/1mg
	Composition	Each Gram Contains: Betamethasone as Dipropionate…1mg Gentamycin as Sulfate…1mg
	Diary No. Date of R& I & fee	Dy No. 16215: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Corticosteroids, Combinations With Antibiotics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications (JP Monograph for Betamethasone Valerate and Gentamicin Sulfate Cream)
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Cream section" from CLB.	
277.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**

	Brand Name +Dosage Form + Strength	Parknil Tablet 25/100/200mg
	Composition	Each Film Coated Tablet Contains: Carbidopa…25mg Levodopa…100mg Entacapone…200mg
	Diary No. Date of R& I & fee	Dy No. 14040: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Dopaminergic Agents in combination
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Baldric Tablet by Bio-Mark
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 30,000 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Levodopa…100mg Carbidopa (as monohydrate)…25mg Entacapone…200mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Film Coated Tablet Contains:** **Levodopa…100mg** **Carbidopa (as monohydrate)…25mg** **Entacapone…200mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
278.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Kufset Capsule 375mg
	Composition	Each Capsule Contains: Carbocysteine…375mg
	Diary No. Date of R& I & fee	Dy No. 14036: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Mucolytic agent
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Mucodyl Capsule by Sanofi (MHRA Approved)
	Me-too status	Rhinathiol Capsule by Sanofi
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications.	

	• **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
279.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Clotix Cream 1%
	Composition	Each Gram of Cream Contains: Clotrimazole…10mg
	Diary No. Date of R& I & fee	Dy No. 14043: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antifungals for topical use
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Canesten Cream by Bayer (**MHRA** Approved)
	Me-too status	Canesten topical cream by Bayer
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division.
	Decision: Deferred for submission of evidence of approval of require dmanufcatuiring facility of "Cream section" from CLB. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
280.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Travolis 0.1/1% w/w Cream
	Composition	Each Gram Contains: Diflucortolone Valerate…1mg Isoconazole Nitrate…10mg
	Diary No. Date of R& I & fee	Dy No. 16219: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Corticosteroids, potent, other combinations
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Troculf Cream by Fynk Pharma
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division.
	Decision: Deferred for submission of evidence of approval of require dmanufcatuiring facility of "Cream section" from CLB. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	

281.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Histafix syrup
	Composition	Each 5ml Contains: Diphenhydramine HCl…14mg Ammonium Chloride…135mg Levomenthol…1.1mg Sodium Citrate…60mg
	Diary No. Date of R& I & fee	Dy No. 14041: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Cough preparation
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	
282.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Epinil Tablet 250mg
	Composition	Each Extended Release Tablet Contains: Divalproex Sodium Eq To Valproic Acid…250mg
	Diary No. Date of R& I & fee	Dy No. 14033: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation

		conducted on 17-08-2021.
	Remarks of the Evaluator[3].	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	
283.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Drotalis Injection 40mg/2ml
	Composition	Each 2ml Vial Contains: Drotaverine Hcl…40mg
	Diary No. Date of R& I & fee	Dy No. 16204: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Anti-spasmodic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	1. NO-SPA 40 mg solution for injection by Sanofi Aventis (OGYEI Hungary Approved) 2. NO-SPA 40 mg / 2 ml solution for injection by Sanofi Romania (NAMMD Romania Approved) 3. No-Spa 20 mg/ml solution for injection by Chinoin Pharmaceutical and Chemical Works Co. Ltd (Executive Agency For Medicinal Products, Bulgaria Approved)
	Me-too status	Dytra Injection by Tabros
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for submission of evidence of approval of require dmanufcatuiring facility of "Cream section" from CLB. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision. •	
284.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Iromax Injection 100mg/5ml
	Composition	Each 5ml Contains: Iron sucrose complex eq to elemental Iron…100mg
	Diary No. Date of R& I & fee	Dy No. 16213: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	(Anti-anemic preparations)
	Type of Form	Form 5

	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Venofer Injection by Vifor Pharma (**MHRA** Approved)
	Me-too status	Ferotein-S by Getz
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division.
	Decision: Deferred for submission of evidence of approval of require dmanufcatuiring facility of "Cream section" from CLB. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
285.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Epril Tablet 10mg
	Composition	Each Uncoated Tablet Contains: Enalapril Maleate…10mg
	Diary No. Date of R& I & fee	Dy No. 14038: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	ACE inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Amotec Tablet by Mass Pharma
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
286.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Aperis 50mg Tablet
	Composition	Each Tablet Contains: Eperisone Hydrochloride…50mg
	Diary No. Date of R& I & fee	Dy No. 14042: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Eperisone Hydrochloride Tablets 50mg "TCK" PMDA Japan Approved (Sugar coated tablet)

	Me-too status	Eprisa Tablet by Fynk Pharma
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	• Revise your label claim along with submission of 7500 fee as per the innovator's product as per following: Each Sugar coated Tablet Contains: Eperisone HCl…50mg
	Decision: Approved with Innovator's specifications and with following label claim: **Each Sugar coated Tablet Contains:** **Eperisone HCl…50mg** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to sugar coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
287.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Mucoset Sachet
	Composition	Each Sachet Contains: Erdosteine…225mg
	Diary No. Date of R& I & fee	Dy No. 14037: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Mucodox 225mg Sachet by Vision Pharma
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for following: • **Submission of evidence of approval of require dmanufcatuiring facility of "Cream section" from CLB.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
288.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Ibu-profen Gel
	Composition	Each Gram of Gel Contains: Ibuprofen……..10% W/W
	Diary No. Date of R& I & fee	Dy No. 14039: 07-03-2019 PKR 20,000/-: 06-03-2019

	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications while product monograph is available in BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Febridex Gel by Evolution Pharma
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division.
	Decision: Deferred for submission of evidence of approval of require dmanufcatuiring facility of "Cream section" from CLB. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
289.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Isobest Cream 0.5mg/gm
	Composition	Each Gram Contains: Isotretinoin…0.5mg
	Diary No. Date of R& I & fee	Dy No. 16199: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Retinoid
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Isotrex 0.05% Cream by GSK (**MHRA** Approved)
	Me-too status	Acnecid Creamby Reko Pharmacal
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division.
	Decision: Deferred for submission of evidence of approval of require dmanufcatuiring facility of "Cream section" from CLB. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
290.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Ligno 2% w/w Gel
	Composition	Each Gram of Gel Contains: Lignocaine HCl…20mg
	Diary No. Date of R& I & fee	Dy No. 16203: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Anesthetics for topical use

	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Lignopharm Gel 2% by E-Pharm Laboratories
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Topical gel section" from CLB. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
291.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Metlis 10mg/2ml Injection
	Composition	Each 2ml Ampoule Contains: Metoclopramide Hcl eq to anhydrous metoclopramide HCl……..10mg
	Diary No. Date of R& I & fee	Dy No. 16217: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Propulsives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Metoclopramide 5mg/ml Injection, as 10mg/2ml and 100mg/20ml ampoules MHRA Approved
	Me-too status	Kamemide Injection 10mg by Amaan Pharma
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Liquid Injectable Ampoule section" from CLB. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
292.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Flyzol Infusion 500mg/100ml
	Composition	Each Vial of 100ml Contains: Metronidazole…500mg
	Diary No. Date of R& I & fee	Dy No. 16206: 07-03-2019 PKR 20,000/-: 07-03-2019

	Pharmacological Group	Imidazole derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Metronidazole 5mg/ml Solution for Infusion by Teva UK (**MHRA** Approved)
	Me-too status	Metrodex infusion by Caraway Pharma
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Liquid Injectable Vial section" from CLB. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
293.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Pirofix Gel 0.5%
	Composition	Each gram of gel Contains: Piroxicam……0.5% w/w
	Diary No. Date of R& I & fee	Dy No. 16218: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications while monograph is available in BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Feldene Gel by Pfizer
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Topical gel section" from CLB. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
294.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Burnil Cream 1%
	Composition	Each Gram of Cream Contains: Silver Sulphadiazine…10mg
	Diary No. Date of R& I & fee	Dy No. 16211: 07-03-2019 PKR 20,000/-: 07-03-2019

	Pharmacological Group	Antibiotic for topical use
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Silvadene by King Pharms (**USFDA** Approved)
	Me-too status	Quench by Ferozesons
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	• Evidence of required manufacturing facility / section approval letter from Licensing Division.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Cream section" from CLB. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
295.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Tamofen 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Tamoxifen as Citrate…20mg
	Diary No. Date of R& I & fee	Dy No. 14031: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Anti-estrogens
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Tamoxidex Tablet by Pacific Pharma
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
296.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	D Max Injeciton 5mg/ml
	Composition	Each ml Contains: Cholecalciferol (Vitamin D3)…5mg
	Diary No. Date of R& I & fee	Dy No. 16212: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Vitamin D
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	VITAMIN D3 BON 200,000 IU/1 ml solution for injection IM ampoule ANSM France Approved.
	Me-too status	Sunny D Insta Ampoule of M/s Scotmann Pharmaceuticals Islamabad.
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
297.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Sipro Injection 200mg/100ml
	Composition	Each 100ml Contains: Ciprofloxacin As Lactate…200mg
	Diary No. Date of R& I & fee	Dy No. 16217: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Novidat infusion by Sami (ciprofloxacin as HCl)
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	Registration Board in its 316th meeting considered the case of review of ciprofloxacin salt form in injectable dosage forms and decided as "*Registration Board decided to defer the case for further deliberation and advised PE&R Division to present the details of "label claim" in terms of salt form of the Ciprofloxacin and of "drug product specifications", granted to already registered products of Ciprofloxacin Infusion.*
	Decision: Registration Board decided to refer the case to Expert Working Group for pharmaceutical products to review of human formulations	
298.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Opride Tablet 50mg
	Composition	Each Tablet Contains: Amisulpride…50mg
	Diary No. Date of R& I & fee	Dy No. 14026: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ampisol Tablets by Sami Pharma
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
299.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Opride Tablet 100mg
	Composition	Each Tablet Contains: Amisulpride…100mg
	Diary No. Date of R& I & fee	Dy No. 14026: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ampisol Tablets by Sami Pharma
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
300.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**
	Brand Name +Dosage Form + Strength	Opride Tablet 200mg
	Composition	Each Tablet Contains: Amisulpride…200mg
	Diary No. Date of R& I & fee	Dy No. 14026: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ampisol Tablets by Sami Pharma
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
301.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi**

	Brand Name +Dosage Form + Strength	Opride Tablet 400mg
	Composition	Each Tablet Contains: Amisulpride…400mg
	Diary No. Date of R& I & fee	Dy No. 14027: 07-03-2019 PKR 20,000/-: 06-03-2019
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ampisol Tablets by Sami Pharma
	GMP status	GMP certificate issued on 17-08-2021, based on evaluation conducted on 17-08-2021.
	Remarks of the Evaluator[3].	•
	Decision: Approved.	
302.	**Name and address of manufacturer / Applicant**	**M/s Liven Pharmaceuticals Pvt Ltd. 49 km, Lahore Multan Road.**
	Brand Name +Dosage Form + Strength	Cardovas 500mg/4ml
	Composition	Each 4ml Ampoule Contains: Citicoline As Sodium…500mg
	Diary No. Date of R& I & fee	Dy No. 16267: 07-03-2019 PKR 20,000/-: 05-03-2019
	Pharmacological Group	Other psychostimulants and nootropics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	4ml ampoule: As per SRO
	Approval status of product in Reference Regulatory Authorities.	CITICOLINA KERN PHARMA 500 mg solution for injection EFG is presented in transparent glass ampoules. Each 4 ml ampoule contains 500 mg CITICOLINE (as sodium salt). Spain Approved
	Me-too status	Seeto-las Injection 500mg/4ml of Astellas Pharma
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Evidence of required manufacturing facility / section approval letter from Licensing Division.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Liquid Injectable section" from CLB. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
303.	**Name and address of manufacturer / Applicant**	**M/s Epla Laboratories. D-12, Estate Avenue, S.I.T.E., Karachi**
	Brand Name +Dosage Form + Strength	Clarbact Tablets 250mg
	Composition	Each Film Coated Tablet Contains: Clarithromycin …250mg

	Diary No. Date of R& I & fee	Dy No. 16370: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Claritek Tablet by Getz
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
304.	**Name and address of manufacturer / Applicant**	**M/s Epla Laboratories. D-12, Estate Avenue, S.I.T.E., Karachi**
	Brand Name +Dosage Form + Strength	Clarbact Tablets 500mg
	Composition	Each Film Coated Tablet Contains: Clarithromycin …500mg
	Diary No. Date of R& I & fee	Dy No. 16370: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Claritek Tablet by Getz
	GMP status	
	Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.**	
305.	**Name and address of manufacturer / Applicant**	**M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi.**
	Brand Name +Dosage Form + Strength	Zonomet 2.5mg Tablet
	Composition	Each Tablet Contains: Metolazone…2.5mg
	Diary No. Date of R& I & fee	Dy No. 16437: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Diuretics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Neumetoz Tablet of Neutro Pharma
	GMP status	GMP certificate based on inspection dated 07.02.2020 (valid till 06.02.2022)
	Remarks of the Evaluator[3].	• Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board. • Registration Board in its 320th meeting decided to give 6 months' time period to all applicants to submit stability study data. The 6 months' time period was lapsed on 31st December 2022. DRAP Authority also decided not to extend the timeline for stability study data submission.
	Decision: Registration Board decided to reject the application since the firm has not submitted stability study data of 3 batches of the drug product before the lapse of deadline decided by DRAP Authority i.e. till 31st December 2022.	
306.	**Name and address of manufacturer / Applicant**	**M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi.**
	Brand Name +Dosage Form + Strength	Zonomet 5mg Tablet
	Composition	Each Tablet Contains: Metolazone…5mg
	Diary No. Date of R& I & fee	Dy No. 14438: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Diuretics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Neumetoz Tablet of Neutro Pharma
	GMP status	GMP certificate based on inspection dated 07.02.2020 (valid till 06.02.2022)
	Remarks of the Evaluator[3].	• Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board. • Registration Board in its 320th meeting decided to give 6 months' time period to all applicants to submit stability study data. The 6 months' time period was lapsed on 31st December 2022. DRAP Authority also decided not to extend the timeline for stability study data submission.
	Decision: Registration Board decided to reject the application since the firm has not submitted stability study data of 3 batches of the drug product before the lapse of deadline decided by DRAP Authority i.e. till 31st December 2022.	
307.	**Name and address of manufacturer / Applicant**	**M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi.**
	Brand Name +Dosage Form + Strength	Zonomet 10mg Tablet
	Composition	Each Tablet Contains: Metolazone…10mg
	Diary No. Date of R& I & fee	Dy No. 16439: 07-03-2019 PKR 20,000/-: 07-03-2019
	Pharmacological Group	Diuretics
	Type of Form	Form 5

	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Neumetoz Tablet of Neutro Pharma
	GMP status	GMP certificate based on inspection dated 07.02.2020 (valid till 06.02.2022)
	Remarks of the Evaluator[3].	• Submit stability study data as per the guidelines approved in 293rd meeting of Registration Board. • Registration Board in its 320th meeting decided to give 6 months' time period to all applicants to submit stability study data. The 6 months' time period was lapsed on 31st December 2022. DRAP Authority also decided not to extend the timeline for stability study data submission.
	Decision: Registration Board decided to reject the application since the firm has not submitted stability study data of 3 batches of the drug product before the lapse of deadline decided by DRAP Authority i.e. till 31st December 2022.	
308	**Name and address of manufacturer / Applicant**	**M/s Hiranis Pharmaceuticals (Pvt.) Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim Karachi**
	Brand Name +Dosage Form + Strength	Clarbact Suspension 125mg/5ml
	Composition	Each 5ml of reconstituted suspension Contains: Clarithromycin…….125mg (Taste masked granules)
	Diary No. Date of R& I & fee	Dy No. 15027: 07-03-2019 (R&I verified) PKR 20,000/-: 06-03-2019 Duplicate dossier is submitted vide Dy No. 6119 dated 03-03-2023.
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Claritek suspension by Getz
	GMP status	Firm has submitted cGMP certificate issued on 12-11-2021 based on inspection conducted on 05-11-2021.
	Remarks of the Evaluator[3].	• Source of pellets: M/s Surge Laboratories.
	Decision: Approved.	
309	**Name and address of manufacturer / Applicant**	**M/s Bio-Mark Pharmaceuticals Plot No. 527, Sunder Industrial Estate, Lahore.**
	Brand Name +Dosage Form + Strength	Telep 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Piracetam……400mg
	Diary No. Date of R& I & fee	Dy No. 7720: 06-07-2017 (R&I verified) PKR 20,000/-: 06-07-2017 Duplicate dossier is submitted vide Dy No. 10159 dated 17-04-2023.
	Pharmacological Group	Nootropics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	ANSM France Approved
	Me-too status	Nootropil Tablet by M/s GSK
	GMP status	Firm has submitted cGMP certificate issued on the basis of inspection dated 13-02-2020.
	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
310	**Name and address of manufacturer / Applicant**	**M/s Bio-Mark Pharmaceuticals Plot No. 527, Sunder Industrial Estate, Lahore.**
	Brand Name +Dosage Form + Strength	Telep 800mg Tablet
	Composition	Each Film Coated Tablet Contains: Piracetam……800mg
	Diary No. Date of R& I & fee	Dy No. 7721: 06-07-2017 (R&I verified) PKR 20,000/-: 06-07-2017 Duplicate dossier is submitted vide Dy No. 10158 dated 17-04-2023.
	Pharmacological Group	Nootropics
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	ANSM France Approved
	Me-too status	Nootropil Tablet by M/s GSK
	GMP status	Firm has submitted cGMP certificate issued on the basis of inspection dated 13-02-2020.
	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
311	**Name and address of manufacturer / Applicant**	**M/s Bio-Mark Pharmaceuticals Plot No. 527, Sunder Industrial Estate, Lahore.**
	Brand Name +Dosage Form + Strength	Sofosb 5/10mg Tablet
	Composition	Each film ocated tablet contains: Rosuvastatin calcium eq to rosuvastatin……5mg Ezetimibe……..10mg
	Diary No. Date of R& I & fee	Dy No. 7716: 06-07-2017 (R&I verified) PKR 20,000/-: 06-07-2017 Duplicate dossier is submitted vide Dy No. 10157 dated 17-04-2023.
	Pharmacological Group	Antihyperlipidemic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	X-plended EZ Tablet by Pharmevo

	GMP status	Firm has submitted cGMP certificate issued on the basis of inspection dated 13-02-2020.
	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
312	**Name and address of manufacturer / Applicant**	**M/s Bio-Mark Pharmaceuticals Plot No. 527, Sunder Industrial Estate, Lahore.**
	Brand Name +Dosage Form + Strength	Sofosb 10/10mg Tablet
	Composition	Each film coated tablet contains: Rosuvastatin calcium eq to rosuvastatin……10mg Ezetimibe……..10mg
	Diary No. Date of R& I & fee	Dy No. 7696: 06-07-2017 (R&I verified) PKR 20,000/-: 06-07-2017 Duplicate dossier is submitted vide Dy No. 10156 dated 17-04-2023.
	Pharmacological Group	Antihyperlipidemic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	X-plended EZ 5mg + 10mg Tablet by Pharmevo
	GMP status	Firm has submitted cGMP certificate issued on the basis of inspection dated 13-02-2020.
	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
313	**Name and address of manufacturer / Applicant**	**M/s Bio-Mark Pharmaceuticals Plot No. 527, Sunder Industrial Estate, Lahore.**
	Brand Name +Dosage Form + Strength	Olysio V Tablet
	Composition	Each Tablet Contains: Neomycin sulphate……108.3mg (65,000 IU) Metronidazole……..500mg Nystatin…….22.73mg (100,000 IU)
	Diary No. Date of R& I & fee	Dy No. 7708: 06-07-2017 (R&I verified) PKR 20,000/-: 06-07-2017 Duplicate dossier is submitted vide Dy No. 10155 dated 17-04-2023.
	Pharmacological Group	Antiinfectives for systemic use
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Neomectin Vaginal Tablet by Genome
	GMP status	Firm has submitted cGMP certificate issued on the basis of inspection dated 13-02-2020.

	Remarks of the Evaluator[3].	•
	Decision: Approved with Innovator's specifications. • **Registration letter will be issued after submission of updated GMP inspection report by the firm.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	

a) Deferred cases

314.	Name and address of manufacturer / Applicant	M/s Skim Pharmaceuticals 10/B value addition city Faisalabad
	Brand Name +Dosage Form + Strength	SKIFENAC Diclofenac Sodium 50mg sustain coated pellets
	Diary No. Date of R& I & fee	Each capsule contains: Diclofenac sodium sustained release pellets….50mg Source of Pellets: M/s Vision Pharmaceutical Islamabad
	Composition	Dy. No. 20075 dated 04-06-2018 Rs20,000/-Dated 04-06-18
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	20,s capsule in Alu/PVC Blister & As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Diclofenac sodium 25mg & 50mg) gastro resistant **Tablet** by M/s Daxcel Pharma, MHRA Approved.
	Me-too Status	Lifdik 50mg capsule by M/s Goodmann, Reg No. 52586
	GMP Status	**DML NO. 000830 ISSUE DATED 03-12-2015 PANEL RECOMMENDED ADDITIONAL SECTIONS INCLUDING CAPSULE (GENERAL) DATED 19-01-2018**
	Remarks of the Evaluator-I	The firm initially applied for Sustained Release Capsule and then it was revised as Enteric coated Capsule as per reference product and submitted fee Rs. 5,000/- vide challan number 0300788 dated 13/04/2020.
	Decision of 296th meeting of Registration Board: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
	Response by the firm: Firm has submitted evidence of approval of applied formulation as under: **Product name:** Difene 50mg Capsules **Composition:** 50mg of diclofenac sodium, Gastro-resistant capsule, hard **RRA:** HPRA Ireland	
	Decision: Approved with BP specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	

315.	Name and address of manufacturer/ Applicant	M/s Quaper Pvt.Ltd.,26-A small Industrial Estate, Lahore road, Sargodha.
	Brand Name + Dosage Form + Strength	ACTIDOL CF Tablet
	Composition	Each Tablet Contains: Paracetamol ……. 500 mg Caffeine ……. 30 mg

<table>
<tr><td></td><td></td><td>Chlorpheniramine Maleate …..… 2 mg</td></tr>
<tr><td></td><td>Diary No. Date of R & I & fee</td><td>Dy. No 11793 dated 06-03-2019; Rs.20,000/- dated 06-03-2019.</td></tr>
<tr><td></td><td>Pharmacological Group</td><td>Analgesic/Antipyretic</td></tr>
<tr><td></td><td>Type of Form</td><td>Form-5</td></tr>
<tr><td></td><td>Finished product Specification</td><td>Innovator’s specifications</td></tr>
<tr><td></td><td>Pack size & Demanded Price</td><td>10’s, As per SRO</td></tr>
<tr><td></td><td>Approval status of product in Reference Regulatory Authorities</td><td>Not found</td></tr>
<tr><td></td><td>Me-too status</td><td></td></tr>
<tr><td></td><td>GMP status</td><td>Firm was granted GMP certificate dated 19-06-2019 on the basis of GMP inspection conducted on 28-01-2019 for Tablet (General).
Panel inspection of firm for grant of additional sections was also conducted on 16-06-2020 & 18-06-2020 and firm was recommended for grant of following additional sections as per approved layout plan:
1. Tablet (General) section
2. Capsule (general) section
3. R&D laboratory
4. Sachet (general)</td></tr>
<tr><td></td><td>Remarks of the Evaluator</td><td>Deficiency letter was issued to firm for submission of evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board. Firm has submitted reply vide dairy No. 1018 (PEC DRAP) dated 13-05-2022 along with pre-registration fee of 30,000 vide challan No.78017563568 dated 13-05-2022 and submitted revised form -5 mentioning revised label claim and composition for standardization of formulation as under:
<table>
<tr><td>Composition</td><td>Each Film Coated Tablet Contains:
Paracetamol……325 mg
Tramadol Hcl…….37.5mg</td></tr>
<tr><td>Pharmacological Group</td><td>Anti-Pyretic/Analgesic</td></tr>
<tr><td>Finished Product specification</td><td>Innovators specification</td></tr>
<tr><td>Pack size & Demanded Price</td><td>10’s, As per SRO</td></tr>
<tr><td>Approval status of product in Reference Regulatory Authorities</td><td>Ultracet Tablet by M/s Janssen Ortho, (USFDA approved)</td></tr>
<tr><td>Me-too status</td><td>Forgesil Tablet by M/s Genome Pharmaceutical
(Reg No:080874</td></tr>
</table></td></tr>
<tr><td colspan="3">Decision of 317th meeting: Deferred for review as firm has changes the ingredients in subsequent application.</td></tr>
<tr><td colspan="3">Firm’s reply: Firm has submitted that on basis of not finding the approval status of product in requested to reconsider for approval of the product with changed composition.</td></tr>
<tr><td colspan="3">Decision of 323rd meeting of Registration Board:</td></tr>
</table>

Registration Board did not accede for change of active ingredient in the applied formulation and deferred for following:

- Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
- Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.

Response by the firm:

Firm has again requested to consider their previosu request in which they have applied for revision of the formulation as per the reference regulatory authorities, since the applied formulation is not approved by any reference regulatory authority. Firm has referred to their already submitted reply as under:

Reply of the firm vide dairy No. 1018 (PEC DRAP) dated 13-05-2022 along with pre-registration fee of 30,000 vide challan No.78017563568 dated 13-05-2022 and submitted revised form -5 mentioning revised label claim and composition for standardization of formulation as under:

Composition	Each Film Coated Tablet Contains: Paracetamol……325 mg Tramadol HCl…….37.5mg
Pharmacological Group	Anti-Pyretic/Analgesic
Finished Product specification	Innovators specification
Pack size & Demanded Price	10's, As per SRO
Approval status of product in Reference Regulatory Authorities	Ultracet Tablet by M/s Janssen Ortho, (USFDA approved)
Me-too status	Forgesil Tablet by M/s Genome Pharmaceutical (Reg No:080874

Firm has also provided reference of their another application in which they have revised the formulation and the same case was also approved by the Board in its 320th meeting. The details of the initial applied formulation, revised formulation and decision of Board is placed below:

Initially applied formulation	**Revised formulation**	**Decision of 320th meeting of RB**
Each Tablet Contains: Paracetamol…….500 mg Pseudoephedrine HCl……60 mg Chlorpheniramine Maleate……4 mg	Each Tablet Contains: Paracetamol……500 mg	Approved. Registration Board further decided that registration letter will be issued after submission of applicable fee that is Rs. 30,000/- for revision of formulation as per reference product as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.

Decision: Registration Board acceded to the request of the firm and decided to approved the application as per following revised label claim with USP specifications:

"Each Film Coated Tablet Contains:

Paracetamol……325 mg

Tramadol HCl…….37.5mg"

316.	Name and address of manufacturer / Applicant	M/s Medisearch Pharma Pvt Ltd 5-Km, Raiwind Manga Road, Lahore
	Brand Name +Dosage Form + Strength	P Caf Tablet 500mg/65mg
	Composition	Each Film Coated Tablet Contains: Paracetamol…500mg Caffeine…65mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13897 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019 (#0845763)

	Pharmacological Group	Analgesic /Xanthine
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	210 per pack As per SRO
	Approval status of product in Reference Regulatory Authorities	Panadol Extra Advance 500 mg/65 mg Film Coated Tablets by M/s GSK, MHRA Approved.
	Me-too status	Paratol Extra tablet by M/s Highnoon (Reg.# 13346)
	GMP status	M/S Medisearch Pharma: 23-08-2019
	Remarks of Evaluator [VII]	
	Decision of 296th meeting of Registration Board: Deferred for consideration on its turn	
	Response by the firm: Firm has requested to reconsider this case since now the cases of 7th March 2019 applied on Form 5 have been considered by the Registration Board.	
	Decision: Approved.	
317.	Name and address of manufacturer / Applicant	M/s Medisearch Pharma Pvt Ltd 5-Km, Raiwind Manga Road, Lahore
	Brand Name +Dosage Form + Strength	Fenrate Capsule 200mg
	Composition	Each capsule contains Fenofibrate…200mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13897 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019 (#0846281)
	Pharmacological Group	Lipid Regulating agent
	Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Fenofibrate 200 mg (MHRA approved)
	Me-too status	Corfibrate 200mg Capsule by M/s OBS (Reg.# 073646)
	GMP status	M/S Medisearch Pharma: 23-08-2019
	Remarks of Evaluator [VII]	In RRA micronized fenofibrate is used
	Decision of 296th meeting of Registration Board: Deferred for consideration on its turn	
	Response by the firm: Firm has requested to reconsider this case since now the cases of 7th March 2019 applied on Form 5 have been considered by the Registration Board.	
	Decision: Approved.	
318.	Name and address of manufacturer / Applicant	M/s Medisearch Pharma Pvt Ltd 5-Km, Raiwind Manga Road, Lahore
	Brand Name +Dosage Form + Strength	Rostatin 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Rosuvastatin Calcium…10mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13897 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019 (#0846278)
	Pharmacological Group	Lipid Regulating agent
	Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Crestor (rosuvastatin as calcium) (5mg, 10mg, 20mg, 40mg) film coated tablet by M/s IPR, USFDA Approved.
	Me-too status	Rosulin Tablets 10 mg tablet by M/s Highnoon Labs, Reg.# 048372
	GMP status	M/S Medisearch Pharma: 23-08-2019
	Remarks of Evaluator [VII]	In RRA Rosuvastatin calcium is approved but the applied product is just Rosuvastatin
	Decision of 296th meeting of Registration Board: Deferred for consideration on its turn	
	Response by the firm: Firm has requested to reconsider this case since now the cases of 7th March 2019 applied on Form 5 have been considered by the Registration Board. The label claim of the reference product is as under: Each Film Coated Tablet Contains: Rosuvastatin Calcium Eq. To Rosuvastatin…10mg	
	Decision: Approved with USP specifications and with following label claim: **Each Film Coated Tablet Contains:** **Rosuvastatin Calcium Eq. To Rosuvastatin…10mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
319.	Name and address of manufacturer / Applicant	M/s Medisearch Pharma Pvt Ltd 5-Km, Raiwind Manga Road, Lahore
	Brand Name +Dosage Form + Strength	Rostatin 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Rosuvastatin Calcium…20mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 13820 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019 (#0846279)
	Pharmacological Group	Lipid Regulating agent
	Form	Form-5
	Finished product Specifications	Manufacture specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Crestor (rosuvastatin as calcium) (5mg, 10mg, 20mg, 40mg) film coated tablet by M/s IPR, USFDA Approved.
	Me-too status	Rosulin Tablets 10 mg tablet by M/s Highnoon Labs, Reg.# 048372
	GMP status	M/S Medisearch Pharma: 23-08-2019
	Remarks of Evaluator [VII]	In RRA Rosuvastatin calcium is approved but the applied product is just Rosuvastatin
	Decision of 296th meeting of Registration Board: Deferred for consideration on its turn	
	Response by the firm: Firm has requested to reconsider this case since now the cases of 7th March 2019 applied on Form 5 have been considered by the Registration Board. The label claim of the reference product is as under: Each Film Coated Tablet Contains: Rosuvastatin Calcium Eq. To Rosuvastatin…20mg	
	Decision: Approved with USP specifications and with following label claim: **Each Film Coated Tablet Contains:** **Rosuvastatin Calcium Eq. To Rosuvastatin…10mg**	

	• **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**

320.	Name and address of manufacturer / Applicant	M/s Hoover Pharmaceuticals (Pvt) Ltd. Plot#16, Zain Park Industrial Area, Saggian bypass Road, Lahore.
	Brand Name +Dosage Form+ Strength	Enemax Enema, Rectal Solution
	Composition	Each ml contains: Monobasic Sodium Phosphate…….161mg Dibasic Sodium Phosphate…….59.3mg
	Diary No. Date of R& I & fee	Dy. No.7209, 29-06-2017; Rs.20,000/- (29-06-2017)
	Pharmacological Group	Laxative
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	135ml / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fleet Ready-To-Use Enema (reformulation) bottle by M/s Care Pharmaceuticals Pty Ltd (TGA Approved)
	Me-too status	Kleen Enema by Nabi Qasim (Reg#006715)
	GMP status	12-02-2018 Inspection for Grant of GMP certificate. Firm has maintained fair level of GMP.
	Previous remarks of the Evaluator.	International availability and me-too status are not confirmed.
	Previous decision(s) 274th Meeting of Registration Board held on 21-23rd September, 2017	Deferred for submission of evidence of approval in reference regulatory authorities and me-too status. Deferred for confirmation of manufacturing facility for applied formulation (M-285).
	Evaluation by PEC	Submitted evidence of approval in RRA: Fleet Ready-To-Use Enema (reformulation) bottle by M/s Care Pharmaceuticals Pty Ltd (TGA Approved) Firm has submitted evidence of me-too status: Kleen Enema by Nabi Qasim (Reg#006715) Firm has submitted fee of Rs.5000/-. Challan#0748683 dated 29-08-2018. The firm has submitted section approval letter No. F.1-22/2000-Lic which shows that firm has following sections: Oral Dry powder Suspension Section (General) Oral liquid section (General) External Liquid Section (General) Sachet Section (General)
	Decision of 297th meeting: Deferred for further deliberation of manufacturing facility / section of applied formulation.	
	Firm's response: "As per best of our Knowledge the product "Enema" is being manufactured bythe other companies in External Liquid Section and as such no dedicated section has advised by DRAP for the preparation of Enema. Howver as we have the facility of oral liquid as well as External Liquid approved sections, the same will be manufactured in the sections as directed by the Board."	
	Decision of 312th meeting of Registration Board: Deferred to review/discuss the manufacturing requirements of Enema including manufacturing facility of already registered products.	
	Response by the firm: Firm has submitted that as per best of our information DRAP has not specified the dedicated section for enema, beside this it would be manufactured either in internal solution or external solution. As	

	wel have approved facility for both i.e. internal as well as external solution and will be manufactured as per direction of DRB. Firm has also submitted copy of letter for grant of amendments / additional section approval dated 11-04-2017 specifying Oral liquid section (General) and External Liquid section (General).	
	Decision: Registration Board after thorough deliberation decided to approve the product for manufacturing in External Liquid section (General) section.	

Case No. 02 Registration applications of CTD cases

a. New cases of local manufacturing

321.	Name, address of Applicant / Marketing Authorization Holder	**M/s Carer Pharmaceutical Industries. Plot No. 27 Main Road, Rawat Industrial Estate, Rawat, Pakistan**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) (Contract manufacturing agreement between both firms dated 25-08-2020 is provided)
	GMP status of the firm	**Seraph Pharmaceuticals:** Firm has submitted copy of GMP certificate dated 11-11-2022 issued on the basis of inspection dated 11-10-2022.
	Evidence of approval of manufacturing facility	Firm (M/s Seraph Pharmaceuticals) has submitted copy of Issuance of DML letter dated 12-06-2017 specifying Dry Vial Cephalosporin section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 4540 dated 17-02-2022
	Details of fee submitted	PKR 75,000/- Dated 13-01-2022
	The proposed proprietary name / brand name	**CEFCAR 1gm IM/IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cefoperazone as Sodium…500mg Sulbactam as Sodium…500mg
	Pharmaceutical form of applied drug	Sterile white to almost white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	JP specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Sulperazone Intravenous Injection 1g (PMDA Japan Approved)
	For generic drugs (me-too status)	Cefbac injection by Seraph Pharmaceuticals
	Name and address of API manufacturer.	Qilu Antibiotics Pharmaceutical Co Ltd. No. 849, Dongia Town Licheng District Jinan City, Shandong Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against Cebac Injection of Bosch Pharm.
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method for the drug substance and product.
STABILITY STUDY DATA		

Manufacturer of API	Qilu Antibiotics Pharmaceutical Co Ltd. No. 849, Dongia Town Licheng District Jinan City, Shandong Province China.		
API Lot No.	1091EJ81NE		
Description of Pack (Container closure system)	Glass Vials		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1000 vials	1000 vials	1000 vials
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	03-03-2022	03-03-2022	03-03-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to following product specific inspection reports • Dexpro (Dexlansoprazole) 30 and 60mg Capsule. PSI was conducted on 11-09-2018 and the product was approved in 285th meeting of Registration Board. • Neovel 800mg Tablet. Its PSI was conducted on 14-12-2018 and the product was approved in 288th meeting of Registration Board. • Serbica 20mg Capsule. Its PSI was conducted on 29-10-2018 and the product was approved in 290th meeting of Registration Board. Firm has further submitted that their product Neogene 2g Injection was approved in 293rd meeting of Registration Board. That product was applied by AGP and contract manufactured by Seraph and was submitted on Form 5F (CTD) along with complete data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted Copy of GMP certificate (No. SD20190876) issued by CFDA China is submitted by the firm. The certificate is valid till 21-04-2024. Firm has also submitted copy of DML of the firm (No. Lu 20160006) issued by CFDA China. The license is valid till 03-11-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of letter of loan and memorandum of understanding with M/s Swiss Pharma for getting 10Kg loan of Cefoperazone sodium and sulbactam sodium. • Firm has submitted copy of invoice specifying import of 40Kg Cefoperazone sodium and sulbactam sodium by M/s Swiss Pharma. The

		invoice is cleared by AD (I&E) DRAP dated 11-08-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that since the stability study of this product was initiated 2 years ago, at that time our HPLC (Schimadzu) was not 21 CFR compliant. However now we have 21 CFR compliant (Perkin Elmer) HPLC system. We undertake that in future we will use 21 CFR compliant HPLC system for stability testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

The same formulation of cefoperazone sulbactam manufactured by M/s Seraph Pharmaceuticals have been approved by Registration Board in its 326th meeting. The details of the product approval in 326th meeting is as under:

Applicant firm	AGP Limited, B-23-C, S.I.T.E., Karachi, Pakistan
Manufacturer firm	Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
Brand Name	CEBACTUM 1gm Injection
Batch No. of drug product	T001 (1000 Vials), T002 (1000 Vials), T003 (1000 Vials)
Case No.	30
Page number	91-94
Registration Board meeting	326th meeting of Registration Board.

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

322.	Name, address of Applicant / Marketing Authorization Holder	**M/s Carer Pharmaceutical Industries. Plot No. 27 Main Road, Rawat Industrial Estate, Rawat, Pakistan**
	Name, address of Manufacturing site.	M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) (Contract manufacturing agreement between both firms dated 25-08-2020 is provided)
	GMP status of the firm	**Seraph Pharmaceuticals:** Firm has submitted copy of GMP certificate dated 11-11-2022 issued on the basis of inspection dated 11-10-2022.
	Evidence of approval of manufacturing facility	Firm (M/s Seraph Pharmaceuticals) has submitted copy of Issuance of DML letter dated 12-06-2017 specifying Dry Vial Cephalosporin section.

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 4541 dated 17-02-2022
	Details of fee submitted	PKR 75,000/- Dated 13-01-2022
	The proposed proprietary name / brand name	**CEFCAR 2gm IM/IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cefoperazone as Sodium…1g Sulbactam as Sodium…1g
	Pharmaceutical form of applied drug	Sterile white to almost white powder filled in transparent glass vials
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Reference to Finished product specifications	JP specs
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Approved in 03 European countries, i.e., **Bulgaria:** Sulcef 1g/1g powder for solution for injection **Lithuania:** Sulcef 1g/1g powder for solution for injection **Slovakia:** Sulcef 2g powder for solution for injection
	For generic drugs (me-too status)	Cefbac injection by Seraph Pharmaceuticals
	Name and address of API manufacturer.	Qilu Antibiotics Pharmaceutical Co Ltd. No. 849, Dongia Town Licheng District Jinan City, Shandong Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and

		stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for their product against Cebac Injection of Bosch Pharm.
	Analytical method validation/verification of product	Firm has submitted report of verification studies of analytical method for the drug substance and product.

STABILITY STUDY DATA

Manufacturer of API	Qilu Antibiotics Pharmaceutical Co Ltd. No. 849, Dongia Town Licheng District Jinan City, Shandong Province China.		
API Lot No.	1091EJ81NE		
Description of Pack (Container closure system)	Glass Vials		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1000 vials	1000 vials	1000 vials
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	03-03-2022	03-03-2022	03-03-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to following product specific inspection reports • Dexpro (Dexlansoprazole) 30 and 60mg Capsule. PSI was conducted on 11-09-2018 and

		the product was approved in 285th meeting of Registration Board. • Neovel 800mg Tablet. Its PSI was conducted on 14-12-2018 and the product was approved in 288th meeting of Registration Board. • Serbica 20mg Capsule. Its PSI was conducted on 29-10-2018 and the product was approved in 290th meeting of Registration Board. Firm has further submitted that their product Neogene 2g Injection was approved in 293rd meeting of Registration Board. That product was applied by AGP and contract manufactured by Seraph and was submitted on Form 5F (CTD) along with complete data.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted Copy of GMP certificate (No. SD20190876) issued by CFDA China is submitted by the firm. The certificate is valid till 21-04-2024. Firm has also submitted copy of DML of the firm (No. Lu 20160006) issued by CFDA China. The license is valid till 03-11-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of letter of loan and memorandum of understanding with M/s Swiss Pharma for getting 10Kg loan of Cefoperazone sodium and sulbactam sodium. • Firm has submitted copy of invoice specifying import of 40Kg Cefoperazone sodium and sulbactam sodium by M/s Swiss Pharma. The invoice is cleared by AD (I&E) DRAP dated 11-08-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that since the stability study of this product was initiated 2 years ago, at that time our HPLC (Schimadzu) was not 21 CFR compliant. However now we have 21 CFR compliant (Perkin Elmer) HPLC system. We undertake that in future we will use 21 CFR compliant HPLC system for stability testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

The same formulation of cefoperazone sulbactam manufactured by M/s Seraph Pharmaceuticals have been approved by Registration Board in its 326th meeting. The details of the product approval in 326th meeting is as under:

Applicant firm	AGP Limited, B-23-C, S.I.T.E., Karachi, Pakistan
Manufacturer firm	Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta Road Islamabad.

Brand Name	CEBACTUM 2gm Injection
Batch No. of drug product	T001 (1000 Vials), T002 (1000 Vials), T003 (1000 Vials)
Case No.	31
Page number	94-98
Registration Board meeting	326th meeting of Registration Board.

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

323.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura.**
	Name, address of Manufacturing site.	M/s Bio-Mark Pharmaceuticals Plot No. 527, Sundar Industrial Estate, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 18-03-2021.
	GMP status of the firm	Firm has submitted copy of GMP certificate of M/s Bio-Mark based upon Evaluation conducted on 13-02-2020
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for issuance of DML dated 12-06-2017 specifying Oral syrup (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5384: 25-02-2022
	Details of fee submitted	PKR 75,000/-: 20-01-2022
	The proposed proprietary name / brand name	**VERISET 4mg/5ml Syrup**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Ondansetron (as HCl)……4mg
	Pharmaceutical form of applied drug	Clear to straw coloured syrup filled in amber coloured PET bottle
	Pharmacotherapeutic Group of (API)	Antiemetic
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zofran Oral Solution **(USFDA** Approved)
	For generic drugs (me-too status)	Zofran Syrup by GSK

	Name and address of API manufacturer.	Anugraha Chemicals, No. D-47 to D-50, C-62 & C-63, KSS DC Industrial Estate, Doddaballapur, Banglore, Karnata India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator i.e. Zofran Syrup of GSK
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.
STABILITY STUDY DATA		
Manufacturer of API	Anugraha Chemicals, No. D-47 to D-50, C-62 & C-63, KSS DC Industrial Estate, Doddaballapur, Banglore, Karnata India.	

API Lot No.	AOND-18006		
Description of Pack (Container closure system)	PET Bottle		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	19A202	19E216	19M244
Batch Size	10,000 bottles	10,000 bottles	10,000 bottles
Manufacturing Date	01-2019	01-2019	01-2019
Date of Initiation	02-01-2019	03-01-2019	04-01-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	No inspection for verification of stability study data has been conducted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. DCD/SPL.CL-1/CR-1510/2020-21) issued by Drugs Control Department Government of Karnataka India dated 06-02-2021. The GMP certificate is valid for one year from the date of issue.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice specifying import of 5Kg Ondansetron hydrochloride dated 18-10-2018. The invoice is cleared by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted that their HPLC system is not 21 CFR compliant.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC(III)::

The same formulation of cefoperazone sulbactam manufactured by M/s Bio-Mark Pharmaceuticals Plot No. 527, Sundar Industrial Estate, Lahore.have been approved by Registration Board in its 317th meeting. The details of the product approval in 317th meeting is as under:

Applicant firm	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 35-A, Small Industrial Estate, Taxila.
Manufacturer firm	Bio-Mark Pharmaceuticals Plot No. 527, Sundar Industrial Estate, Lahore.
Brand Name	ONDATRO Syrup 4mg/5ml

	Batch No. of drug product	19A202 (10,000 bottles), 19E216 (10,000 bottles), 19M244 (10,000 bottles)
	Case No.	7
	Page number	315-318
	Registration Board meeting	317th meeting of Registration Board.

Decision: Approved.

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

b. Deferred cases of local manufacturing

324.	Name, address of Applicant / Marketing Authorization Holder	**M/s Sami Pharmaceuticals, F-95, SITE, Karachi.**
	Name, address of Manufacturing site.	M/s Sami Pharmaceuticals, F-95, SITE, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 8323 dated 15-03-2021
	Details of fee submitted	PKR 50,000/-: dated 08.01.2021
	The proposed proprietary name / brand name	**D-Tres oral 400 IU Drops**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each drop contains: Cholecalciferol (Vitamin D3) Ph. Eur….400 IU (10µg) Innovator Specs
	Pharmaceutical form of applied drug	Oral drops
	Pharmacotherapeutic Group of (API)	Vitamin D ATC code: A11CC05
	Reference to Finished product specifications	Innovator Specs
	Proposed Pack size	10ml, 15 ml, 20 ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SAPVIT D3 Oral Drops Solution
	For generic drugs (me-too status)	NA
	GMP status of the Finished product manufacturer	GMP Certificate issued date 11-08-2020
	Name and address of API manufacturer.	FERMENTA BIOTECH LIMITED Plot No. Z-109 B & C, SEEZ II, Dahej Taluka – Vagra, Distt. Bharuch 392 130 Gujarat, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.

		Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Cholecalciferol is present in Ph. Eur. The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances and specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 5 ± 3°C for 36 months Accelerated: 25°C ± 2°C / 60% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence not performed due to the unavailability of the innovator sample, CDP is not applicable
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	FERMENTA BIOTECH LIMITED, Plot NO. Z-109B & C, SEZ-II, DEHAJ, TAL_VAGRA, Dist. Bharuch, India		
API Lot No.	CLC0419047		
Description of Pack (Container closure system)	Glass bottle USP Type-III with dropper applicator		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1,2,3,4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Lab-01	Lab-02	Lab-03
Batch Size	2000 ml	2000 ml	2000 ml
Manufacturing Date	Jan 2020	Jan 2020	Jan 2020
Date of Initiation	24-01-2020	24-01-2020	24-01-2020

No. of Batches		03
Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted the relevant document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 2062043 issued by Food and drug control administration valid till 17/06/2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice specifying import of 10 kg of Cholecalciferol (Batch # CLC0419047). (invoice # RV1002000056) attested by AD (I&E), Karachi dated 09/05/2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

	Shortcomings	Reply of the firm
2.3.S.4.3	The drug product manufacturer has performed impurity and residual solvent testing in the drug substance. The firm did not perform the method validation/verification for the same	We performed assay method validation of the drug substance as per CTD requirement. Validation of Impurity and residual solvent testing is performed by drug substance manufacturer.
3.2.P.1	Justification/scientific rationale is required for addition of 20% overage along with submission of stability assay report of the latest time point	Some active pharmaceutical ingredients including several vitamins in certain dosage forms or packaging condition may be susceptible to degrade or deteriorate and may not remain their native form over the shelf life of product. Degradation or deterioration of vitamins is one of the major factors that lead manufacturer to require excess amount of vitamins in their products, to ensure the amount of the drug substance meets the requirement of 100% of the label claim amount throughout the shelf life of the product. (**Referred ANNEXURE –I** Pharmacopeial Forum Vol.42.42 (3) [May-June 2016], Stimuli to the Revision Process, Factors to Consider in Setting Adequate Overages of Vitamins and Minerals in Dietary Supplements). Outside the U.S., many jurisdictions recognize the minimum value as 80-90% of label claim. For example, the Danish and Korean authorities allow a shelf-life minimum of 80% of label claim for added vitamins and minerals, and the United Kingdom allows -50% for water soluble vitamins

<table>
<tr><td></td><td></td><td>and minerals, and -30% for oil soluble vitamins. U.S.-designed products with inputs typically 10-50% higher than the label claim to meet 100% minimum requirement at end of shelf life can exceed upper specifications limits for non-U.S. countries with maximum overage limits. (Referred ANNEXURE –II Council for Responsible Nutrition-Docket No.FDA-2012-N-1210; Food labelling: Revision of the Nutrition and Supplement Facts Labels, Page No.27).
For development of our product i.e. D-Tres 400 IU/Drop, 20% overage of cholecalciferol (vitamin D_3) was taken to compensate initial process loss followed by the expected loss in assay during stability studies. The initial test results and stability trending of our product shows about 3% initial process loss and 3 to 4% loss in assay under accelerated condition as well as in long term condition.
Moreover, 20% overage was not fixed, as mentioned above, it is a global practice to take overages for vitamins during development studies. However, after evaluation of the stability data and stability study report of the latest time period i.e. 18 months it is observed that our product is stable and no further loss in assay observed after 18 month. (Referred ANNEXURE –III Stability trending of our product i.e. D-Tres 400 IU/Drop).
Therefore, based on the above data and stability trend analysis of our product, we recommend to reduce the overage of cholecalciferol (vitamin D_3) from 20% to 5%. However, this 5% overage will not effect safety and efficacy of product, because this 5% overage is well within the tolerable upper intake levels recommend for Vitamin D (Referred ANNEXURE –IV National Institutes of Health).</td></tr>
<tr><td>3.2.P.2.1</td><td>The theoretical dispensed weight of cholecalciferol is 12,000 IU per ml (without overages), while it is 14,400 IU per ml in the reference product. Justification is required</td><td>We have developed our product D-Tres 400 IU/Drop against the reference listed drug (RLD) i.e. Sapvit-D3 14,400 IU/ml Oral Drops, Solution (400 IU/ Drop marketed by M/s. Fresenius Kabi Limited UK.
The literate data of RLD shows that one ml of RLD is equivalent to 36 drops. 1 drop of RLD is equivalent to 400 IU (10 µg) cholecalciferol (vitamin D_3). As 0.025 µg Cholecalciferol is equivalent to 1 IU Cholecalciferol so, 360 µg is equivalent to 14,400 IU cholecalciferol (vitamin D_3) for 36 drops which is equivalent to one ml
Furthermore, please note that One ml of our product contains 30 drops. However, the label claim of Cholecalciferol per drop is same as of the RLD i.e. One drop of our product is equivalent to 400 IU (10 µg) cholecalciferol (vitamin D_3). As 0.025 µg Cholecalciferol is equivalent to 1 IU Cholecalciferol so, 300 µg is equivalent to 12,000 IU cholecalciferol (vitamin D_3) for 30 drops which is equivalent to one ml. (Referred ANNEXURE –V Package leaflet: Information for the user, Sapvit-D3 14,400 IU/ml Oral Drops, Solution (400 IU/ Drop), page no.5)
The comparative analysis of D-Tres 400 IU/Drop against Sapvit-D3 14,400 IU/ml Oral Drops, Solution (400 IU/ Drop) is mention below
<table>
<tr><th>SAMI's Product
D-Tres 400IU/Drop</th><th>RLD
Sapvit-D3 14,400 IU/ml Oral Drops, Solution (400 IU/ Drop)</th></tr>
<tr><td>1ml contains 30 drops</td><td>1ml contains 36 drops</td></tr>
<tr><td>1drop contains 400 IU (10 µg) cholecalciferol (vitamin D_3)</td><td>1drop contains 400 IU (10 µg) cholecalciferol (vitamin D_3)</td></tr>
<tr><td>30 drops =12,000 IU (300 µg)</td><td>36 drops =14,400 IU (360 µg)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td></td><td></td><td>Based on the above details we can conclude that our product contain the same labelled amount of cholecalciferol as of the reference listed drug (RLD) i.e. 400 IU (10 µg) cholecalciferol (vitamin D_3) per drop</td></tr>
<tr><td>3.2.P.2.2.1</td><td>You have not performed pharmaceutical equivalence. Justification is required</td><td>The reference product is not available in Pakistan. We have tried to arrange it from the country of origin but unfortunately not succeeded.
Please note that the dosage form is oral solution for which BE studies also exempted (See reference guideline of FDA “Guidance for Industry, Bioavailability and Bioequivalence Studies Submitted in NDAs or INDs”,
Solutions and Other Solubilized Dosage Forms
“For oral solutions, elixirs, syrups, tinctures, or other solubilized forms, in vivo BA and/or BE are generally self-evident and a requirement of in vivo data for a product may be waived (21 CFR 320.22(b)(3)). In such instances, the applicant would be deemed to have complied with and fulfilled any requirement for in vivo data. Although a comparative study is not necessary, characterization of the pharmacokinetics of the drug is required (21 CFR 314.50(d)(3)). In addition, in vivo BE studies that compare different solution formulations are waived based on the assumptions that release of drug substance from the drug product is self-evident and that the solutions do not contain any excipients that significantly affect drug absorption. However, there are certain excipients that may alter the BA (e.g., sorbitol may reduce the BA of drugs, and vitamin E may enhance the BA) in amounts sometimes used in oral liquid dosage forms. In this case, evaluation of in vivo BA and/or BE may be required”.
Please also note that our formulation is similar to the innovator in the following,
1. API: Same as that of Reference listed drug.
2. Dosage form: Same as that of Reference listed drug.
3. Indication: Same as that of Reference listed drug.
4. Excipients: Same as that of Reference listed drug .
5. Label claim: Same as that of Reference listed drug.
However, for assay and other chemical / microbiological attributes, we have tested the product according to the general monograph of pharmacopeia and complied.</td></tr>
<tr><td>3.2.P.4.1</td><td>The coconut oil is available in pharmacopeia. The drug product manufacturer has claimed in-house specifications; and did not perform the chromium test. Justification is required</td><td>Yes, it is available in BP and testing was done according to the BP specifications. As per our procedure for excipients, we do not mention the material reference on the specifications.
The missing Chromium test performed and incorporated in our specifications.</td></tr>
<tr><td>3.2.P.5.1</td><td>Pharmacopeial monograph for the Cholecalciferol solution has the different vehicle / solvent from the innovator and our formulation is based</td><td>Pharmacopeial monograph for the Cholecalciferol solution has the different vehicle / solvent from the innovator and our formulation is based on reference listed drug (RLD), which using only API and medium chain triglyceride (coconut oil). Therefore we cannot claim it Pharmacopeial and claim it as Innovator specifications.
Please see below the difference of the formulations
<table>
<tr><th>Pharmacopeia</th><th>Innovator</th><th>SAMI</th></tr>
</table>
</td></tr>
</table>

	on reference listed drug (RLD), which using only API and medium chain triglyceride (coconut oil). Therefore we cannot claim it Pharmacopeial and claim it as Innovator specifications.	edible vegetable oil	Medium chai triglyceride (Fractionated coconut oil)	Medium chai triglyceride (Fractionated coconut oil)
		Polysorbate 80 or	-	-
		Propylene Glycol	-	-
3.2.P.5.1	Filled volume/weight variation test has not been performed	We have already performed filled volume test but not submitted to you as this is the part of our in-process testing. Please find attached the in-process report for your ready reference		
3.2.P.5.2	The applied drug product is available in pharmacopeia. The drug product manufacturer has validated their own testing method for the assay. Justification is required	As already mentioned in 3.2.P.5.1, the product available in pharmacopeia has different vehicle / solvent from the innovator. Our formulation is based on innovator. Therefore, we use the in-house developed, validated method.		
3.2.P.5.6	The drug product manufacturer has performed additional tests (other than those mentioned in the pharmacopeia). The specifications for such tests shall be justified	Pharmacopoeia tests are the minimum requirement. As per general pharmacopoeial monograph, additional tests can be performed according to the nature of substance and considering the formulation.		
3.2.P.8.3	You shall clarify whether the stability was conducted placing the bottles upright or inverted	The product is placed in inverted position.		

Decision of 316th meeting of Registration Board:

Deferred for following:

- Pharmaceutical equivalence studies of the applied product along with innovator / reference product.
- Evidence of approval of applied formulation as a pharmaceutical drug product in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.
- Scientific justification that the applied formulation is equivalent to the innovator's product in terms of cholecalciferol contents per ml as well as per drop.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Pharmaceutical equivalence studies of the applied product along with innovator / reference product.	We have developed our product D-Tres 400 IU/Drop against the reference listed drug (RLD) i.e. Sapvit-D3 Oral Drops solution (400 IU/ Drop) marketed by M/s. Fresenius Kabi Limited UK. However, due to unavailability of the reference product, pharmaceutical Equivalence has been performed against Baby Ddrops 400IU per drop - which is similar to our formulation

		Reference Document attached https://health-products.canada.ca/lnhpd-bdpsnh/index-eng.jsp
2.	Evidence of approval of applied formulation as a pharmaceutical drug product in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	**Sapvit-D3 400 IU/drop oral drops, solution** **Qualitative and Quantitative Composition** One ml (= 36 drops) contains: 14,400 IU (360 microgram) cholecalciferol (vitamin D3) One drop = 400 IU (10 microgram) cholecalciferol (vitamin D3) **Health Products Regulatory Authority (HPRA) Ireland**
3.	Scientific justification that the applied formulation is equivalent to the innovator's product in terms of cholecalciferol contents per ml as well as per drop.	SmPC of the Innovator product clearly mentions that 1 drop is equivalent to 400IU The Leaflet & SmPC of the Innovator product SAPVIT D3 mentions the following dosage guidelines: **The Method of administration mentions that the best way to take** Sapvit-D3 oral drops is to add them drop by drop into the mouth or, if necessary, administer with a spoon and some liquid. **Prevention of vitamin D deficiency:** The usual daily dose is: For newborns, infants and children from the second week of life to the age of 3 years: between 1-2 drops For children aged 4 years and above and adolescents: between 1-3 drops For adults aged 19 to 70 years: between 1-4 drops For elderly people aged above 70 years: between 2-4 drops **Treatment of rickets** The total amount of required vitamin D depends on the severity of the disease. In existing rickets, treatment is started with a preparation with a higher concentration of vitamin D for the initial treatment. Subsequently, the usual dose is between 2 to 12 drops of Sapvit-D3 daily. **Treatment of vitamin D deficiency** The usual daily dose is: For children and adolescents: 5 drops daily for 6 weeks, then between 1-3 drops daily For adults aged 19 to 70 years and elderly people aged above 70 years: 15 drops daily for 8 weeks, then between 3-5 drops daily **Adjunct to osteoporosis treatment of patients who are at risk of vitamin D deficiency** The usual daily dose is: For adults aged 19 years and above: between 2-4 drops daily or between 14-26 drops weekly. **Based on the dosage guidelines for multiple conditions as mentioned above, SAPVIT D3 is available in 12.5 ml (corresponding to 450 drops) or 25 ml (corresponding to 900 drops), whereas our product D-Tres Oral Drops applied pack size is 10ml.**

		The literate data of RLD shows that one ml of RLD is equivalent to 36 drops. 1 drop of RLD is equivalent to 400 IU (10 µg) cholecalciferol (vitamin D_3). As 0.025 µg Cholecalciferol is equivalent to 1 IU Cholecalciferol so, 360 µg is equivalent to 14,400 IU cholecalciferol (vitamin D_3) for 36 drops which is equivalent to one ml. Furthermore, please note that One ml of our product contains 30 drops. However, the label claim of Cholecalciferol per drop is same as of the RLD i.e. One drop of our product is equivalent to 400 IU (10 µg) cholecalciferol (vitamin D_3). As 0.025 µg Cholecalciferol is equivalent to 1 IU Cholecalciferol so, 300 µg is equivalent to 12,000 IU cholecalciferol (vitamin D_3) for 30 drops which is equivalent to one ml. Finally, the firm summarized that their per drop content is same as that of the reference product.

Decision of 320th meeting of Registration Board:

Deferred for following points:

- Clarification since the concentration of Cholecaliferole per mL of the innovator's product is 360ug (Eq. to 14,440IU) while the applied product contains 30ug (12,000IU) per mL.
- Confirmation of RDA value for Cholecalciferole.

Response by the firm:

The firm vide its letter dated 24-05-2023 has submitted that they have again developed their product as per the reference product and conducted its stability studies. The new formulation comparison with the reference product is given below:

Formulation of our product D-Tres 400 IU/Drop has been developed as per Innovator's product viz. Sapvit-D3 14,400 IU/ml Oral Drops, Solution (400 IU/ Drop); details are appended below:

Parameters	SAPVIT-D3 Solution (400 IU/ Drop)/14,400 IU/ml Oral Drops	D-Tres 400 IU/Drop
Contents per Drops Cholecalciferol (Vitamin D3)	1 drop contains 400IU (10 µg)	1 drop contains 400IU (10 µg)
Number of drops per ml	36 drops	36 drops
Contents per ml (Cholecalciferol)	14,400 IU (360 µg)	14,400 IU (360 µg)
Filled Volume (pack size)	12.5ml and 25ml	10.0ml

The new product development and stability data submitted by the firm is as under:

STABILITY STUDY DATA	
Manufacturer of API	Fermenta Biotech Limited, Plot No. Z-109B & C, SEZ-II, Dehaj, Taluka Vagara District Bharuch Gujrat India.
API Lot No.	CLC0422100
Description of Pack (Container closure system)	Glass bottle USP Type-III with dropper applicator
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,3,6 (Months) Real Time: 0,1,3,6 (Months)		
Batch No.	Lab-07	Lab-08	Lab-09
Batch Size	200 Bottles	200 Bottles	200 Bottles
Manufacturing Date	09-2022	09-2022	09-2022
Date of Initiation	04-10-2022	30-09-2022	30-09-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 2062043 issued by Food and drug control administration valid till 17/06/2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate dated 08-09-2022 specifying import of 5Kg cholecalciferol.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted relevant analytical record for the product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports for the product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger

Remarks oF Evaluator:

-

Decision: Registration Board after thorough deliberated decided to approve the product with following label claim:

Each drop contains:
Cholecalciferol (Vitamin D3)….400 IU (10µg)
Each ml contains:
Cholecalciferol (Vitamin D3)….14,400 IU (360 µg)

- **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**
- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

325.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Akhsah Pharmaceuticals (Pvt) Ltd. Plot No 47, Street No. S-10, RCCI Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Akhsah Pharmaceuticals (Pvt) Ltd. Plot No 47, Street No. S-10, RCCI Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000943) dated 14-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000943) dated 14-09-2021. The letter specifies following section: 1. Tablet Section (General) 2. Capsule Section (General) 3. Cream/Ointmnt section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10886: 29-04-2022
	Details of fee submitted	PKR 30,000/- : 28-04-2022
	The proposed proprietary name / brand name	**DENSA 30mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Dexlansoprazole (as dual delayed release pellets)…..30mg
	Pharmaceutical form of applied drug	White to off white spherical pellets filled in hard gelatin capsule
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	USP
	Proposed Pack size	30’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA Approved**
	For generic drugs (me-too status)	Razodex Capsule by Getz
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23 Industrial Traingle Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator product Delanzo capsule of Sami Pharmaceuticals. Firm has submitted results of CDP for their product against the comparator product Delanzo capsule of Sami Pharmaceuticals.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA	
Manufacturer of API	Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23 Industrial Traingle Kahuta Road, Islamabad.
API Lot No.	DSL825
Description of Pack (Container closure system)	Alu-alu blister
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	CP-01/D30	CP-02/D30	CP-03/D30
Batch Size	5000 Capsule	5000 Capsule	5000 Capsule
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	21-01-2022	21-01-2022	21-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued on 31-07-2019 based on the inspection dated 11-02-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 29-11-2021 specifying purchase of 7Kg 22.5% dexlansoprazole DDR pellets.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance of 21 CFR.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Submission of data in section 3.2.S.4.1 as per DRAP guideline which specifies that copies of drug substance specification and analytical procedure used for routine testing of drug substance by both drug substance and drug product manufacturer is provided.
2.	Provide verification studies of drug substance from drug product manufacturer.	As we have used ready to fill pellets and has same specification of raw material and filled capsule and we have performed verification in product stage so please consider it as verification.
3.	Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product.	Firm has submitted COA of batch number DSL825 from both API manufacturer as well as drug product manufacturer
4.	Justify why pharmaceutical equivalence studies does not include dissolution test.	In pharmaceutical equivalence study we have performed dissolution but mistakenly not include in the report, now the firm has submitted the report.
5.	Provide detailed results of Comparative Dissolution Profile (CDP) since you have only provided average results at	We performed detail result of comparative dissolution profile according to FDA next time and revised our method as per DRAP guideline. As we mention only

	each time point instead of providing result of individual tablet release.	the similarity factor of reference product and sample product in our CDP. **Firm has not submitted complete results of CDP studies.**
6.	The innovator product is available as dual delayed release pellets in HPMC capsule shells while your product is in hard gelatin capsule shells. Justification is required in this regard.	The innovator product is available as delay released pellets in HPMC capsule shell while our product is in hard gelatin capsule shell we have performed stability studies there is no effect of capsule shell in stability study
7.	The drug substance manufacturer specifies that dissolution testing in buffer stage is to be carried out at 284nm, while you have specified dissolution testing in buffer at 292nm. Justification is required in this regard.	According to drug substance manufacturer the wavelength of dissolution of dexlansoprazole in buffer stage at about 284nm we revised our SAP as per drug substance manufacturer and set wavelength about 292nm in our revised SAP but next time we change our revised SAP about 284nm. **Firm has not submitted revised analytical method or relevant analytical record.**
8.	You have used a different HPLC column for assay testing of the drug product from that recommended by drug substance manufacturer. Justification is required in this regard.	We performed the assay of Densa 30mg Capsule by HPLC according to **USP monograph**, and our column was expired so that is why we change the old with new one having same specifications i.e dimension, length and pore size. **USP monograph for the applied product does not exist, moreover no analytical record is submitted which shows that the HPLc column have been changed. Moreover the verification studies are performed at old column.**
9.	Provide stability data sheets for accelerated and real time stability studies results for the three batches, since your results sheets are not properly arranged.	Firm has submitted stability data sheets for accelerated and real time stability studies results for the three batches
10.	Justify the assay testing of drug product using UV method, since the innovator product as well as drug substance manufacturer specifies HPLC method for assay testing.	We performed the assay on UV method according to drug substance manufacturer UV method. Drug substance manufacturer specifies HPLC method as well as UV method for assay which is already provided.
11.	Submit evidence of procurement of drug substance incuding copy of commercial invoice.	Firm has submitted copy of commercial invoice dated 29-11-2021 specifying purchase of 7Kg 22.5% dexlansoprazole DDR pellets.

Decision of 321st meeting of Registration Board:

Deferred for following:

- Submission of stability study data of the drug product at next time on revised specifications and analytical method in which assay test is performed using HPLC method since applied poduct is non pharmacopoeial and drug substance manufacturer has applied HPLC method for the Assay test of Dexlansoprazole pellets.
- Submission of 7500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

Response by the firm:

- Firm has submitted Fee PKE 7,500/- dated 05-04-2023 for change in specifications.
- Firm has submitted revised specifications in which the assay method has been shifted to HPLC method. Firm has also submitted results of assay test at 9th month time point of stability studies in which product testing has been conducted at 28-10-2022. Firm has also submitted HPLC chromatograms, raw data sheets and record of digital data logger.

Decision: Approved with Innovator's specifications.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
326.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Akhsah Pharmaceuticals (Pvt) Ltd. Plot No 47, Street No. S-10, RCCI Industrial Estate, Rawat.**
	Name, address of Manufacturing site.	M/s Akhsah Pharmaceuticals (Pvt) Ltd. Plot No 47, Street No. S-10, RCCI Industrial Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000943) dated 14-09-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000943) dated 14-09-2021. The letter specifies following section: 1. Tablet Section (General) 2. Capsule Section (General) 3. Cream/Ointmnt section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10887: 29-04-2022
	Details of fee submitted	PKR 30,000/- : 28-04-2022
	The proposed proprietary name / brand name	**DENSA 60mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Dexlansoprazole (as dual delayed release pellets)…..60mg
	Pharmaceutical form of applied drug	White to off white spherical pellets filled in hard gelatin capsule
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	USP
	Proposed Pack size	30’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**USFDA Approved**
	For generic drugs (me-too status)	Razodex Capsule by Getz
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23 Industrial Traingle Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related

		to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 36 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator product Delanzo capsule of Sami Pharmaceuticals. Firm has submitted results of CDP for their product against the comparator product Delanzo capsule of Sami Pharmaceuticals.
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA	
Manufacturer of API	Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23 Industrial Traingle Kahuta Road, Islamabad.
API Lot No.	DSL825
Description of Pack (Container closure system)	Alu-alu blister
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CP-01/D60	CP-02/D60	CP-03/D60
Batch Size	5000 Capsule	5000 Capsule	5000 Capsule
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	21-01-2022	21-01-2022	21-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued on 31-07-2019 based on the inspection dated 11-02-2019.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice dated 29-11-2021 specifying purchase of 7Kg 22.5% dexlansoprazole DDR pellets.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches along with water loss test at each time point. Firm has submitted analytical report at each stability testing interval.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of compliance of 21 CFR.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit data in section 3.2.S.4.1 as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."	Submission of data in section 3.2.S.4.1 as per DRAP guideline which specifies that copies of drug substance specification and analytical procedure used for routine testing of drug substance by both drug substance and drug product manufacturer is provided.
2.	Provide verification studies of drug substance from drug product manufacturer.	As we have used ready to fill pellets and has same specification of raw material and filled capsule and we have performed verification in product stage so please consider it as verification.
3.	Provide COA of relevant batch of drug substance from both API manufacturer as well as drug product manufacturer which is used in the manufacturing of batches of drug product.	Firm has submitted COA of batch number DSL825 from both API manufacturer as well as drug product manufacturer

4.	Justify why pharmaceutical equivalence studies does not include dissolution test.	In pharmaceutical equivalence study we have performed dissolution but mistakenly not include in the report, now the firm has submitted the report.
5.	Provide detailed results of Comparative Dissolution Profile (CDP) since you have only provided average results at each time point instead of providing result of individual tablet release.	We performed detail result of comparative dissolution profile according to FDA next time and revised our method as per DRAP guideline. As we mention only the similarity factor of reference product and sample product in our CDP. **Firm has not submitted complete results of CDP studies.**
6.	The innovator product is available as dual delayed release pellets in HPMC capsule shells while your product is in hard gelatin capsule shells. Justification is required in this regard.	The innovator product is available as delay released pellets in HPMC capsule shell while our product is in hard gelatin capsule shell we have performed stability studies there is no effect of capsule shell in stability study
7.	The drug substance manufacturer specifies that dissolution testing in buffer stage is to be carried out at 284nm, while you have specified dissolution testing in buffer at 292nm. Justification is required in this regard.	According to drug substance manufacturer the wavelength of dissolution of dexlansoprazole in buffer stage at about 284nm we revised our SAP as per drug substance manufacturer and set wavelength about 292nm in our revised SAP but next time we change our revised SAP about 284nm. **Firm has not submitted revised analytical method or relevant analytical record.**
8.	You have used a different HPLC column for assay testing of the drug product from that recommended by drug substance manufacturer. Justification is required in this regard.	We performed the assay of Densa 30mg Capsule by HPLC according to **USP monograph**, and our column was expired so that is why we change the old with new one having same specifications i.e dimension, length and pore size. **USP monograph for the applied product does not exist, moreover no analytical record is submitted which shows that the HPLc column have been changed. Moreover the verification studies are performed at old column.**
9.	Provide stability data sheets for accelerated and real time stability studies results for the three batches, since your results sheets are not properly arranged.	Firm has submitted stability data sheets for accelerated and real time stability studies results for the three batches
10.	Justify the assay testing of drug product using UV method, since the innovator product as well as drug substance manufacturer specifies HPLC method for assay testing.	We performed the assay on UV method according to drug substance manufacturer UV method. Drug substance manufacturer specifies HPLC method as well as UV method for assay which is already provided.
11.	Submit evidence of procurement of drug substance incuding copy of commercial invoice.	Firm has submitted copy of commercial invoice dated 29-11-2021 specifying purchase of 7Kg 22.5% dexlansoprazole DDR pellets.

Decision of 321st meeting of Registration Board:

Deferred for following:

- Submission of stability study data of the drug product at next time on revised specifications and analytical method in which assay test is performed using HPLC method since applied poduct is non pharmacopoeial and drug substance manufacturer has applied HPLC method for the Assay test of Dexlansoprazole pellets.
- Submission of 7500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

Response by the firm:

• Firm has submitted Fee PKE 7,500/- dated 05-04-2023 for change in specifications. • Firm has submitted revised specifications in which the assay method has been shifted to HPLC method. Firm has also submitted results of assay test at 9th month time point of stability studies in which product testing has been conducted at 28-10-2022. Firm has also submitted HPLC chromatograms, raw data sheets and record of digital data logger.
Decision: Approved with Innovator's specifications. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

327.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.**
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: 1. Liquid Injectable Infusion (SVP) LDPE (General) 2. Liquid Injectable Infusion (LVP) LDPE (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12294: 20-05-2022
	Details of fee submitted	PKR 30,000/- : 20-05-2022
	The proposed proprietary name / brand name	**SAFESOL-RL IV Infusion 500ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Calcium chloride ……0.027g Potassium chloride……0.04g Sodium chloride…… 0.60g Sodium lactate….. ..0.32g
	Pharmaceutical form of applied drug	Clear, odorless and colorless solution filled in PP bottle
	Pharmacotherapeutic Group of (API)	Electrolytes
	Reference to Finished product specifications	BP
	Proposed Pack size	500ml

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA Approved**
	For generic drugs (me-too status)	Could not be confirmed in applied strength
	Name and address of API manufacturer.	**Sodium Chloride:** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Calcium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Potassium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Sodium lactate** Luoyang Longmen Pharmaceutical Co. Ltd. County Industrial Zone Luoning Henan Province P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Sodium Chloride:** Not submitted. **Calcium chloride:** Not submitted. **Potassium chloride:** Firm has submitted stability data of 3 batches of API as per zone IV-A conditions. **Sodium lactate:** Not submitted.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator product 'Sterifluid-RL Infusion

		by M/s FDL Pharma."
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	**Sodium Chloride:** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Calcium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Potassium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Sodium lactate** Luoyang Longmen Pharmaceutical Co. Ltd. County Industrial Zone Luoning Henan Province P.R. China.		
API Lot No.	**Sodium Chloride:** 210909 **Calcium chloride:** 210806 **Potassium chloride:** 211204 **Sodium lactate:** B-2108-517		
Description of Pack (Container closure system)	Polypropylene		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	300 liters	300 liters	300 liters
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	25-01-2022	25-01-2022	25-01-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sodium Chloride:** Firm has submitted copy of GMP certificate (No. HE20180030) issued by China Food and Drug Administration. The certificate is valid till 22-04-2023. **Calcium chloride:** Firm has submitted copy of GMP certificate (No. HE20180030) issued by China Food and Drug Administration. The certificate is valid till 22-04-2023. **Potassium chloride:** Firm has submitted copy of GMP certificate (No. HE20180030) issued by China Food and Drug Administration. The certificate is valid till

		22-04-2023. **Sodium lactate:** Firm has submitted copy of GMP certificate (No. HA20190099) issued by China Food and Drug Administration. The certificate is valid till 29-11-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sodium Chloride:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 25Kg sodium chloride (Batch No. 210909). **Calcium chloride:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 5Kg calcium chloride. **Potassium chloride:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 5Kg potassium chloride. **Sodium lactate:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 10Kg Sodium lactate.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Revise your label claim as per the innovator's product along with submission of full fee since innovator product specifies clalcium chloride dihydrate 0.027g/100ml while you have mentioned calcium chloride 0.027g/100ml.	*Applied formulation contains calcium chloride dihydrate as per BP innovator product also contains calcium chloride dihydrate. In master formulation typographic error found. New master formulation has been submitted.* **Firm has not revised the label claim nor submitted any fee.**
2.	Evidence of me-too status of the applied product since the submitted me-too contains sodium lactate 0.31g while your applied formulation contains 0.32g sodium lactate.	*our main competitor is FRONTIER DEXTROSE LIMITED PHARMA HATTAR having formulation sodium lactate 0.32g/100 ml which is same as our formulation 0.32g/100 ml.* **The available data base shows that Sterifluid RL Infusion (Reg # 052739) of M/s Frontier Dextrose Ltd contains Sodium Lactate 0.31gm**
3.	Provide reference of finished product specifications in module 1 along with submission of fee for revision of specifications.	*Typographic error found. Our product is BP Specifications.* **Firm has not submitted any fee**

4.	Submit verification studies of the Calcium chloride drug substance in section 3.2.S.4.3	**Firm has not submitted verification studies for the drug substance.**
5.	Provide actual signed data sheets for three batches of the calcium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions, since you have submitted unsigned data sheets on which stamp of Ashrafsons Pharmaceuticals is placed instead of being signed and stamped by drug substance manufacturer. Furthermore, the submitted stabilility sheets does not specify any batch number, manufacturing or expiry date etc.	**Firm has not submitted stability study data sheets for API from API manufacturer.**
6.	Submit verification studies of the Potassium chloride drug substance in section 3.2.S.4.3	**Firm has not submitted verification studies for the drug substance.**
7.	Submit verification studies of the Sodium chloride drug substance in section 3.2.S.4.3	**Firm has not submitted verification studies for the drug substance.**
8.	Provide actual signed data sheets for three batches of the Sodium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions, since you have submitted unsigned data sheets on which stamp of Ashrafsons Pharmaceuticals is placed instead of being signed and stamped by drug substance manufacturer.	**Firm has not submitted stability study data sheets for API from API manufacturer.**
9.	Submit verification studies of the sodium lactate drug substance in section 3.2.S.4.3	**Firm has not submitted verification studies for the drug substance.**
10.	Provide actual signed data sheets for three batches of the Sodium lactate drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions, since you have submitted unsigned data sheets on which stamp of Ashrafsons Pharmaceuticals is placed instead of being signed and stamped by drug substance manufacturer.	**Firm has not submitted stability study data sheets for API from API manufacturer.**
11.	The innovator's product is using 0.027g/100ml of clalcium chloride dihydrate while your formulation contains 0.027g/100ml of calcium chloride. Justify how your formulation is similar to that of innovator's product.	*Our formulation is similar to that of innovators product that is 0.027g/100ml of clacium chloride dihydrate.* **The submitted formulation as well as BMR shows that firm is using 0.027g/100ml of calcium chloride.**
12.	Justify why pharmaceutical equivalence is conducted against a comparator product instead of performing against the innovator's product.	*Because they have the same active ingredients, the same dosage form and are identical in strength, quality, purity, and identity as the brand-name product.* **Firm has not submitted any relevant response.**
13.	Justify why complete tests as mentioned in BP monograph is not performed in pharmaceutical equivalence studies.	*Skip testing is the performance of specified tests at release on pre-selected batches and / or at predetermined intervals, rather than on a batch-to-batch basis with the understanding that those*

		batches not being tested still must meet all acceptance criteria established for that product. This represents a less than full schedule of testing and should therefore be justified and presented to and approved by the regulatory authority prior to implementation. **Firm has not submitted any relevant response.**
14.	Justify how you can perform pharmaceutical equivalence against a product which have different quantitative composition as compared to your product.	*We cannot perform pharmaceutical equivalence against a product which has different quantitative composition to our product.* **Firm has not submitted any relevant response.**
15.	Provide microbiological attributes of the drug product in section 3.2.P.2.5.	*Our product is compatible with drug container made of polypropylene of pharmaceutical grade and heat resistant and we can easily sterilize our product at 121°C for 30 minutes to make our product properly sterile.* **Firm has not submitted any relevant response.**
16.	Provide details how terminal sterilization method was validated for PP bottles.	***Terminal sterilization method was validated for PP bottles was validated from external agency.***
17.	Justify why the drug product specifications does not contain test of particulate matter.	*Product specification concentrate on quality of product till expiry with 100% efficiency .detail is given by literature support.* **Firm has not submitted any relevant response.**
18.	Justify why the acceptance criteria of all assay tests in pharmaceutical equivalence is not as per BP monograph.	*All the test acceptance criteria of all assay tests in pharmaceutical complies BP 2022.* **The acceptance criteria of all tests is not as per the BP monograph.**
19.	Justify why the test for sodium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.	*All the test acceptance criteria of all assay tests in pharmaceutical complies BP 2022.* **The tests is not as per the BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.**
20.	Justify why the test for potassium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.	*Potassium test is according to BP 2022.* **The tests is not as per the BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.**
21.	Justify why the test for lactate content in the drug product is different from that mentioned in BP monograph, since HPLC test is specified in BP monograph while you have specified titration method.	*The method of sodium lactate is HPLC method in BP 2022. We give the HPLC print is attached with the file.* **Firm has used titration method as submitted in the application.**
22.	Provide verification studies of the analytical method of drug product in section 3.2.P.5.3 instead of providing process validation report.	*We have submitted verification studies.* **Firm has submitted process validation report instead of analytical method verification.**
23.	Provide details of the container closure system of the applied product.	*Our sterile product is filled in polypropylene container properly sealed and sterilized. Polypropylene plastic is of pharmaceutical grade and provide strength to the container and .polypropylene is heat resistant and we can easily*

		sterilize our product at 121c. to make our product sterile
24.	Describe your container closure system in detail whether it contains Eurocap or not along with evidence of this facility (if applicable).	*Firm has both facility of manufacturing the simple cap & Eurocap.*
25.	Specify whether the bottles placed in stability chambers were with Europcap or not.	*At present we are using simple cap to reduce cost of our product but we have the facility of Eurocap machine facility.*
26.	Provide total capacity of each stability chamber and details of number of bottles of each product placed in the stability chambers. Also provide details how many bottles of the applied product are placed in real time and accelerated stability chamber.	*40 bottles in real stabilty chamber.* *60 bottles in accelerated stabilty chamber.*
27.	Justify why the stability studies have been performed using method and acceptance criteria which is completely different from that specified in BP monograph.	*All the test acceptance criteria of all assay tests in pharmaceutical complies BP 2022.* **The acceptance criteria of all tests is not as per the BP monograph.**
28.	Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.	*We have submitted the stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container.* **Firm has not submitted any relevant response.**
29.	Justify why you have not perfoemed test of water loss during the stability studies.	**Firm has not submitted any response.**
30.	The analytical method in section 3.2.P.5.2 specifies titration method for analysis of lactate while in stability studies you have provided single HPLC chromatogram for analysis in which the UV wavelength is also different from that specified in BP monograph.	*we have sumbitted the sodium lactate method on hplc according to BP2022.* **Firm has not submitted any relevant response.**
31.	Justify how a single chromatogram of HPLC run at 210nm UV wavelength be used to determine assay of lactate for the applied product.	**Firm has not submitted any response.**
32.	Provide details of the HPLC system, model along with details of the software available in your QC lab and status of its 21 CFR compliance.	*Our HPLC is LAB SOLUTION 21CFR software in our labortaory.*
33.	Provide evidence of atomic emission spectroscopy required for analysis of drug product as per BP monograph.	**Firm has not submitted any response.**
34.	Provide analysis report for all the testing performed through atomic emission spectroscopy.	**Firm has not submitted any response.**

Decision of 323rd meeting of Registration Board:
Deferred for following submissions:

- Revision of label claim of the applied product as per the innovator's product along with submission of full fee of registration.
- Evidence of me-too status of the applied product since the submitted me-too contains sodium lactate 0.31g while your applied formulation contains 0.32g sodium lactate.
- Report of verification studies of the Calcium chloride drug substance.
- Submission of actual signed data sheets for three batches of the calcium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.
- Report of verification studies of the Potassium chloride drug substance.
- Report of verification studies of the Sodium chloride drug substance.
- Submission of actual signed data sheets for three batches of the Sodium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.
- Report of verification studies of the sodium lactate drug substance.
- Submission of actual signed data sheets for three batches of the Sodium lactate drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.
- Scientific justification for having the formulation containing 0.027g/100ml of calcium chloride while the innovator's product is using 0.027g/100ml of clalcium chloride dihydrate.
- Pharmaceutical equivalence studies against the innovator's product.
- Submission of microbiological attributes of the drug product in section 3.2.P.2.5.
- Scientific justification for performing validation studies of terminal sterilization procedure from external agency only.
- Scientific justification for the drug product specifications which does not contain test of particulate matter.
- Scientific justification for having different acceptance criteria of all assay tests in specifications as compared to that specified in BP monograph.
- Scientific justification why the test for sodium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.
- Scientific justification why the test for potassium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.
- Scientific justification why the test for lactate content in the drug product is different from that mentioned in BP monograph, since HPLC test is specified in BP monograph while you have specified titration method.
- Report of verification studies of the analytical method of drug product.
- Scientific justification why the test of water loss is not performed during the stability studies.
- Scientific justification how a single chromatogram of HPLC run at 210nm UV wavelength be used to determine assay of lactate for the applied product.
- Evidence of atomic absorption and atomic emission spectroscopy required for analysis of drug product as per BP monograph along with IQ, OQ and PQ of both equipments.
- Submission of analysis report and raw data sheets for all the testing performed through atomic emission spectroscopy.
- Batch size of drug product stability batches in terms of no. of units.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Revision of label claim of the applied product as per the innovator's product along with submission of full fee of registration.	Firm has revised the label claim as per innovator's product
2.	Evidence of me-too status of the applied product since the submitted me-too contains sodium lactate 0.31g	Our me-too competitor is FDL which have 0.32g/100ml

	while your applied formulation contains 0.32g sodium lactate.	
3.	Report of verification studies of the Calcium chloride drug substance.	Not submitted
4.	Submission of actual signed data sheets for three batches of the calcium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.	Firm has initially submitted data sheets without any sign and stamp of the API manufacturer, later the firm submitted signed data sheets.
5.	Report of verification studies of the Potassium chloride drug substance.	Not submitted
6.	Submission of actual signed data sheets for three batches of the Sodium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.	Firm has initially submitted data sheets without any sign and stamp of the API manufacturer, later the firm submitted signed data sheets.
7.	Report of verification studies of the sodium lactate drug substance.	Not submitted
8.	Submission of actual signed data sheets for three batches of the Sodium lactate drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.	Firm has initially submitted data sheets without any sign and stamp of the API manufacturer, later the firm submitted signed data sheets.
9.	Scientific justification for having the formulation containing 0.027g/100ml of calcium chloride while the innovator's product is using 0.027g/100ml of clalcium chloride dihydrate.	Our formulation is similar to that of innovator's product
10.	Pharmaceutical equivalence studies against the innovator's product.	Not submitted againt the innovator's product
11.	Submission of microbiological attributes of the drug product in section 3.2.P.2.5.	Not submitted.
12.	Scientific justification for performing validation studies of terminal sterilization procedure from external agency only.	No justification is submitted by the firm.
13.	Scientific justification for the drug product specifications which does not contain test of particulate matter.	Not submitted.
14.	Scientific justification for having different acceptance criteria of all assay tests in specifications as compared to that specified in BP monograph.	No justification is submitted.
15.	Scientific justification why the test for sodium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification	No justification submitted.

	parameters of atomic emission spectrophotometry.	
16.	Scientific justification why the test for potassium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.	No justification submitted.
17.	Scientific justification why the test for lactate content in the drug product is different from that mentioned in BP monograph, since HPLC test is specified in BP monograph while you have specified titration method.	No justification submitted.
18.	Report of verification studies of the analytical method of drug product.	Not submitted.
19.	Scientific justification why the test of water loss is not performed during the stability studies.	Submitted by the firm.
20.	Scientific justification how a single chromatogram of HPLC run at 210nm UV wavelength be used to determine assay of lactate for the applied product.	No justification submitted.
21.	Evidence of atomic absorption and atomic emission spectroscopy required for analysis of drug product as per BP monograph along with IQ, OQ and PQ of both equipments.	Not submitted.
22.	Submission of analysis report and raw data sheets for all the testing performed through atomic emission spectroscopy.	Not submitted.
23.	Batch size of drug product stability batches in terms of no. of units.	100 bottles

Decision of 326th meeting of Registration Board:

Deferred for following submissions:

- Revision of label claim of the applied product as per the innovator's product and labelling requirements of BP monograph along with submission of full fee of registration.
- Protocol and report of verification studies of the Calcium chloride drug substance as per the ICH Q2 Guidelines.
- Scientific justification for initial submission of stability study data of the calcium chloride drug substance without signatures of responsible personnel, later the same data was presented as signed data sheets but without any details of the batches on which stability was performed.
- Protocol and report of verification studies of the Potassium chloride drug substance as per the ICH Q2 Guidelines.
- Protocol and report of verification studies of the Sodium chloride drug substance as per the ICH Q2 Guidelines.
- Scientific justification for initial submission of stability study data of the sodium chloride drug substance without signatures of responsible personnel, later the same data was presented as signed data sheets but without any details of the batches on which stability was performed.
- Protocol and report of verification studies of the sodium lactate drug substance as per the ICH Q2 Guidelines.

- Scientific justification for initial submission of stability study data of the Sodium lactate drug substance without signatures of responsible personnel, later the same data was presented as signed data sheets but without any details of the batches on which stability was performed.
- Scientific justification for having the formulation containing 0.027g/100ml of calcium chloride while the innovator's product is using 0.027g/100ml of clalcium chloride dihydrate.
- Submission of picture / image of the innovator's product against which Pharmaceutical equivalence studies have been performed.
- Submission of microbiological attributes of the drug product in section 3.2.P.2.5.
- Scientific justification for performing validation studies of terminal sterilization procedure from external agency only.
- Scientific justification for the drug product specifications which does not contain test of particulate matter.
- Scientific justification for having different acceptance criteria of all assay tests in specifications as compared to that specified in BP monograph.
- Scientific justification why the test for sodium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.
- Scientific justification why the test for potassium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.
- Scientific justification why the test for lactate content in the drug product is different from that mentioned in BP monograph, since HPLC test is specified in BP monograph while you have specified titration method.
- Protocol and report of verification studies of the analytical method of drug product as per the ICH Q2 Guidelines.
- Scientific justification how a single chromatogram of HPLC run at 210nm UV wavelength be used to determine assay of lactate for the applied product.
- Evidence of atomic absorption and atomic emission spectroscopy required for analysis of drug product as per BP monograph along with IQ, OQ and PQ of both equipments.
- Submission of analysis report and raw data sheets for all the testing performed through atomic emission spectroscopy.

Response by the firm:
Firm vide its reply dated 16-05-2023 submitted revised data of newly manufactured batches in which product testing has been conducted as per BP monograph. The details of newly manufactured batches is as under:

STABILITY STUDY DATA

Manufacturer of API	**Sodium Chloride:** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Calcium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Potassium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Sodium lactate** Luoyang Longmen Pharmaceutical Co. Ltd. County Industrial Zone Luoning Henan Province P.R. China.
API Lot No.	**Sodium Chloride:** 210909 **Calcium chloride:** 210806 **Potassium chloride:** 211204 **Sodium lactate:** B-2108-517
Description of Pack	Polypropylene

(Container closure system)			
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial # 1	Trial # 2	Trial # 3
Batch Size	500 Bottles	500 Bottles	500 Bottles
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	15-11-2022	16-11-2022	17-11-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sodium Chloride:** Firm has submitted copy of GMP certificate (No. HE20180030) issued by China Food and Drug Administration. The certificate is valid till 22-04-2023. **Calcium chloride:** Firm has submitted copy of GMP certificate (No. HE20180030) issued by China Food and Drug Administration. The certificate is valid till 22-04-2023. **Potassium chloride:** Firm has submitted copy of GMP certificate (No. HE20180030) issued by China Food and Drug Administration. The certificate is valid till 22-04-2023. **Sodium lactate:** Firm has submitted copy of GMP certificate (No. HA20190099) issued by China Food and Drug Administration. The certificate is valid till 29-11-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sodium Chloride:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 25Kg sodium chloride (Batch No. 210909). **Calcium chloride:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 5Kg calcium chloride. **Potassium chloride:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 5Kg potassium chloride. **Sodium lactate:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 10Kg Sodium lactate.
4.	Data of stability batches will be supported by attested respective documents like	Firm has submitted stability study data of 3 batches

	chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Firm has submitted following documents

- Pharmaceutical equivalence study report against Ringolact Infusion of Otsuka Pakistan Ltd.
- Complete Module 3
- Process validation protocols
- Revised pecifications as per BP monograph and verification studies of the analytical method.
- Complete stability studies till 6 months time point.

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim and submission of stability study data of newly manufactured batches as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**

328.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.**
	Name, address of Manufacturing site.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd. Plot No. 40, Road R-2, Industrial Estate, Gadoon Amazai District Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of Drug Manufacturing License (DML No. 000947) dated 11-11-2021. The letter specifies following section: 1. Liquid Injectable Infusion (SVP) LDPE (General) 2. Liquid Injectable Infusion (LVP) LDPE (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 12295: 20-05-2022
	Details of fee submitted	PKR 30,000/- : 20-05-2022

	The proposed proprietary name / brand name	**SAFESOL-RL IV Infusion 1000ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml contains: Calcium chloride ……0.027g Potassium chloride……0.04g Sodium chloride…… 0.60g Sodium lactate….. ..0.32g
	Pharmaceutical form of applied drug	Clear, odorless and colorless solution filled in PP bottle
	Pharmacotherapeutic Group of (API)	Electrolytes
	Reference to Finished product specifications	BP
	Proposed Pack size	1000ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**MHRA Approved**
	For generic drugs (me-too status)	Could not be confirmed
	Name and address of API manufacturer.	**Sodium Chloride:** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Calcium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Potassium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Sodium lactate** Luoyang Longmen Pharmaceutical Co. Ltd. County Industrial Zone Luoning Henan Province P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Sodium Chloride:** Not submitted. **Calcium chloride:** Not submitted. **Potassium chloride:** Firm has submitted stability data of 3 batches of API as per zone IV-A conditions.

		Sodium lactate: Not submitted.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for the quality tests for their product against the comparator product 'Sterifluid-RL Infusion by M/s FDL Pharma."
	Analytical method validation/verification of product	Firm has submitted report of verification of analytical method for the drug substance. Firm has submitted report of verification of analytical method for the drug product.

STABILITY STUDY DATA			
Manufacturer of API	**Sodium Chloride:** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Calcium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Potassium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Sodium lactate** Luoyang Longmen Pharmaceutical Co. Ltd. County Industrial Zone Luoning Henan Province P.R. China.		
API Lot No.	**Sodium Chloride:** 210909 **Calcium chloride:** 210806 **Potassium chloride:** 211204 **Sodium lactate:** B-2108-517		
Description of Pack (Container closure system)	Polypropylene		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	300 liters	300 liters	300 liters
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	25-01-2022	25-01-2022	25-01-2022
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sodium Chloride:** Firm has submitted copy of GMP certificate (No. HE20180030) issued by China Food and Drug Administration. The certificate is valid till 22-04-2023. **Calcium chloride:** Firm has submitted copy of GMP certificate (No. HE20180030) issued by China Food and Drug Administration. The certificate is valid till 22-04-2023. **Potassium chloride:** Firm has submitted copy of GMP certificate (No. HE20180030) issued by China Food and Drug Administration. The certificate is valid till 22-04-2023. **Sodium lactate:** Firm has submitted copy of GMP certificate (No. HA20190099) issued by China Food and Drug Administration. The certificate is valid till 29-11-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sodium Chloride:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 25Kg sodium chloride (Batch No. 210909). **Calcium chloride:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 5Kg calcium chloride. **Potassium chloride:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 5Kg potassium chloride. **Sodium lactate:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 10Kg Sodium lactate.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	Revise your label claim as per the innovator's product along with submission of full fee since innovator product specifies clalcium chloride dihydrate 0.027g/100ml while you have mentioned calcium chloride 0.027g/100ml.	*Applied formulation contains calcium chloride dihydrate as per BP innovator product also contains calcium chloride dihydrate. In master formulation typographic error found. New master formulation has been submitted.*

		Firm has not revised the label claim nor submitted any fee.
2.	Evidence of me-too status of the applied product since the submitted me-too contains sodium lactate 0.31g while your applied formulation contains 0.32g sodium lactate.	*our main competitor is FRONTIER DEXTROSE LIMITED PHARMA HATTAR having formulation sodium lactate 0.32g/100 ml which is same as our formulation 0.32g/100 ml.* **The available data base shows that Sterifluid RL Infusion (Reg # 052739) of M/s Frontier Dextrose Ltd contains Sodium Lactate 0.31gm**
3.	Provide reference of finished product specifications in module 1 along with submission of fee for revision of specifications.	*Typographic error found. Our product is BP Specifications.* **Firm has not submitted any fee**
4.	Submit verification studies of the Calcium chloride drug substance in section 3.2.S.4.3	**Firm has not submitted verification studies for the drug substance.**
5.	Provide actual signed data sheets for three batches of the calcium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions, since you have submitted unsigned data sheets on which stamp of Ashrafsons Pharmaceuticals is placed instead of being signed and stamped by drug substance manufacturer. Furthermore, the submitted stabilility sheets does not specify any batch number, manufacturing or expiry date etc.	**Firm has not submitted stability study data sheets for API from API manufacturer.**
6.	Submit verification studies of the Potassium chloride drug substance in section 3.2.S.4.3	**Firm has not submitted verification studies for the drug substance.**
7.	Submit verification studies of the Sodium chloride drug substance in section 3.2.S.4.3	**Firm has not submitted verification studies for the drug substance.**
8.	Provide actual signed data sheets for three batches of the Sodium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions, since you have submitted unsigned data sheets on which stamp of Ashrafsons Pharmaceuticals is placed instead of being signed and stamped by drug substance manufacturer.	**Firm has not submitted stability study data sheets for API from API manufacturer.**
9.	Submit verification studies of the sodium lactate drug substance in section 3.2.S.4.3	**Firm has not submitted verification studies for the drug substance.**
10.	Provide actual signed data sheets for three batches of the Sodium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions, since you have submitted unsigned data sheets on which stamp of Ashrafsons Pharmaceuticals is placed instead of being signed and stamped by drug substance manufacturer.	**Firm has not submitted stability study data sheets for API from API manufacturer.**

11.	The innovator's product is using 0.027g/100ml of clalcium chloride dihydrate while your formulation contains 0.027g/100ml of calcium chloride. Justify how your formulation is similar to that of innovator's product.	*Our formulation is similar to that of innovators product that is 0.027g/100ml of clacium chloride dihydrate.* **The submitted formulation as well as BMR shows that firm is using 0.027g/100ml of calcium chloride.**
12.	Justify why pharmaceutical equivalence is conducted against a comparator product instead of performing against the innovator's product.	*Because they have the same active ingredients, the same dosage form and are identical in strength, quality, purity, and identity as the brand-name product.* **Firm has not submitted any relevant response.**
13.	Justify why complete tests as mentioned in BP monograph is not performed in pharmaceutical equivalence studies.	*Skip testing is the performance of specified tests at release on pre-selected batches and / or at predetermined intervals, rather than on a batch-to-batch basis with the understanding that those batches not being tested still must meet all acceptance criteria established for that product. This represents a less than full schedule of testing and should therefore be justified and presented to and approved by the regulatory authority prior to implementation.* **Firm has not submitted any relevant response.**
14.	Justify how you can perform pharmaceutical equivalence against a product which have different quantitative composition as compared to your product.	*We cannot perform pharmaceutical equivalence against a product which has different quantitative composition to our product.* **Firm has not submitted any relevant response.**
15.	Provide microbiological attributes of the drug product in section 3.2.P.2.5.	*Our product is compatible with drug container made of polypropylene of pharmaceutical grade and heat resistant and we can easily sterilize our product at 121°C for 30 minutes to make our product properly sterile.* **Firm has not submitted any relevant response.**
16.	Provide details how terminal sterilization method was validated for PP bottles.	***Terminal sterilization method was validated for PP bottles was validated from external agency.***
17.	Justify why the drug product specifications does not contain test of particulate matter.	*Product specification concentrate on quality of product till expiry with 100% efficiency .detail is given by literature support.* **Firm has not submitted any relevant response.**
18.	Justify why the acceptance criteria of all assay tests in pharmaceutical equivalence is not as per BP monograph.	*All the test acceptance criteria of all assay tests in pharmaceutical complies BP 2022.* **The acceptance criteria of all tests is not as per the BP monograph.**
19.	Justify why the test for sodium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.	*All the test acceptance criteria of all assay tests in pharmaceutical complies BP 2022.* **The tests is not as per the BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.**
20.	Justify why the test for potassium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and	*Potassium test is according to BP 2022.* **The tests is not as per the BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.**

	specification parameters of atomic emission spectrophotometry.	
21.	Justify why the test for lactate content in the drug product is different from that mentioned in BP monograph, since HPLC test is specified in BP monograph while you have specified titration method.	*The method of sodium lactate is HPLC method in BP 2022. We give the HPLC print is attached with the file.* **Firm has used titration method as submitted in the application.**
22.	Provide verification studies of the analytical method of drug product in section 3.2.P.5.3 instead of providing process validation report.	*We have submitted verification studies.* **Firm has submitted process validation report instead of analytical method verification.**
23.	Provide details of the container closure system of the applied product.	*Our sterile product is filled in polypropylene container properly sealed and sterilized. Polypropylene plastic is of pharmaceutical grade and provide strength to the container and .polypropylene is heat resistant and we can easily sterilize our product at 121c. to make our product sterile*
24.	Describe your container closure system in detail whether it contains Eurocap or not along with evidence of this facility (if applicable).	*Firm has both facility of manufacturing the simple cap & Eurocap.*
25.	Specify whether the bottles placed in stability chambers were with Europcap or not.	*At present we are using simple cap to reduce cost of our product but we have the facility of Eurocap machine facility.*
26.	Provide total capacity of each stability chamber and details of number of bottles of each product placed in the stability chambers. Also provide details how many bottles of the applied product are placed in real time and accelerated stability chamber.	*40 bottles in real stabilty chamber.* *60 bottles in accelerated stabilty chamber.*
27.	Justify why the stability studies have been performed using method and acceptance criteria which is completely different from that specified in BP monograph.	*All the test acceptance criteria of all assay tests in pharmaceutical complies BP 2022.* **The acceptance criteria of all tests is not as per the BP monograph.**
28.	Justify the performance of stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container, while ICH guidelines recommend performing stability studies at 30°C ± 2°C / 35% ± 5%RH and 40°C ± 2°C / NMT 25% RH for products packed in semi permeable containers.	*We have submitted the stability studies at 30°C ± 2°C / 65% ± 5%RH and 40°C ± 2°C / 75% ± 5%RH being a product packed in PP (semi permeable) container.* **Firm has not submitted any relevant response.**
29.	Justify why you have not perfoemed test of water loss during the stability studies.	**Firm has not submitted any response.**
30.	The analytical method in section 3.2.P.5.2 specifies titration method for analysis of lactate while in stability studies you have provided single HPLC chromatogram for analysis in which the UV wavelength is also different from that specified in BP monograph.	*we have sumbitted the sodium lactate method on hplc according to BP2022.* **Firm has not submitted any relevant response.**

31.	Justify how a single chromatogram of HPLC run at 210nm UV wavelength be used to determine assay of lactate for the applied product.	**Firm has not submitted any response.**
32.	Provide details of the HPLC system, model along with details of the software available in your QC lab and status of its 21 CFR compliance.	*Our HPLC is LAB SOLUTION 21CFR software in our labortaory.*
33.	Provide evidence of atomic emission spectroscopy required for analysis of drug product as per BP monograph.	**Firm has not submitted any response.**
34.	Provide analysis report for all the testing performed through atomic emission spectroscopy.	**Firm has not submitted any response.**

Decision of 323rd meeting of Registration Board:

Deferred for following submissions:

- Revision of label claim of the applied product as per the innovator's product along with submission of full fee of registration.
- Evidence of me-too status of the applied product since the submitted me-too contains sodium lactate 0.31g while your applied formulation contains 0.32g sodium lactate.
- Report of verification studies of the Calcium chloride drug substance.
- Submission of actual signed data sheets for three batches of the calcium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.
- Report of verification studies of the Potassium chloride drug substance.
- Report of verification studies of the Sodium chloride drug substance.
- Submission of actual signed data sheets for three batches of the Sodium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.
- Report of verification studies of the sodium lactate drug substance.
- Submission of actual signed data sheets for three batches of the Sodium lactate drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.
- Scientific justification for having the formulation containing 0.027g/100ml of calcium chloride while the innovator's product is using 0.027g/100ml of clalcium chloride dihydrate.
- Pharmaceutical equivalence studies against the innovator's product.
- Submission of microbiological attributes of the drug product in section 3.2.P.2.5.
- Scientific justification for performing validation studies of terminal sterilization procedure from external agency only.
- Scientific justification for the drug product specifications which does not contain test of particulate matter.
- Scientific justification for having different acceptance criteria of all assay tests in specifications as compared to that specified in BP monograph.
- Scientific justification why the test for sodium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.
- Scientific justification why the test for potassium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.
- Scientific justification why the test for lactate content in the drug product is different from that mentioned in BP monograph, since HPLC test is specified in BP monograph while you have specified titration method.
- Report of verification studies of the analytical method of drug product.
- Scientific justification why the test of water loss is not performed during the stability studies.

- Scientific justification how a single chromatogram of HPLC run at 210nm UV wavelength be used to determine assay of lactate for the applied product.
- Evidence of atomic absorption and atomic emission spectroscopy required for analysis of drug product as per BP monograph along with IQ, OQ and PQ of both equipments.
- Submission of analysis report and raw data sheets for all the testing performed through atomic emission spectroscopy.
- Batch size of drug product stability batches in terms of no. of units.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Revision of label claim of the applied product as per the innovator's product along with submission of full fee of registration.	Firm has revised the label claim as per innovator's product
2.	Evidence of me-too status of the applied product since the submitted me-too contains sodium lactate 0.31g while your applied formulation contains 0.32g sodium lactate.	Our me-too competitor is FDL which have 0.32g/100ml
3.	Report of verification studies of the Calcium chloride drug substance.	Not submitted
4.	Submission of actual signed data sheets for three batches of the calcium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.	Firm has initially submitted data sheets without any sign and stamp of the API manufacturer, later the firm submitted signed data sheets.
5.	Report of verification studies of the Potassium chloride drug substance.	Not submitted
6.	Submission of actual signed data sheets for three batches of the Sodium chloride drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.	Firm has initially submitted data sheets without any sign and stamp of the API manufacturer, later the firm submitted signed data sheets.
7.	Report of verification studies of the sodium lactate drug substance.	Not submitted
8.	Submission of actual signed data sheets for three batches of the Sodium lactate drug substance in which accelerated and real time stability study is conducted as per zone IV-A conditions.	Firm has initially submitted data sheets without any sign and stamp of the API manufacturer, later the firm submitted signed data sheets.
9.	Scientific justification for having the formulation containing 0.027g/100ml of calcium chloride while the innovator's product is using 0.027g/100ml of clalcium chloride dihydrate.	Our formulation is similar to that of innovator's product
10.	Pharmaceutical equivalence studies against the innovator's product.	Not submitted againt the innovator's product
11.	Submission of microbiological attributes of the drug product in section 3.2.P.2.5.	Not submitted.

12.	Scientific justification for performing validation studies of terminal sterilization procedure from external agency only.	No justification is submitted by the firm.
13.	Scientific justification for the drug product specifications which does not contain test of particulate matter.	Not submitted.
14.	Scientific justification for having different acceptance criteria of all assay tests in specifications as compared to that specified in BP monograph.	No justification is submitted.
15.	Scientific justification why the test for sodium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.	No justification submitted.
16.	Scientific justification why the test for potassium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.	No justification submitted.
17.	Scientific justification why the test for lactate content in the drug product is different from that mentioned in BP monograph, since HPLC test is specified in BP monograph while you have specified titration method.	No justification submitted.
18.	Report of verification studies of the analytical method of drug product.	Not submitted.
19.	Scientific justification why the test of water loss is not performed during the stability studies.	Submitted by the firm.
20.	Scientific justification how a single chromatogram of HPLC run at 210nm UV wavelength be used to determine assay of lactate for the applied product.	No justification submitted.
21.	Evidence of atomic absorption and atomic emission spectroscopy required for analysis of drug product as per BP monograph along with IQ, OQ and PQ of both equipments.	Not submitted.
22.	Submission of analysis report and raw data sheets for all the testing performed through atomic emission spectroscopy.	Not submitted.
23.	Batch size of drug product stability batches in terms of no. of units.	100 bottles

Decision of 326th meeting of Registration Board:
Deferred for following submissions:

- Revision of label claim of the applied product as per the innovator's product and labelling requirements of BP monograph along with submission of full fee of registration.
- Protocol and report of verification studies of the Calcium chloride drug substance as per the ICH Q2 Guidelines.
- Scientific justification for initial submission of stability study data of the calcium chloride drug substance without signatures of responsible personnel, later the same data was presented as signed data sheets but without any details of the batches on which stability was performed.
- Protocol and report of verification studies of the Potassium chloride drug substance as per the ICH Q2 Guidelines.
- Protocol and report of verification studies of the Sodium chloride drug substance as per the ICH Q2 Guidelines.
- Scientific justification for initial submission of stability study data of the sodium chloride drug substance without signatures of responsible personnel, later the same data was presented as signed data sheets but without any details of the batches on which stability was performed.
- Protocol and report of verification studies of the sodium lactate drug substance as per the ICH Q2 Guidelines.
- Scientific justification for initial submission of stability study data of the Sodium lactate drug substance without signatures of responsible personnel, later the same data was presented as signed data sheets but without any details of the batches on which stability was performed.
- Scientific justification for having the formulation containing 0.027g/100ml of calcium chloride while the innovator's product is using 0.027g/100ml of clalcium chloride dihydrate.
- Submission of picture / image of the innovator's product against which Pharmaceutical equivalence studies have been performed.
- Submission of microbiological attributes of the drug product in section 3.2.P.2.5.
- Scientific justification for performing validation studies of terminal sterilization procedure from external agency only.
- Scientific justification for the drug product specifications which does not contain test of particulate matter.
- Scientific justification for having different acceptance criteria of all assay tests in specifications as compared to that specified in BP monograph.
- Scientific justification why the test for sodium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.
- Scientific justification why the test for potassium content in the drug product is different from that mentioned in BP monograph in terms of concentration of standard solution and specification parameters of atomic emission spectrophotometry.
- Scientific justification why the test for lactate content in the drug product is different from that mentioned in BP monograph, since HPLC test is specified in BP monograph while you have specified titration method.
- Protocol and report of verification studies of the analytical method of drug product as per the ICH Q2 Guidelines.
- Scientific justification how a single chromatogram of HPLC run at 210nm UV wavelength be used to determine assay of lactate for the applied product.
- Evidence of atomic absorption and atomic emission spectroscopy required for analysis of drug product as per BP monograph along with IQ, OQ and PQ of both equipments.
- Submission of analysis report and raw data sheets for all the testing performed through atomic emission spectroscopy.

Response by the firm:

Firm vide its reply dated 16-05-2023 submitted revised data of newly manufactured batches in which product testing has been conducted as per BP monograph. The details of newly manufactured batches is as under:

STABILITY STUDY DATA

Manufacturer of API	**Sodium Chloride:** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Calcium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Potassium chloride** M/s Hebei Huachen Pharmaceutical Co. Ltd. Huanghua Economic Development Zone, Hebei PR China. **Sodium lactate** Luoyang Longmen Pharmaceutical Co. Ltd. County Industrial Zone Luoning Henan Province P.R. China.		
API Lot No.	**Sodium Chloride:** 210909 **Calcium chloride:** 210806 **Potassium chloride:** 211204 **Sodium lactate:** B-2108-517		
Description of Pack (Container closure system)	Polypropylene		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial # 4	Trial # 5	Trial # 6
Batch Size	500 Bottles	500 Bottles	500 Bottles
Manufacturing Date	11-2022	11-2022	11-2022
Date of Initiation	15-11-2022	16-11-2022	17-11-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable since it is a newly established license.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Sodium Chloride:** Firm has submitted copy of GMP certificate (No. HE20180030) issued by China Food and Drug Administration. The certificate is valid till 22-04-2023. **Calcium chloride:** Firm has submitted copy of GMP certificate (No. HE20180030) issued by China Food and Drug Administration. The certificate is valid till 22-04-2023. **Potassium chloride:** Firm has submitted copy of GMP certificate (No. HE20180030) issued by China Food and Drug Administration. The certificate is valid till 22-04-2023. **Sodium lactate:** Firm has submitted copy of GMP certificate (No. HA20190099) issued by China Food and Drug Administration. The certificate is valid till 29-11-2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sodium Chloride:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP

		dated 04-01-2022. The invoice declare purchase of 25Kg sodium chloride (Batch No. 210909). **Calcium chloride:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 5Kg calcium chloride. **Potassium chloride:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 5Kg potassium chloride. **Sodium lactate:** Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 04-01-2022. The invoice declare purchase of 10Kg Sodium lactate.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability study data of 3 batches
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Firm has submitted following documents

- Pharmaceutical equivalence study report against Ringolact Infusion of Otsuka Pakistan Ltd.
- Complete Module 3
- Process validation protocols
- Revised pecifications as per BP monograph and verification studies of the analytical method.
- Complete stability studies till 6 months time point.

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim and submission of stability study data of newly manufactured batches as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**

329.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Don Valley Pharmaceuticals (Pvt.) Ltd 31-Km, Ferozepur Road, Lahore.**
	Name, address of Manufacturing site.	M/s Don Valley Pharmaceuticals (Pvt) Ltd 31-Km, Ferozepur Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	The firm has submitted copy of inspection report dated 13-02-2020 confirming good compliance to GMP.

	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 23-08-2019 issued on the basis of inspection dated 06-08-2019 which specifies Tablet (General) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2254: 24-01-2023
	Details of fee submitted	PKR 30,000/-: 18-01-2023
	The proposed proprietary name / brand name	**EMPADON 25mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin…25mg
	Pharmaceutical form of applied drug	Pink colored, round biconvex coated tablet plain on both sides
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	In house specs
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**(USFDA** Approved)
	For generic drugs (me-too status)	Xelglu Tablet by Hilton
	Name and address of API manufacturer.	Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County Fuxin City Liaoning Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ±

		5% RH for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted results of pharmaceutical equivalence for all the quality tests for their product against Jardiance Tablet Firm has submitted results of CDP for their product against Jardiance Tablet.
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and analytical method validation of the drug product.

STABILITY STUDY DATA

Manufacturer of API	Fuxin Long Rui Pharmaceutical Co. Ltd. Fluoride Industrial Park, Fumeng County Fuxin City Liaoning Province China.		
API Lot No.	L-E-20211130-D06-E06-02		
Description of Pack (Container closure system)	Alu-alu blister pack		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-IY-22-01	T-IY-22-02	T-IY-22-03
Batch Size	5000 Tablet	5000 Tablet	5000 Tablet
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	27-05-2022	27-05-2022	27-05-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted by the firm
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML certificate No. Liao20150233, dated: 21/12/2017 valid till 20/12/2022, issued by Food & Drug Administration of Liaoning Province- China is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of clearance certificate specifying import of 0.25Kg Empagliflozin. The clearance certificate is issued on 20-04-2022.
4.	Data of stability batches will be supported by attested respective documents like	Firm has submitted complete record of testing of all batches along with raw data sheets, COA and

	chromatograms, Raw data sheets, COA, summary data sheets etc.	summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

- Submit data in section 3.2.S.4.1 and 3.2.S.4.2 for Nirmatrelvir drug substance as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required."
- Justify the verification studies of analytical procedure of drug substance from drug product manufacturer, since the drug product manufacturer has adopted a different analytical method in terms of column size, column temperature, standard solution and sample solution.
- The result of sample 3 at 80% concentration in repeatability test gives 60% result. Justify how you passed this test since the test does not qualify the acceptance criteria.
- The HPLC chromatograms of verification studies depict that the date acquired for all analysis of linearity and range is 1-May -22: 10:07AM which is not practically possible. Justify how multiple HPLC chromatograms having different peak areas were acquired on same date and same time.
- The analytical method provided in verification studies specifies 20µL injection volume while all chromatograms specify 10µL injection volume.
- HPLC chromatogram for sample 1 of 120% specify the height as 544.73 while the scale of chromatogram is till 480. Justify how the height could be 544 while the chromatogram is below 480 as per vertifcal scale.
- Three chromatograms submitted after sample 3 of 140% concentration with sample name 0, date acquired 1-May-22 10:07AM and date processed 1-May-22 12:59 PM show retention time 2.59 with exactly same peak as in other chromtaograms but the area and height is 0. Clarify how the peak area and height is 0 with the clear peak in the print.
- Justify why the qualitative composition of your formulation is different from the innovator's product.
- Provide information regarding batch number, expiry date and manufacturer of the innovator product against which pharmaceutical equivalence and CDP studies were conducted.
- Justify the adaptation of dissolution parameters, since they are different from that recommended by the innovator's product in terms of RPM. You have selected 100RPM while the innovator's product has specified 75 RPM.
- Justify the dissolution acceptance criteria NLT 75%(Q) in 45 minutes, while the innovator's product acceptance criteria is NLT (Q) in 15 minutes. Justify your dissolution criteria in the light of decision of Registration Board taken in its 293rd meeting which specifies that "*For rapidly dissolving as well as immediate release drug products, wherein the stability batches will be manufactured after 01-06-2020, variation from innovator / reference product with reference to dissolution specification will not be acceptable"*
- Justify why content uniformity test is not included in the drug product specifications.
- Analytical method of drug product specifies that concentration of standard and sample preparation is 0.025mg/ml while you have performed verification studies keeping the target concentration 0.1mg/ml. Justify how these studies represent your analytical method.
- USFDA review documents reveals that the innovator's drug product shows more than 85% release in 15 minutes, while your stability results indicate that the product disintegration time is greater than 15 minutes. Justify how your product could be considered equivalent to the innovator's product.
- Submit valid GMP certificate / Drug manufacturing license of API manufacturer issued by relevant regulatory authority of country of origin, since the submitted GMP is not issued by relevant regulatory authority of China.

- The submitted audit trail report shows different time of acquisition of HPLC chromatograms than that mentioned on the relevant chromatograms. Clarification is required in this regard.
- Submit BMR of three executed stability batches.

Decision of 326th meeting of Registration Board:
Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response by the firm:

Sr #	Deficiencies	Response by the firm
1.	Justify the verification studies of analytical procedure of drug substance from drug product manufacturer, since the drug product manufacturer has adopted a different analytical method in terms of column size, column temperature, standard solution and sample solution.	Analytical procedure for quantification/Validation of drug substance has been selected on the basis of research articles and all parameters have been validated as per ICH/USP guidelines. Guidelines has been attached for your reference. Please read page no 10, clause 5, sub clause 5.1.
2.	The result of sample 3 at 80% concentration in repeatability test gives 60% result. Justify how you passed this test since the test does not qualify the acceptance criteria.	As per ICH guidelines Precision Repeatability minimum of 9 determination should be covered we have prepared 60%, 80%, 100%, 120%. 80% sample was in actual is 60% of sample prepared, which results was also shows 60% Results. Report have typo error, updated report is shared.
3.	The HPLC chromatograms of verification studies depict that the date acquired for all analysis of linearity and range is 1-May -22:10:07AM which is not practically possible. Justify how multiple HPLC chromatograms having different peak areas were acquired on same date and same time.	Date acquired in report template is saved as time of sequence submission and all injections have been fed in the sequence at the same time. Date acquired reflects the time of sequence submission. That is why multiple injections have same acquired time. Date processed depicts the time of injection starting of every injections.
4.	The analytical method provided in verification studies specifies 20µL injection volume while all chromatograms specify 10µL Injection volume.	All the analysis have been carried out at 10µL. Testing procedure have typo error. Test method has been revised and attached for your reference.
5.	HPLC chromatogram for sample 1 of 120% specify the height as 544. 73 while the scale of chromatogram is till 480. Justify how the height could be 544 while the Chromatogram is below 480 as per vertical scale.	Report template and chromatogram depict same data but unit of measurement of signal in peak table is different from chromatogram. Vendor have been called for the proper setting of report template to remove the ambiguity in this regard. Moreover our main concern to carry out calculations is with Area under curve. That's why in all compendia monograph like USP/BP/JP Peak Area is used for calculations.
6.	Three chromatograms submitted after sample 3 of 140% concentration with sample name 0, date acquired 1-May-22 10:07AM and date processed 1-May-22 12:59 PM show retention time 2.59 with exactly same peak as in other chromatograms but the area and height is 0. Clarify how the peak area and height is 0 with the clear peak in the print.	In Our HPL software After every analysis Report template has to be selected for any product. Mistakenly None saved templated was selected due to which its shows these type of error. These Chromatogram is basically for 160% to check the slope criteria. We already have successfully performed the Linearity and Range parameters till Max.140%. These are Chromatogram are not used in our calculations.

7.	Provide information regarding batch number, expiry date and manufacturer of the innovator product against which pharmaceutical equivalence and CDP studies were conducted.	Innovator samples pictures has been attached and sent for your reference.
8.	Justify the adaptation of dissolution parameters, since they are different from that recommended by the innovator's product in terms of RPM. You have selected 100RPM while the innovator's product has specified 75 RPM.	All submitted data has been performed as per innovator specifications. Test method has been updated with right specifications and attached.
9.	Justify the dissolution acceptance criteria NLT 75%(0) in 45 minutes, while the innovator's product acceptance criteria is NLT (Q) in 15 minutes. Justify your dissolution criteria in the light of decision of Registration Board taken in its 293rd meeting which specifies that "For rapidly dissolving as well as immediate release drug products, wherein the stability batches will be manufactured after 01-06-2020, variation from innovator / reference product with reference to dissolution specification will not be acceptable"	As per Refer to FDA's Dissolution Guidance, 2018, Dissolution acceptance criteria is NLT80% in 30 minute, As in stability study and at 0 time Our Products shows more than 90% of dissolution. We have revised the test method 75% in 15 minute for our drug product. And all testing will be conducted accordingly. Also in our CDP study at pH 6.8 buffer our drug Product shows more than 90% results after 10 minutes.
10.	Justify why content uniformity test is not included in the drug product specifications.	Content uniformity have been performed at finished stage and also included in pharmaceutical equivalence. Testing procedure and specifications have been updated accordingly.
11.	Analytical method of drug product specifies that concentration of standard and sample preparation is 0.025mg/ml while you have performed verification studies keeping the target concentration 0.1 mg/ml. Justify how these studies represent your analytical method.	Concentrations adjustment is made for output of HPLC chromatogram to get peak behavior and accuracy in results. If we go down or go up for concertation. Analytical method sample concentrations during analysis, we have made as per article based method. That's why this sample was prepared by 0.1mg/mL. Moreover as we already have validated method with this concentrations and also verified by testing same time competitor sample. After validation with different parameters will not affect the dilution concentrations
12.	USFDA review documents reveals that the innovator's drug product shows more than 85% release in 15 minutes, while your stability results indicate that the product disintegration time is greater than 15 minutes. Justify how your product could be considered equivalent to the innovator's product.	Disintegration and dissolution both are different test and different mechanism of actions. Disintegrations release mechanism by erosion. Dissolution release mechanism is different. As our product falls in acceptance criteria is pharmaceutically equal. Disintegration is a physical performance test. Whereas Dissolution is Chemical performance test and shows better study for bioavailability of product.

13.	The submitted audit trail report shows different time of acquisition of HPLC chromatograms than that mentioned on the relevant chromatograms. Clarification is required in this regard.	All the audit trails reports are generated by our HPLC Software, which practically not possible to shows different date and time. May be our File compilation officer have attached or placed in different place.

Decision: Approved with Innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

330.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmark Pharmaceuticals Plot # 122 Block-B, Phase-V, Industrial Estate Hattar.**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals Plot # 122 Block-B, Phase-V, Industrial Estate Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted copy of GMP certificate dated 23-11-2021 issued based on inspection dated 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 23-11-2021 issued based on inspection dated 11-11-2021. The certificate specifies Tablet (General) Section.
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No 6127 dated 07-03-2022
	Details of fee submitted	PKR 75,000/- Dated 24-02-2022
	The proposed proprietary name / brand name	**ZILTAN 80mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Azilsartan medoxomil potassium eq to Azilsartan medoxomil…… 80mg
	Pharmacotherapeutic Group of (API)	Angiotensin Receptor Blocker
	Pharmaceutical form of applied drug	White to off white colored uncoated round shape core tablet plain from both sides
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	4 x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Edarbi Tablet (**USFDA** Approved)
	For generic drugs (me-too status)	NA

	Name and address of API manufacturer.	CTX Lifesciences Pvt Ltd. Block No. 251-252, Sachin Magdalla Road G.I.D.C, Sachin Surat Gujrat India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 5°C ± 3°C for 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the innovator's product Edarbi Tablet 80mg manufactured by Takeda Ireland Ltd.. Firm has submitted CDP results of their product against the innovator's product Edarbi Tablet 80mg in 3 dissolution medias.
	Analytical method validation/verification of product	Firm has submitted analytical method validation study reports for drug substance as well as drug product.

STABILITY STUDY DATA

Manufacturer of API	CTX Lifesciences Pvt Ltd. Block No. 251-252, Sachin Magdalla Road G.I.D.C, Sachin Surat Gujrat India
API Lot No.	19AK00006
Description of Pack (Container closure system)	Alu-alu Blister
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T025	T026	T027
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	22-03-2021	24-03-2021	25-03-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Last PSI was conducted for Dapzin Tablet, for which the inspection was conducted on 27-04-2021 and the report was presented in 307th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR compliant. • Firm has demonstrated audit trail reports of testing.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of Retention of License (No. G/25/1723) dated 29-01-2021 issued by Food and Drugs Control Administration Gujrat State India. The certificate specifies that the license to manufacture has been retained from 24/01/2021 to 23/01/2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 16-052-2019 specifying 0.540Kg Azilsartan medoxomil potassium. The invoice is cleared by AD (I&E) DRAP.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted certificate of 21 CFR compliance for the HPLC system
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	The label claim of innovator's product specifies that each tablet contains 80mg of Azilsartan medoxomil as potassium salt, while your label claim specifies that each tablet contains 80mg of Azilsartan medoxomil potassium. Revise your label claim as per the innovator's product.	That was a typographic mistake that we have corrected the label claim that is Each tablet contains: Azilsartan Medoxomil as potassium …..80mg (Innovators spec) Firm has **not** submitted any fee

2.	Analytical method for assay testing of drug substance specifies a gradient elution system with a run time upto 40 minutes, while the drug product manufacturer has specified isocratic elution with run time upto 10 minutes. Clarification is required how drug product manufacturer can use a different analytical method of the drug substance from that recommended by the drug substance manufacturer.	We have used gradient method of analysis for drug substance provided by the drug substances manufacturer with a run time upto 40 minutes. Although we have used isocratic method of analysis for drug product with run time of upto 10 minutes.
3.	Justify the performance of specificity test under verification studies of drug substance in the light of ICH guidelines, since you have specified that the test was performed by spiking blank sample with test sample and excipients. Justify what was the blank and test sample and how excipients were spiked in drug substance testing.	We have performed specificity test under verification studies of drug substance in the light of ICH guidelines. We run blank sample and standard dilution sample dilution and impurity standard but excipients are spiked during product method validation We use diluent as blank sample
4.	Specify the exact concentration of each solution studied at 80%, 100% and 120% in accuracy and recovery studies. Further specify the formula used to calculate accuracy and recovery results.	The exact concentration of 80% is 0.2mg/ml, 100% is 0.25mg/ml and 120 % is 0.3mg/ml. Accuracy should be assessed using a minimum of 9 determinations over a minimum of 3 concentration levels covering the specified range (e.g., 3 concentrations/3 replicates each of the total analytical procedure), Accuracy should be reported as percent recovery by the assay of known added amount of analyte in the sample or as the difference between the mean and the accepted true value together with the confidence intervals.
5.	Analysis of the drug substance lot number 19AK00006 was performed on 24-12-2020 while API verification studies were performed on 26-12-2020. Justify how the testing of drug substance was carried prior to verification studies.	We have retested the drug substance and verification studied according to ICH guideline lot number 19AK00006 was performed on March 2020. Again we have retested and reverification study performed. Intra- day precision was performed on next day
6.	The COA of API lot number 19AK00006 specifies the retest date as March 2020 while you have performed API testing on 24-12-2020 (almost 9 months after the API retest period). Justify how you have used an API which have exceeded its limit of use as specified by its manufacturer.	We have retested the drug substance lot number 19AK00006 was performed on March 2020. According to API stability study provided by manufacturer. This salt is stable for 2 year on basis of stability study. We have again retested the drug substance in December 2020 before manufacturing trial batches of Ziltan 40 and 80 mg tablet
7.	As per the product review documents issued by USFDA, the drug product is practically insoluble in acidic and neutral aqueous solutions and is unstable in aqueous solution between pH 1 and pH 7. Data from other	We have reviewed comparative dissolution profile. Azilsartan is unstable in 0.1 HCL solution and 4.5 acetate buffer the result in 0.1 N HCL solution 32 to 35% of both Welmark and innovator product and result were found 35 to 40% in 4.5 acetate buffer in 45 minutes

	manufacturers as well as innovator's product shows very less drug release in 0.1 N HCl as well as 4.5 phosphate acetate buffer. Justify your results showing more than 60% results at 10 minutes in both of these medias.	
8.	Justify the dissolution specifications NLT 75% in 45 minutes without specifying the value of Q as well as adopting 45 minutes for dissolution test contrary to that recommended by USFDA for the innovator's product.	FDA has approved up to 45 minutes for dissolution but our product is dissolved before 30 min. We have reviewed time limit for dissolution. Our specification is the valu of (Q) NLT 75% in 30 minutes.
9.	Your sample and standard solution concentration is 0.25mg/ml, while in detection limit and quantitation limit test your results are 90% - 110% which does not specify result of this test, furthermore justify the performance of this test as per ICH guidelines including interpretation of results of this test.	The limit of detection (LOD) and limit of quantitation (LOQ) is 0.0155% and 0.0062% respectively
10.	Justify why the peak for fumaric acid is not observed during the stability studies since fumaric acid is included in the formulation.	We have used fumaric acid in very small quantity in formulation and very small peak observed in 3 minutes
11.	Azilsartan base is identified as an impurity in azilsartan medoxomil and the peak for azilsartan is also observed in HPLC analysis. Clarify why azilsartan base is not observed in any analysis during stability studies.	Azilsaratan base impurity is shown in our chromatogram and it lies with in the limits.
12.	Justify the dispensing of 85.360mg API in each tablet since each tablet is claimed to contain 80mg Azilsartan medoxomil.	Azilsartan Medoxomil as potassium …..80mg (Innovators spec) documents of formulation and calculation of potassium factor are submitted.

Decision of 326th meeting of Registration Board:

Deferred for following submissions:

- Submission of full fee of registration for pre-approval change in label claim/ master formula as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
- Scientific justification for adapting isocratic elution with run time upto 10 minutes for analysis of drug substance, since the drug substance manufacturer has specified a gradient elution system with a run time upto 40 minutes.
- Justify the analysis of drug substance prior to the performance of verification studies of analytical method of drug substance.
- Scientific justification for the use of an API which have exceeded its limit of use as specified by its manufacturer, since you have used API lot number 19AK00006 on 24-12-2020, while the drug substance manufacturer has specified the retest date as March 2020.
- Scientific justification for the dissolution specifications NLT 75% in 45 minutes without specifying the value of Q as well as adopting 45 minutes for dissolution test contrary to that recommended by USFDA for the innovator's product.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm

1.	Submission of full fee of registration for pre-approval change in label claim/ master formula as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	Firm has submitted full fee of registration for pre-approval change in label claim/ master formula
2.	Scientific justification for adapting isocratic elution with run time upto 10 minutes for analysis of drug substance, since the drug substance manufacturer has specified a gradient elution system with a run time upto 40 minutes.	We have used the gradient method of analysis for drug substance provided by the drug substances manufacturer with a run time upto 40 minutes. Firm has also submitted copy of the specifications along with chromatograms for analysis of drug substance.
3.	Justify the analysis of drug substance prior to the performance of verification studies of analytical method of drug substance.	API verification studies were performed on 23-12-2020. However the report was signed on 26-12-2020, the actual analysis and verification studies have been performed on 23-12-2020, the firm has also submitted chromatograms of verification studies conducted on 23-12-2020.
4.	Scientific justification for the use of an API which have exceeded its limit of use as specified by its manufacturer, since you have used API lot number 19AK00006 on 24-12-2020, while the drug substance manufacturer has specified the retest date as March 2020.	We received azilsartan raw material sample on 10-07-2019 and tested it on 17-07-2019 and again we retested the drug substance in December 2020 before manufacturing of trial batches of Azilsartan 40mg and 80mg. The drug substance is stable for 2 years as evident from the stability studies.
5.	Scientific justification for the dissolution specifications NLT 75% in 45 minutes without specifying the value of Q as well as adopting 45 minutes for dissolution test contrary to that recommended by USFDA for the innovator's product.	The firm has now revised the dissolution specifications to NLT 75% (Q) in 30 minutes. Firm has also submittedresults of dissolution test for their batches at 24th month time point in which the results complied the acceptance criteria.

Decision: Deferred for clarification from the drug substance manufacturer whether the drug substance can be used after the lapse of 1 month from the retest date.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability GMP Inspection Report Date & Remarks
331	M/s Welmark Pharmaceuticals Plot # 122 Block-B, Phase-V, Industrial Estate Hattar.	ZILTAN 40mg Tablet Each tablet contains: Azilsartan medoxomil potassium eq to Azilsartan medoxomil…… 40mg (Angiotensin Receptor Blocker) In-house specifications	Form 5-D Dy No. 16469 07-03-2019 PKR. 20,000/- (06-03-2019) + PKR 55,000/- (08-02-2022) As per SRO	Approved by USFDA Firm has submitted copy of GMP certificate dated 23-11-2021 issued based on inspection dated 11-11-2021.

Remarks of Evaluator:

- The firm has submitted stability study data along with required documents as per checklist approved in 293rd meeting of Registration Board. Details of submitted data are as under:

(Dy.# 3623 dated 08-02-2022)				
STABILITY STUDY DATA				
Manufacturer of API		CTX Lifesciences Pvt Ltd. Block No. 251-252, Sachin Magdalla Road G.I.D.C, Sachin Surat Gujrat India		
API Lot No.		19AK00006		
Description of Pack (Container closure system)		Alu-Alu blister foil with unit carton		
Stability Storage Condition		Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 65% ± 5%RH		
Time Period		Accelerated: 6 Months Real Time: 6 Months		
Frequency		Real Time: 0,3 & 6 (months) Accelerated: 0,3, 6 (months)		
Batch No.		T022	T023	T024
Batch Size		1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date		03-2021	03-2021	03-2021
Date of Initiation		15-03-2021	16-03-2021	17-03-2021
No. of Batches		03		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT				
1.	Reference of previous approval of applications with stability study data of the firm	Last PSI was conducted for Dapzin Tablet, for which the inspection was conducted on 27-04-2021 and the report was presented in 307th meeting of Registration Board. The report confirms following points: • The HPLC software is 21CFR compliant. • Firm has demonstrated audit trail reports of testing.		
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted copy of COA of the drug substance from both API Manufacturer and Finished Product manufacturer.		
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Firm has submitted copy of method used for analysis of API from both API Manufacturer and Finished Product manufacturer		
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 5°C ± 3°C for 24 months.		
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of Retention of License (No. G/25/1723) dated 29-01-2021 issued by Food and Drugs Control Administration Gujrat State India. The certificate specifies that the license to manufacture has been retained from 24/01/2021 to 23/01/2026.		
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice cleared dated 16-052-2019 specifying 0.540Kg Azilsartan medoxomil potassium. The invoice is cleared by AD (I&E) DRAP.		

7.	Protocols followed for conduction of stability study	Firm has submitted protocols followed for conduction of stability study
8.	Method used for analysis of FPP	Firm has provided detailed method for analysis of FPP
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same excipients as that of the innovator's product therefore compatibility studies are not required
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the batches
11.	Record of comparative dissolution data (where applicable)	Firm has submitted CDP results of their product against the innovator's product Edarbi Tablet 40mg.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted documents like chromatograms, raw data sheets, COA, summary data sheets for the stability studies
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Audit trail report is not submitted by the firm.
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for both stability chambers for accelerated as well as real time stability studies.

Evaluation by PEC:

Sr. No	Shortcomings communicated	Response by the firm
1.	The COA of API lot number 19AK00006 specifies the retest date as March 2020 while you have performed API testing on 24-12-2020 (almost 9 months after the API retest period). Justify how you have used an API which have exceeded its limit of use as specified by its manufacturer.	We have retested the drug substance and verification studied according to ICH guideline lot number 19AK00006 was performed on March 2020. Again we have retested and reverification study performed. Intra- day precision was performed on next day
2.	Provide comparative dissolution profile of the applied product against the innovator's product.	Comparative dissolution profile of the applied drug product against the innovators product is submitted.
3.	Justify the dissolution specifications NLT 75% in 45 minutes without specifying the value of Q as well as adopting 45 minutes for dissolution test contrary to that recommended by USFDA for the innovator's product.	FDA has approved up to 45 minutes for dissolution but our product is dissolved before 30 min. We have reviewed time limit for dissolution. Our specification is the valu of (Q) NLT 75% in 30 minutes
4.	Justify why the peak for fumaric acid is not observed during the stability studies since fumaric acid is included in the formulation.	We have used fumaric acid in very small quantity in formulation and very small peak observed in 3 minutes
5.	Azilsartan base is identified as an impurity in azilsartan medoxomil and the peak for azilsartan is also observed in HPLC analysis. Clarify why azilsartan base is not observed in any analysis during stability studies.	Azilsaratan base impurity is shown in our chromatogram and it lies with in the limits
6.	Submit BMR of three stability batches.	Firm has submitted BMR of three stability batches.
7.	Provide audit trail report on product testing as compliance Record of HPLC software 21CFR compliance.	Audit trail report is not submitted by the firm.

Decision of 326th meeting of Registration Board:

Deferred for following submissions:

- Submission of full fee of registration for pre-approval change in label claim/ master formula as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
- Scientific justification for adapting isocratic elution with run time upto 10 minutes for analysis of drug substance, since the drug substance manufacturer has specified a gradient elution system with a run time upto 40 minutes.
- Justify the analysis of drug substance prior to the performance of verification studies of analytical method of drug substance.
- Scientific justification for the use of an API which have exceeded its limit of use as specified by its manufacturer, since you have used API lot number 19AK00006 on 24-12-2020, while the drug substance manufacturer has specified the retest date as March 2020.
- Scientific justification for the dissolution specifications NLT 75% in 45 minutes without specifying the value of Q as well as adopting 45 minutes for dissolution test contrary to that recommended by USFDA for the innovator's product.

Response by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	Submission of full fee of registration for pre-approval change in label claim/ master formula as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	Firm has submitted full fee of registration for pre-approval change in label claim/ master formula
2.	Scientific justification for adapting isocratic elution with run time upto 10 minutes for analysis of drug substance, since the drug substance manufacturer has specified a gradient elution system with a run time upto 40 minutes.	We have used the gradient method of analysis for drug substance provided by the drug substances manufacturer with a run time upto 40 minutes. Firm has also submitted copy of the specifications along with chromatograms for analysis of drug substance.
3.	Justify the analysis of drug substance prior to the performance of verification studies of analytical method of drug substance.	API verification studies were performed on 23-12-2020. However the report was signed on 26-12-2020, the actual analysis and verification studies have been performed on 23-12-2020, the firm has also submitted chromatograms of verification studies conducted on 23-12-2020.
4.	Scientific justification for the use of an API which have exceeded its limit of use as specified by its manufacturer, since you have used API lot number 19AK00006 on 24-12-2020, while the drug substance manufacturer has specified the retest date as March 2020.	We received azilsartan raw material sample on 10-07-2019 and tested it on 17-07-2019 and again we retested the drug substance in December 2020 before manufacturing of trial batches of Azilsartan 40mg and 80mg. The drug substance is stable for 2 years as evident from the stability studies.
5.	Scientific justification for the dissolution specifications NLT 75% in 45 minutes without specifying the value of Q as well as adopting 45 minutes for dissolution test contrary to that recommended by USFDA for the innovator's product.	The firm has now revised the dissolution specifications to NLT 75% (Q) in 30 minutes. Firm has also submittedresults of dissolution test for their batches at 24th month time point in which the results complied the acceptance criteria.

Decision: Deferred for clarification from the drug substance manufacturer whether the drug substance can be used after the lapse of 1 month from the retest date.

332.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nagarsons Pharmaceuticals. Plot No. 34, St. No. NS-2, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s EG Pharmaceuticals, 13/A Industrial Triangle Kahuta Road, Islamabad.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver) Firm has submitted copy of contract manufacturing agreement with applicant firm dated 24-02-2021.
	GMP status of the firm	Firm has submitted copy of inspection report of M/s EG Pharmaceuticals dated 13-02-2019 recommending the renewal of DML.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML (No. 000752) dated 29-08-2012 specifying capsule (cephalosporin) section.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 23181: 25-08-2021
	Details of fee submitted	PKR 75,000/-: 21-06-2021
	The proposed proprietary name / brand name	**CEFINAG 400mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule Contains: Cefixime (as trihydrate)……400mg
	Pharmaceutical form of applied drug	Sterile clear and colourless oily solution filled in glass ampoules
	Pharmacotherapeutic Group of (API)	Cephalosporin Antibiotic
	Reference to Finished product specifications	JP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Cefixime 400mg capsule **(MHRA** Approved)
	For generic drugs (me-too status)	Cefim Capsule by Hilton
	Name and address of API manufacturer.	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone, Port Qasim, Karchi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.

	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	
	Module-III Drug Product:	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	

STABILITY STUDY DATA

Manufacturer of API			
API Lot No.			
Description of Pack (Container closure system)			
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.			
Batch Size			
Manufacturing Date			
Date of Initiation			
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Evaluation by PEC:

- The application for contract manufacturing from M/s EG Pharmaceuticals Islamabad is not submitted as per the guidance document approved by Registration Board. The submitted application is in variation to the guidance document in module 1 and various sections of module 3. The submitted COA of drug substance, batch analysis report of drug product and stability study data of drug product is not in line with the recommendations of Registration Board and as per the guidance document.
- The drug product testing has been carried out using specifications which are not in line with the specifications of cefixime capsule approved by Registration Board, furthermore the firm has carried out dissolution testing using UV method and the assay test during stability studies are also carried out using a single chromatogram of standard and sample.
- Therefore, you are advised to resubmit your application compiled in the light of the guidance document approved by Registration Board in which product development and stability studies has been conducted as per the monograph approved by Registration Board and notified vide No.F.14-1/2022-PEC dated 14-03-2022 along with submission of requisite fee so that further evaluation of your application could be carried out.

Decision of 323rd meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response by the firm: Firm has submitted data as per Guidance document, the detail of which is as under

Name and address of API manufacturer.	Saakh Pharma (Pvt) Ltd. C-7/1, North Western Industrial Zone, Port Qasim, Karchi.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability data of 3 batches of API at accelerated and real time conditions
Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has also submitted results of comparative dissolution profile of their product with Fixval Capsule of M/s GSK. Firm has performed CDP in 0.1 N HCl, buffer pH 4.5 and phosphate buffer pH 6.8. Firm also calculated factor f2 which was above 50. The firm has submitted results and comparison of Fixval Capsule, manufactured by M/s GSK and Ficx Capsule of M/s EG. Test results of this study found satisfactory, comparable and within specifications.
Analytical method validation/verification of product	Firm has submitted analytical method validation data.

STABILITY STUDY DATA

Manufacturer of API	SAAKH PHARMA (Pvt)Ltd C-7/1,NWIZ,Port Qasim Karachi		
API Lot No.	8CF10131,18CF10111,18CF10039		
Description of Pack (Container closure system)	Alu-Alu blister in unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	961	990	933
Batch Size	3500 Packs	4370 Packs	4000 Packs
Manufacturing Date	03-2019	04-2019	02-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate 039/2019-DRAP (K) issued by the DRAP has been submitted. Which is valid up to 03-01-2020
3.	Documents for the procurement of API with approval from DRAP (in case of import).	N/A As API Purchased from Saakh Pharma (Pvt)Ltd C-7/1,NWIZ, Port Qasim Karachi
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Yes
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	NA
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Yes

Evaluation by PEC:

The same formulation of cefixime 400mg capsule manufactured by M/s EG Pharmaceuticals have been approved by Registration Board in its 296th meeting as a case of "*Request for Change in Registration Status of Product from M/s Swat Pharmaceuticals to M/s Wahabsons Pharma (Pvt) Ltd. Swat Through Contract Manufacturing at M/s EG Pharmaceuticals, Islamabad*".

Applicant firm	M/s Wahab sons pharma Pvt Ltd 4km Buner Road Barikot Swat
Manufacturer firm	EG Pharmaceuticals 13A Industrial Triangle, Kahuta road Islamabad
Brand Name	Soxime Capsules 400mg
Batch No. of drug product	961 (3500 Packs), 990 (4370 Packs), 933 (4000 Packs)
Case No.	1
Page number	2461-2463
Registration Board meeting	296th meeting of Registration Board.

Decision: Approved.
Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.

Case No. 03 Registration applications of imported products applied on Form-5A

a) New cases

333		
	Name and address of Applicant	**M/s Revive Healthcare, Office 503, 5th Floor, 6 Main Gulberg Jail Road, Lahore.**
	Detail of Drug Sale License	**Address:** Office 503, 5th Floor, Eden Heights, 6 Main Gulberg Jail Road, Lahore. **Validity: 21-05-2027** **Status:** License to sell drugs as distributor
	Name and address of manufacturer	United Biotech (Pvt) Ltd. Baghbania Baddi Nalagarh Road, District Solan, Himachal Pradesh, India.
	Name and address of marketing authorization holder	United Biotech (Pvt) Ltd. Baghbania Baddi Nalagarh Road, District Solan, Himachal Pradesh, India.
	Name of exporting country	India
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No. 16463: 07-03-2019
	Fee including differential fee	PKR 50,000/-: 07-03-2019
	Brand Name +Dosage Form + Strength	FLUDABINE 50 powder for injection
	Composition	Each vial contains: Fludarabine phosphate…….50mg
	Finished Product Specification	USP
	Pharmacological Group	Anticancer
	Shelf life	24 months
	Demanded Price	As per SRO
	Pack size	1's vial
	International availability	Fludarabine 50 mg powder for solution for injection or infusion (**MHRA** Approved)
	Me-too status	Fludara 50Mg Powder For Solution For Injection/Infusion by Sanofi Aventis

	Detail of certificates attached	• Firm has submitted attested, legalized CoPP (No. HFW-H(DRUGS) 427/05/21-116) issued by state drugs controller, licensing authority cum controlling authority Baddi, District Solan Himachal Pradesh India valid up to 22-02-2024 confirming free sale and GMP of the manufacturer. • Firm has submitted copy of authorization letter dated 29-12-2022 between United Biotech Limited and Revice Healthcare.

Remarks of the Evaluator.

Sr. No	Shortcomings	Response by the firm
1.	Submit Drug Sale License of the importer / applicant firm.	Firm has submitted copy of valid DSL
2.	Submit pack size of the applied product.	1's vial
3.	Submit stability study data of 3 batches of drug product as per zone IV-A conditions since the submitted data is as per zone II.	Firm has submitted stability data sheet of 3 batches at real time and accelerated conditions as per zone IV-A conditions. The real time stability data is till 24 months
4.	Submit notarized / legalized sole agency agreement.	Firm has submitted copy of authorization letter dated 29-12-2022 between United Biotech Limited and Revice Healthcare.

Decision: Approved as per Policy for inspection of Manufacturer abroad and verification of local storage facility.

334.	**Name and address of Applicant**	**M/s Revive Healthcare, Office 503, 5th Floor, 6 Main Gulberg Jail Road, Lahore.**
	Detail of Drug Sale License	**Address:** Office 503, 5th Floor, Eden Heights, 6 Main Gulberg Jail Road, Lahore. **Validity: 21-05-2027** **Status:** License to sell drugs as distributor
	Name and address of manufacturer	United Biotech (Pvt) Ltd. Baghbania Baddi Nalagarh Road, District Solan, Himachal Pradesh, India.
	Name and address of marketing authorization holder	United Biotech (Pvt) Ltd. Baghbania Baddi Nalagarh Road, District Solan, Himachal Pradesh, India.
	Name of exporting country	India
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No. 16464: 07-03-2019
	Fee including differential fee	PKR 50,000/-: 07-03-2019
	Brand Name +Dosage Form + Strength	DAUNORUBITEC 20mg/vial powder for injection
	Composition	Each vial contains: Daunorubicin HCl eq to Daunorubicin…….20mg
	Finished Product Specification	USP
	Pharmacological Group	Anticancer
	Shelf life	24 months
	Demanded Price	As per SRO
	Pack size	1's vial
	International availability	Daunorubicin 20mg Powder for I.V. Injection (**MHRA** Approved)
	Me-too status	Danolem 20mg Injection by Getz pharma
	Detail of certificates attached	• Firm has submitted attested, legalized CoPP (No. HFW-H(DRUGS) 427/05/21-109) issued by state drugs controller, licensing authority cum controlling authority Baddi, District Solan Himachal Pradesh India valid up to 22-02-2024 confirming free sale and GMP of the manufacturer.

Remarks of the Evaluator.

Sr. No	Shortcomings	Response by the firm
1.	Submit Drug Sale License of the importer / applicant firm.	Firm has submitted copy of valid DSL
2.	Submit pack size of the applied product.	1's vial
3.	Submit notarized / legalized sole agency agreement.	Firm has submitted copy of authorization letter dated 29-12-2022 between United Biotech Limited and Revice Healthcare.
4.	Firm has performed real time stability studies at 5°C ± 3°C while the reference product has recommended the storage conditions to store at room temperature (below 25°C).	It was a typo mistake. Now long term stability data provided as per zone IV-A.

Decision: The board deferred the case for clarification as how typo mistake occurred in complete stability study data of the drug product.

Agenda of Evaluator PEC-IV

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

a. New cases

335.	Name, address of Applicant / Marketing Authorization Holder	M/s Getz Pharma (Pvt.) Limited 29-30/27, Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s Getz Pharma (Pvt.) Limited 29-30/27, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3727 dated 09-02-2022
	Details of fee submitted	PKR 75,000/-: Deposit slip # 0776568103
	The proposed proprietary name / brand name	URSOVA Tablets 250mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Ursodeoxycholic Acid (Ursodiol) …250mg
	Pharmaceutical form of applied drug	Red colored, oblong shaped, biconvex film- coated tablet, bisect line on one side and plain on other side.
	Pharmacotherapeutic Group of (API)	Bile acids and derivatives
	Reference to Finished product specifications	USP Specs.
	Proposed Pack size	10's
	Proposed unit price	Rs. 750/- (10's)
	The status in reference regulatory authorities	URSO Forte Tablets 250mg by M/s Allergan USA Inc., USA. USFDA Approved.

	For generic drugs (me-too status)	Not Applicable
	GMP status of the Finished product manufacturer	Last GMP Inspection dated 17-01-2023 concludes as 'GOOD' based on continuous improvement of current GMP levels. Tablet (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	Zhejiang Warrant Pharmaceutical Co., Ltd. Workshop 1 , No. 4290, Xingbin Road, Binhai Industrial Zone, Keqiao District, Shaoxing, Zhejiang, P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Ursodeoxycholic Acid (Ursodiol) is present in EP pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 18 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (UDCA-II-20191101, UDCA-II-20191108, UDCA-II-20191202)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the 'Urso 250 Tablet 250mg' by M/s Allergan USA, Inc. (Manufactured in Canada) by performing quality tests (Appearance, Average Weight, Assay & Dissolution). CDP has been performed against 'Urso 250 Tablet 250mg' by M/s Allergan USA, Inc. (Manufactured in Canada) in Acidic media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The f2 values are in the acceptable range.
	Analytical method validation/verification of product	Method Verification studies have submitted including system suitability, linearity, range,

		accuracy, precision, specificity and stability of solution.

STABILITY STUDY DATA			
Manufacturer of API	Zhejiang Warrant Pharmaceutical Co., Ltd. Workshop 1 No. 4290, Xingbin Road, Binhai Industrial Zone, Keqiao District, Shaoxing, Zhejiang, P.R. China.		
API Lot No.	UDCA-II-20191218 (CA20191218)		
Description of Pack (Container closure system)	Alu-PVDC blister packed in unit carton (10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12 (Months)		
Batch No.	538DS01	538DS02	538DS03
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	09.06.2020	29.06.2020	29.06.2020
Date of Initiation	21.07.2020	21.07.2020	21.07.2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product Estine (Ebastine) tablets 10mg & 20mg which was conducted on 06th May 2019 and was presented in 289th meeting of Registration Board held on 14th -16th May 2019. The case was approved and the inspection report confirms following points: • The HPLC software is 21CFR Compliant as per record available with the firm. • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well. • Related manufacturing area, equipment, personnel and utilities are GMP compliant.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of Drug Manufacturing License no. Zhe 20070479 issued by Zhejiang Provincial Drug Administration valid till 11-05-2026.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of, invoice (invoice# 20ATGZ046) dated 02-04-2020 cleared by DRAP Karachi office dated 14-04-2020 specifying import of Ursodeoxycholic Acid 7.50Kg (Batch# CA20191218s).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator:		
Decision: Approved with USP specifications. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
336.	Name, address of Applicant / Marketing Authorization Holder	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5388 dated 25-02-2022
	Details of fee submitted	PKR 75,000/-: Deposit slip # 0322632792
	The proposed proprietary name / brand name	Orinin 12.5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Omarigliptin…….12.5mg
	Pharmaceutical form of applied drug	Film coated Tablet
	Pharmacotherapeutic Group of (API)	Dipeptidyl-Peptidase IV Inhibitors (Antidiabetic)
	Reference to Finished product specifications	Innovator specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Marizev 12.5mg Tablet by M/s MSD K.K, PMDA Approved.
	For generic drugs (me-too status)	OMARIL 12.5mg Tablet by M/s Genix Pharma Pvt. .Ltd**., Registration Letter not issued**
	GMP status of the Finished product manufacturer	cGMP certificate on the basis of Evaluation conducted on 18-06-2022 and valid for two (02) years
	Name and address of API manufacturer.	M/s Chifeng Arker Pharmaceutical Technology Co., Ltd. No.8 Mysun street, hongshan Economic development Zone, chifeng, Inner Mongolia, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers,

		description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Omarigliptin is not present in any pharmacopeia. The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (OMG20160101, OMG20160102, OMG20160201)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Marizev 12.5mg tablets by MSD company limited Tokyo Japan, by performing quality tests (Physical Appearance, identification, Average weight, Disintegration Time, Assay). CDP has been performed against the same brand that is Marizev 12.5mg tablets by MSD company limited Tokyo Japan, in Acid media (pH 1.0-1.2) Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptablerange.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s Chifeng Arker Pharmaceutical Technology Co., Ltd. No.8 Mysun street, hongshan Economic development Zone, chifeng, Inner Mongolia, China
API Lot No.	D85-200401
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×10's)
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Period	Real time: 6 months Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.	OPL-001	OPL-002
Batch Size	5000 Tablets	5000 Tablets
Manufacturing Date	07-2020	07-2020
Date of Initiation	29-07-2020	29-07-2020
No. of Batches	03	

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of Drug Manufacturing License no. 20160053 issued by Inner Mongolia Drug Administration valid till 28-12-2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of, invoice (invoice# PSPW-200401) dated 16-04-2020 cleared by DRAP Islamabad office dated 23-04-2020 specifying import of Omarigliptin 0.450Kg (Batch# D85-200401)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted Data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator:

S.No	Section	Shortcomings Communicated	Reply
1.	3.2.S.1	Specify the exact crystal form of the drug substance / API used in the stability study, since the innovator product have revealed that this drug substance have 5 crystal forms with different stability and Solubility	The drug substance was used in pharmaceutical manufacturing having crystalline form I.
2.	3.2.P.5.2	Scientific justification for dissolution parameters including type of apparatus, speed and dissolution medium is required.	The dissolution parameters were selected by taking into account of USP chapter <1092> "The dissolution Procedure: Development and validation" for immediate release tablet i.e., 1. Apparatus II (Paddle) 2. Speed 75 RPM as per USP" For immediate-releasecapsule or tablet formulations, Apparatus 1 (baskets) at 50-100 rpm or Apparatus2 (paddles) at 50 or

			75 rpm are used commonly". 3. 0.1 Hydrochloric acid is used as medium

Decision: Approved with innovator's specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

337.	Name, address of Applicant / Marketing Authorization Holder	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5389 dated 25-02-2022
	Details of fee submitted	PKR 75,000/-: Deposit slip # 9337069664
	The proposed proprietary name / brand name	Orinin 25mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Omarigliptin…….25mg
	Pharmaceutical form of applied drug	Film coated Tablet
	Pharmacotherapeutic Group of (API)	Dipeptidyl-Peptidase IV Inhibitors (Antidiabetic)
	Reference to Finished product specifications	Innovator specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Marizev 25mg Tablet by M/s MSD K.K, PMDA Approved.
	For generic drugs (me-too status)	OMARIL 25mg Tablet by M/s Genix Pharma Pvt. .Ltd**., Registration Letter not issued**
	GMP status of the Finished product manufacturer	cGMP certificate on the basis of Evaluation conducted on 18-06-2022 and valid for two (02) years
	Name and address of API manufacturer.	M/s Chifeng Arker Pharmaceutical Technology Co., Ltd. No.8 Mysun street, hongshan Economic development Zone, chifeng, Inner Mongolia, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Omarigliptin is not present in any pharmacopeia. The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (OMG20160101, OMG20160102, OMG20160201)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Marizev 25mg tablets by MSD company limited Tokyo Japan, by performing quality tests (Physical Appearance, identification, Average weight, Disintegration Time, Assay). CDP has been performed against the same brand that is Marizev 12.5mg tablets by MSD company limited Tokyo Japan, in Acid media (pH 1.0-1.2) Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s Chifeng Arker Pharmaceutical Technology Co., Ltd. No.8 Mysun street, hongshan Economic development Zone, chifeng, Inner Mongolia, China
API Lot No.	D85-200401
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×10's)
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.	OPH-001	OPH-002
Batch Size	5000 Tablets	5000 Tablets
Manufacturing Date	07-2020	07-2020
Date of Initiation	31-07-2020	31-07-2020
No. of Batches	03	

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of Drug Manufacturing License no. 20160053 issued by Inner Mongolia Drug Administration valid till 28-12-2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of, invoice (invoice# PSPW-200401) dated 16-04-2020 cleared by DRAP Islamabad office dated 23-04-2020 specifying import of Omarigliptin 0.450Kg (Batch# D85-200401)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted Data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator:

S.No	Section	Shortcomings Communicated	Reply
1.	3.2.S.1	Specify the exact crystal form of the drug substance / API used in the stability study, since the innovator product have revealed that this drug substance have 5 crystal forms with different stability and Solubility	The drug substance was used in pharmaceutical manufacturing having crystalline form I.
2.	3.2.P.5.2	Scientific justification for dissolution parameters including type of apparatus, speed and dissolution medium is required.	The dissolution parameters were selected by taking into account of USP chapter <1092> "The dissolution Procedure: Development and validation" for immediate release tablet i.e., 1. Apparatus II (Paddle) 2. Speed 75 RPM as per USP" For immediate-releasecapsule or tablet formulations, Apparatus 1 (baskets) at 50-100 rpm or Apparatus2 (paddles) at 50 or 75 rpm are used commonly". 3. 0.1 Hydrochloric acid is used as medium

Decision: Approved with innovator's specification.

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
338.	Name, address of Applicant / Marketing Authorization Holder	M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Name, address of Manufacturing site.	M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4304 dated 15-02-2022
	Details of fee submitted	PKR 30,000/-: Deposit slip # 08293489
	The proposed proprietary name / brand name	Empaglif 25mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…….25mg
	Pharmaceutical form of applied drug	Film coated Tablet
	Pharmacotherapeutic Group of (API)	Antidiabetic (Sodium-glucose cotransporter 2 (SGLT2) inhibitors)
	Reference to Finished product specifications	Innovator specifications
	Proposed Pack size	7's, 14's, 20's, 28's , 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	JARDIANCE tablets of Boehringer Ingelheim by (USFDA) approved
	For generic drugs (me-too status)	Empator Tablet 25mg by M/s Martin Dow (Reg# 098823)
	GMP status of the Finished product manufacturer	Last inspection report dated 18-02-2022 which concludes that panel recommends the renewal of DML.
	Name and address of API manufacturer.	M/s Jiangsu Yongan Pharmaceutical Co., Limited Address: No. 18,237 Provincial Road, Economic Development Zone, Huaian, Jiangsu, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure

		system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Empagliflozin is not present in any Pharmacopeia. The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (130701, 130702, 130801)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the JARDIANCE Tablet 25mg by Boehringer Ingelheim by performing quality tests (Physical Appearance, identification, Disintegration Time, Assay). CDP has been performed against the same brand that JARDIANCE Tablet 25mg by Boehringer Ingelheim, in Acid media (pH 1.0-1.2) Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Jiangsu Yongan Pharmaceutical Co., Limited Address: No. 18,237 Provincial Road, Economic Development Zone, Huaian, Jiangsu, China.		
API Lot No.	4500-201909001		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-0001TAB	T-0002TAB	T-0003TAB

Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	17-01-2020	14-02-2020	14-02-2020
Date of Initiation	13-07-2020	13-07-2020	13-07-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No # JS2020921 of M/s Jiangsu Yongan Pharmaceutical Co. Ltd., China issued by Jiangsu Drugs Administration, China. The certificate is valid till 20-09-2025 Copy of Drug Manufacturing License no. Su 20160324 issued by Jiangsu Drug Administration (Huai'an Inspection Branch) valid till 06-12-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of, invoice (invoice# ZY19101701G/W) dated 17-10-2019 cleared by DRAP Islamabad office dated 24-10-2019 specifying import of Empagliflozin 500g (Batch# 4500-201909001)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted Data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator:

S.No	Section	Shortcomings Communicated	Reply
1.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Copy of BMR's for all the batches of drug product for which stability data is provided are submitted.
2.	3.2.S.4.1	Copies of the Drug substance specifications of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Copy of Drug Substance specifications of API by Drug Product manufacturer are submitted.
3.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Copy of Analytical procedures of API by Drug Product manufacturer are submitted..
4.	3.2.P.8	• Documents for the procurement of API with approval from DRAP. • Manufacturing of batch # T-0001TAB is done in January	• Document for procurement of API with approval from DRAP are submitted.. • The batches were stored in controlled environment of production quarantine area before testing. After testing and

		2020,and Batch # T-0002TAB and Batch # T-0003TAB2020 is done in February. Initial testing is conducted in march 2020 while stability studies started in July. justify where batch were stored before initial testing and before placement in stability chamber.	before placement in stability chamber, the sample was stored in controlled environment of QC sample retained area.

Decision: Approved with innovator's specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

339.	Name, address of Applicant / Marketing Authorization Holder	M/s Lucky Core Industries Limited (Formerly M/s ICI Pakistan Limited.) 32/2A Phase III, Industrial Estate Hattar Pakistan
	Name, address of Manufacturing site.	M/s Lucky Core Industries Limited (Formerly M/s ICI Pakistan Limited.) 32/2A Phase III, Industrial Estate Hattar Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5381 dated 25-02-2022
	Details of fee submitted	PKR 30,000/-: Deposit slip # 63153831454
	The proposed proprietary name / brand name	Ropizam 1mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ropinirole as HCl…….1mg
	Pharmaceutical form of applied drug	Film coated Tablet
	Pharmacotherapeutic Group of (API)	Dopamine Antagonists
	Reference to Finished product specifications	USP
	Proposed Pack size	7 x 3's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	REQUIP (ropinirole) film coated tablets, USFDA approved.
	For generic drugs (me-too status)	Ronirol 1mg Tablet by M/s Hilton Pharma Pvt. .Ltd**.,** (Reg# 047378)
	GMP status of the Finished product manufacturer	cGMP certificate on the basis of Evaluation conducted on 18-06-2022 and valid for two (02) years
	Name and address of API manufacturer.	M/s Glenmark Lifesciences Ltd

		Plot No 3109, GIDC, Industrial Estate, Ankleshwar, District. Bharuch Gujrat state India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Ropinirole Hydrochloride is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (AB16013001, AB16013002, AB16013003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Ronirol 1mg Tablet by Hilton Pharma by performing quality tests (Physical Appearance, identification, Uniformity weight, Disintegration Time, Dissolution, Assay). CDP has been performed against the same brand that is Ronirol 1mg Tablet by Hilton Pharma, in Acid media (pH 1.0-1.2) Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s Glenmark Lifesciences Ltd Plot No 3109, GIDC, Industrial Estate, Ankleshwar, District. Bharuch Gujrat state India.
API Lot No.	802002827

Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ST1F 080	ST1F 081	ST1F 082
Batch Size	4000 Tablets	4000 Tablets	4000 Tablets
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	03-07-2021	03-07-2021	03-07-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No# 22063353ssued by Food and Drug Control Administration Gandhinagar, Gujrat state India. valid until 05-06-2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of, invoice (invoice# 6205/SR/ROW/20-21) dated 22-03-2021 specifying import of Ropinirole HCl 50g (Batch# 802002827)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted Data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator: Firm submitted Fee of Rs:30000/- Deposit slip # 43288059475 For change of Title of Firm from M/s ICI Pakistan Limited to M/s Lucky Core Industries Limited.

S.No	Section	Shortcomings Communicated	Reply
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is submitted.
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3 are attached.

3.	3.2.P.2.2.1	• 6 units of each of both test and reference product are used for CDP. Clarification is required in the light of FDA guidance for industry and EMA guidelines of comparative dissolution. • One measurement should be considered after 85% dissolution of both the products according to FDA guidance for industry and EMA guidelines of Comparative dissolution. Provide reference of time points selected. • For f2 calculations as per EMA guidelines A minimum of three time points (zero excluded) than how you have calculated f2 with two (02) time points.	• Comparative Dissolution Profiling (CDP) were performed on Dissolution Apparatus having six vessels only, thus the study was performed using six units of Test & Reference Product at the time of Development. However, dissolution apparatus having 12 vessels has been acquired and fresh study will be submitted after completion within a week time. *Now firm submitted CDP data performed using 12 units Dissolution apparatus.* • The rationale for selecting time points of sampling is as per FDA TGA & EMA guidelines and is also in compliance with 293rd minutes of DRB meeting. The guidelines suggest that for rapidly dissolving products, time interval with 5 or 10-minutes may be chosen to adequately characterize the dissolution profiles. In our case, initial sampling time point as 10minutes was chosen after a preliminary study conducted both on test & reference product and likewise, after acquiring 85% dissolution results, one measurement has been considered only, i.e., 15 minutes. • Agreed with the statement in question, the f2 cannot be calculated with two time points. According to EMA and FDA guidelines, where more than 85% of the drug is dissolved for both test and reference products within 15 min, dissolution profiles may be accepted as similar without further mathematical evaluation. However, in this case, f2 factor was not required.
4.	3.2.P.5.1	Specify which from USP monograph which dissolution test is used.	USP Dissolution Test 2 has been used.
5.	3.2.P.8	Documents for the procurement of API with approval from DRAP	Sample of Ropinirole was Free of Cost however invoice and DHL tracking is attached .

Decision: Approved with USP specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

340.	Name, address of Applicant / Marketing Authorization Holder	M/s Lucky Core Industries Limited (Formerly M/s ICI Pakistan Limited.) 32/2A Phase III, Industrial Estate Hattar Pakistan
	Name, address of Manufacturing site.	M/s Lucky Core Industries Limited (Formerly M/s ICI Pakistan Limited.) 32/2A Phase III, Industrial Estate Hattar Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5382 dated 25-02-2022
	Details of fee submitted	PKR 30,000/-: Deposit slip # 516889274915
	The proposed proprietary name / brand name	Ropizam 2mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ropinirole as Hcl…….2mg
	Pharmaceutical form of applied drug	Film coated Tablet
	Pharmacotherapeutic Group of (API)	Dopamine Antagonists
	Reference to Finished product specifications	USP
	Proposed Pack size	7 x 3's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	REQUIP (ropinirole) 2mg film coated tablets, USFDA approved.
	For generic drugs (me-too status)	Ronirol 2mg Tablet by M/s Hilton Pharma Pvt. .Ltd**.,** (Reg# 047379)
	GMP status of the Finished product manufacturer	cGMP certificate on the basis of Evaluation conducted on 18-06-2022 and valid for two (02) years
	Name and address of API manufacturer.	M/s Glenmark Lifesciences Ltd Plot No 3109, GIDC, Industrial Estate, Ankleshwar, District. Bharuch Gujrat state India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Ropinirole Hydrochloride is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months

		Batches: (AB16013001, AB16013002, AB16013003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Ronirol 2mg Tablet by Hilton Pharma by performing quality tests (Physical Appearance, identification, Uniformity weight, Disintegration Time, Dissolution, Assay). CDP has been performed against the same brand that is Ronirol 2mg Tablet by Hilton Pharma, in Acid media (pH 1.0-1.2) Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Glenmark Lifesciences Ltd Plot No 3109, GIDC, Industrial Estate, Ankleshwar, District. Bharuch Gujrat state India.		
API Lot No.	802002827		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	ST1F 083	ST1F 084	ST1F 085
Batch Size	4000 Tablets	4000 Tablets	4000 Tablets
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	04-07-2021	04-07-2021	04-07-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No# 19061427 issued by Food and Drug Control Administration Gandhinagar, Gujrat state India. issued on 18-06-2019 and valid until 17-06-2022.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of, invoice (invoice# 6205/SR/ROW/20-21) dated 22-03-2021 specifying import of Ropinirole HCl 50g (Batch# 802002827)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted Data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator: Firm submitted Fee of Rs:30000/- Deposit slip # 28085172935 For change of Title of Firm from M/s ICI Pakistan Limited To M/s Lucky Core Industries Limited.

S.No	Section	Shortcomings Communicated	Reply
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is submitted.
2.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3 are attached.
3.	3.2.P.2.2.1	• 6 units of each of both test and reference product are used for CDP. Clarification is required in the light of FDA guidance for industry and EMA guidelines of comparative dissolution. • One measurement should be considered after 85% dissolution of both the products according to FDA guidance for industry and EMA guidelines of Comparative dissolution. Provide reference of time points selected. • For f2 calculations as per EMA guidelines A minimum of three time points (zero excluded) than how you have calculated f2 with two (02) time points.	• Comparative Dissolution Profiling (CDP) were performed on Dissolution Apparatus having six vessels only, thus the study was performed using six units of Test & Reference Product at the time of Development. However, dissolution apparatus having 12 vessel has been acquired and fresh study will be submitted after completion within a week time. *Now firm submitted CDP data performed using 12 units Dissolution apparatus .* • The rationale for selecting time points of sampling is as per FDA TGA & EMA guidelines and is also in compliance with 293rd minutes of DRB meeting. The guidelines suggest that for rapidly dissolving products, time interval with 5 or 10-minutes may be chosen to adequately characterize the dissolution profiles. In our case, initial sampling time point as 10minutes was chosen after a preliminary study conducted both on test & reference product and likewise, after acquiring 85% dissolution results, one measurement has been considered only, i.e., 15 minutes.

			• Agreed with the statement in question, the f2 cannot be calculated with two time points. According to EMA and FDA guidelines, where more than 85% of the drug is dissolved for both test and reference products within 15 min, dissolution profiles may be accepted as similar without further mathematical evaluation. However, in this case, f2 factor was not required.
4.	3.2.P.5.1	Specify which from USP monograph which dissolution test is used.	USP Dissolution Test 2 has been used.
5.	3.2.P.8	Documents for the procurement of API with approval from DRAP	Sample of Ropinirole was Free of Cost however invoice and DHL tracking is attached .

Decision: Approved with USP specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

b. Deferred cases (Form 5)

341.	Name and address of manufacturer / Applicant	M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi By M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Sodium Chloride Injection 0.9%/5ml
	Composition	Each 5ml contains: Sodium chloride(B.P)……..45mg
	Diary No. Date of R& I & fee	Dy.No. 20597 dated 07-06-2018 Rs.50,000/- Dated 06-06-2018
	Pharmacological Group	Electrolyte
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	5ml : As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO recommended formulation
	Me-too status	Sacro Injection of Macter Intr. Karachi. (Reg.# 079756)
	GMP status	Panel inspection for renewal of DML of the firm conducted on 02-06-2021, wherein inter-alia following remarks given: "The panel found an adequate level of GMP compliance after thorough review of their system. Based on the stated facts and observations, production facilities, QA system, QC labs, stores, utilities and people met during inspection, the panel unanimously recommended" the grant of renewal of DML for different sections, including Capsule (General/antibiotic) section. **&**

		The firm was inspected on 24.03.2021, wherein GMP was rated as GOOD
	Remarks of the Evaluator	• In manufacturing method Sodium Bicarbonate is mentioned. Clarify • Submit Form 5 by applicant. • Contract manufacturing agreement.
	Previous Decision (M-324): Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.	
	Evaluation: **S.NO** / Reason of deferment / **Reply** 1. In manufacturing method Sodium Bicarbonate is mentioned. Clarify — Manufacturing method with correction submitted. 2. Submit Form 5 by applicant. — Form 5 submitted by applicant. 3. Contract manufacturing agreement. — Contract manufacturing agreement Submitted.	
	Decision: Approved. Firm shall submit the fee of Rs. 30,000 for revision of form 5 and correction/pre-approval in the method of manufacture as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. **Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi.**	
342.	Name and address of manufacturer / Applicant	M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi By M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Sodium Bicarbonate 5% Injection
	Composition	Each 2ml contains: Sodium Bicarbonate….100mg
	Diary No. Date of R& I & fee	Dy.No. 20596 dated 07-06-2018 Rs.50,000/- Dated 06-06-2018
	Pharmacological Group	Antacids, Antiflatulent, Electrolyte
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	2ml : As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO recommended formulation only for Reconstitution Of Artesunate Injection.
	Me-too status	Sodium Bicarbonate Injection 5% of M/s Genix Pharma
	GMP status	Panel inspection for renewal of DML of the firm conducted on 02-06-2021, wherein inter-alia following remarks given: "The panel found an adequate level of GMP compliance after thorough review of their system. Based on the stated facts and observations, production facilities, QA system, QC labs, stores, utilities and people met during inspection, the panel unanimously recommended" the grant of renewal of DML for different sections, including Capsule (General/antibiotic) section. **&** The firm was inspected on 24.03.2021, wherein GMP was rated as GOOD
	Remarks of the Evaluator	• Submit Form 5 by applicant. • Contract manufacturing agreement.

Previous Decision (M-324): Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Evaluation:

S.NO	Reason of deferment	Reply
1.	Submit Form 5 by applicant.	Form 5 submitted by applicant.
2.	Contract manufacturing agreement.	Contract manufacturing agreement submitted.

Decision: Approved. Firm shall submit the fee of Rs. 30,000 for revision of form 5 and correction/pre-approval in the method of manufacture as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.
Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi.

343.	Name and address of manufacturer / Applicant	M/s Medicraft Pharmaceuticals Pvt Ltd, Hayatabad,Peshawar.
	Brand Name +Dosage Form + Strength	Procidine Injection
	Composition	Each 2ml contains:- Procyclidine…….10mg
	Diary No. Date of R& I & fee	Dy.No. 198 dated 08-04-2013 Rs.20,000/-
	Pharmacological Group	Antimuscarinic tertiary amine
	Type of Form	Form 5
	Finished product Specification	B.P specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	Local. Epsent 10mg/2m by M/s Genetics.
	GMP status	Firm is GMP compliant as per inspection dated 29-07-2015
	Remarks of the Evaluator	Approval status in reference countries is not provided.

Previous Decision (M-324): Deferred for the confirmation of approval status by Reference regulatory authorities

Evaluation:

Approval status of product in Reference Regulatory Authorities	Kemadrin 5mg/ml Solution for injection (10mg in each 2m1 ampoule)
GMP status	Last inspection report of dated: 10-05-2022 which concludes that firm was considered to be operating at Good level of cGMP compliance and panel recommends grant of cGMP certificate for export purpose as requested by firm.

Decision: Approved.

344.	Name and address of manufacturer / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura BY M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name +Dosage Form + Strength	MC-Ethin 2mg/35mcg Tablets
	Composition	Each Film Coated Tablet Contains: Cyproterone Acetate…2mg Ethinyloestradiol…35mcg
	Diary No. Date of R& I & fee	Dy.No. 41776 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Pharmacological Group	Anti-androgen/estrogen
	Type of Form	Form -5

	Finished product Specification	Manufacturer specificartions
	Pack size & Demanded Price	3 x 7's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Co-cyprindiol 2000/35 microgram Film-coated Tablets of MHRA approved
	Me-too status	Acne-Heal Tablet by M/s OBS (Reg# 073476)
	GMP status	Last GMP inspection of Mcolson conducted on 24-10-2019, and the report concludes that the panel recommend the grant of renewal of DML by way of formulation. & Last GMP inspection of Dyson conducted on 11-01-2019, and the report concludes that the firm has satisfactory GMP compliance, hence panel recommend issuance of GMP certificate
	Remarks of the Evaluator	Tablet hormone section available (but steroidal or non steroidal not confirm and Steroidal hormone tablet section is required) Number of sections of applicant approved by Licensing Board : 05 Number of products already registered/approved on contract manufacturing in the name of applicant: 08
	Previous Decision (M-295): Deferred for confirmation whether manufacturing facility is approved for "Steroidal hormone tablets" or "Non Steroidal hormone tablets"	
	Evaluation: Firm provided letter for grant of revised section/facilities approval of dated: 22-02-2023 in which Tablet (Steroidal Hormone) section approved. **GMP status:** Last inspection report of Mcolson Research Laboratories of dated: 04-06-2022 which concludes that firm was considered to be operating at Good level of cGMP compliance. & Last inspection report of Dyson Research Laboratories of dated: 07-11-2022 which concludes that firm was considered to be operating at Satisfactory level of cGMP compliance.	
	Decision: Approved with innovator's specification.	
345.	Name and address of manufacturer / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura BY M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name +Dosage Form + Strength	MC-Day Tablets 5mg
	Composition	Each Tablet Contains: Norethisterone Acetate…5mg
	Diary No. Date of R& I & fee	Dy.No. 41774 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Pharmacological Group	Progestogen
	Type of Form	Form -5
	Finished product Specification	BP
	Pack size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Primolut N of MHRA approved
	Me-too status	Postpon-M Tablet by M/s OBS, (Reg# 073532)
	GMP status	Last GMP inspection of Mcolson conducted on 24-10-2019, and the report concludes that the panel recommend the grant of renewal of DML by way of formulation. & Last GMP inspection of Dyson conducted on 11-01-2019, and the report concludes that the firm has satisfactory GMP compliance, hence panel recommend issuance of GMP certificate

	Remarks of the Evaluator	Tablet hormone section available (but steroidal or non steroidal not confirm and Steroidal hormone tablet section is required) Number of sections of applicant approved by Licensing Board : 05 Number of products already registered/approved on contract manufacturing in the name of applicant: 08
	Previous Decision (M-295): Deferred for confirmation whether manufacturing facility is approved for "Steroidal hormone tablets" or "Non Steroidal hormone tablets"	
	Evaluation: Firm provided letter for grant of revised section/facilities approval of dated: 22-02-2023 in which Tablet (Steroidal Hormone) section approved. **GMP status:** Last inspection report of Mcolson Research Laboratories of dated: 04-06-2022 which concludes that firm was considered to be operating at Good level of cGMP compliance. & Last inspection report of Dyson Research Laboratories of dated: 07-11-2022 which concludes that firm was considered to be operating at Satisfactory level of cGMP compliance.	
	Decision: Approved with innovator's specification.	
346.	Name and address of manufacturer / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura BY M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name +Dosage Form + Strength	MC-Ster 25mg Tablets
	Composition	Each Tablet Contains: Mesterolon…25mg
	Diary No. Date of R& I & fee	Dy.No. 41773 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Pharmacological Group	Androgen (5-androstanon (3) derivative)
	Type of Form	Form -5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	2 x 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Pro-viron of MHRA approved
	Me-too status	Androviron 25mg Tablets by M/s Global Pharmaceuticals, (Reg# 030471)
	GMP status	Last GMP inspection of Mcolson conducted on 24-10-2019, and the report concludes that the panel recommend the grant of renewal of DML by way of formulation. & Last GMP inspection of Dyson conducted on 11-01-2019, and the report concludes that the firm has satisfactory GMP compliance, hence panel recommend issuance of GMP certificate
	Remarks of the Evaluator	Tablet hormone section available (but steroidal or non steroidal not confirm and Steroidal hormone tablet section is required) Number of sections of applicant approved by Licensing Board : 05 Number of products already registered/approved on contract manufacturing in the name of applicant: 08
	Previous Decision (M-295): Deferred for confirmation whether manufacturing facility is approved for "Steroidal hormone tablets" or "Non Steroidal hormone tablets"	
	Evaluation: Firm provided letter for grant of revised section/facilities approval of dated: 22-02-2023 in which Tablet (Steroidal Hormone) section approved. **GMP status:** Last inspection report of Mcolson Research Laboratories of dated: 04-06-2022 which concludes that firm was considered to be operating at Good level of cGMP compliance. &	

	Last inspection report of Dyson Research Laboratories of dated: 07-11-2022 which concludes that firm was considered to be operating at Satisfactory level of cGMP compliance.	
	Decision: Approved with innovator's specification. **Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore.**	
347.	Name and address of manufacturer / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura BY M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name +Dosage Form + Strength	MC-Lone 2.5mg Tablets
	Composition	Each Tablet Contains: Tibolone…2.5mg
	Diary No. Date of R& I & fee	Dy.No. 41775 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Pharmacological Group	Estrogens
	Type of Form	Form -5
	Finished product Specification	BP
	Pack size & Demanded Price	3 x 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Livial 2.5 mg tablets of MHRA approved
	Me-too status	Tibopause Tablets 2.5mg by M/s Zafa Pharmaceuticals (Reg# 024213)
	GMP status	Last GMP inspection of Mcolson conducted on 24-10-2019, and the report concludes that the panel recommend the grant of renewal of DML by way of formulation. & Last GMP inspection of Dyson conducted on 11-01-2019, and the report concludes that the firm has satisfactory GMP compliance, hence panel recommend issuance of GMP certificate
	Remarks of the Evaluator	Tablet hormone section available (but steroidal or non steroidal not confirm and Steroidal hormone tablet section is required) Number of sections of applicant approved by Licensing Board : 05 Number of products already registered/approved on contract manufacturing in the name of applicant: 08
	Previous Decision (M-295): Deferred for confirmation whether manufacturing facility is approved for "Steroidal hormone tablets" or "Non Steroidal hormone tablets"	
	Evaluation: Firm provided letter for grant of revised section/facilities approval of dated: 22-02-2023 in which Tablet (Steroidal Hormone) section approved. **GMP status:** Last inspection report of Mcolson Research Laboratories of dated: 04-06-2022 which concludes that firm was considered to be operating at Good level of cGMP compliance. & Last inspection report of Dyson Research Laboratories of dated: 07-11-2022 which concludes that firm was considered to be operating at Satisfactory level of cGMP compliance.	
	Decision: Approved with innovator's specification. **Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore.**	
348.	Name and address of manufacturer / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura BY M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore

	Brand Name +Dosage Form + Strength	MC-Lone 2.5mg Tablets
	Composition	MC-Nest 500mcg Tablet
	Diary No. Date of R& I & fee	Each Tablet Contains: Lynestrenol …500mcg
	Pharmacological Group	Dy.No. 41772 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Type of Form	Progestogen
	Finished product Specification	Form -5
	Pack size & Demanded Price	Manufacturer specifications
	Approval status of product in Reference Regulatory Authorities	3 x 10's: As per SRO
	Me-too status	Exluton, 0.5 mg tablet by M/s N.V. Organon (Netherland approved)
	GMP status	Last GMP inspection of Mcolson conducted on 24-10-2019, and the report concludes that the panel recommend the grant of renewal of DML by way of formulation. & Last GMP inspection of Dyson conducted on 11-01-2019, and the report concludes that the firm has satisfactory GMP compliance, hence panel recommend issuance of GMP certificate
	Remarks of the Evaluator	Tablet hormone section available (but steroidal or non steroidal not confirm and Steroidal hormone tablet section is required) Number of sections of applicant approved by Licensing Board : 05 Number of products already registered/approved on contract manufacturing in the name of applicant: 08
	Previous Decision (M-295): Deferred for confirmation whether manufacturing facility is approved for "Steroidal hormone tablets" or "Non Steroidal hormone tablets"	
	Evaluation: Firm provided letter for grant of revised section/facilities approval of dated: 22-02-2023 in which Tablet (Steroidal Hormone) section approved. **GMP status:** Last inspection report of Mcolson Research Laboratories of dated: 04-06-2022 which concludes that firm was considered to be operating at Good level of cGMP compliance. & Last inspection report of Dyson Research Laboratories of dated: 07-11-2022 which concludes that firm was considered to be operating at Satisfactory level of cGMP compliance.	
	Decision: Approved with innovator's specification. **Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore.**	
349.	Name and address of manufacturer / Applicant	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura BY M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Brand Name +Dosage Form + Strength	MC-Ges 0.02mg/0.075mg Tablets
	Composition	Each Film Coated Tablet Contains: Ethinylestradiol…0.2mg Gestodene…0.075mg
	Diary No. Date of R& I & fee	Dy.No. 41771 dated 07-12-2018 Rs.50,000/- Dated 07-12-2018
	Pharmacological Group	Hormonal contraceptives for systemic use (Progestogens and estrogens, fixed Combinations)
	Type of Form	Form -5
	Finished product Specification	Manufacturer specifications

	Pack size & Demanded Price	21's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Aidulan 20/75 microgram film-coated tablets of MHRA approved
	Me-too status	Meliane Tablets of M/s Medipharm Reg# 024076
	GMP status	Last GMP inspection of Mcolson conducted on 24-10-2019, and the report concludes that the panel recommend the grant of renewal of DML by way of formulation. & Last GMP inspection of Dyson conducted on 11-01-2019, and the report concludes that the firm has satisfactory GMP compliance, hence panel recommend issuance of GMP certificate
	Remarks of the Evaluator	Tablet hormone section available (but steroidal or non steroidal not confirm and Steroidal hormone tablet section is required) Number of sections of applicant approved by Licensing Board : 05 Number of products already registered/approved on contract manufacturing in the name of applicant: 08
	Previous Decision (M-295): Deferred for confirmation whether manufacturing facility is approved for "Steroidal hormone tablets" or "Non Steroidal hormone tablets"	
	Evaluation: Firm provided letter for grant of revised section/facilities approval of dated: 22-02-2023 in which Tablet (Steroidal Hormone) section approved. **GMP status:** Last inspection report of Mcolson Research Laboratories of dated: 04-06-2022 which concludes that firm was considered to be operating at Good level of cGMP compliance. & Last inspection report of Dyson Research Laboratories of dated: 07-11-2022 which concludes that firm was considered to be operating at Satisfactory level of cGMP compliance.	
	Decision: Approved with innovator's specification. **Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore.**	

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

a. New DML

M/s Pharman Pharmaceuticals **. (New DML)**
CLB in its 286th meeting held on 11th May 2022 has considered and approved the grant of Drug Manufacturing License by way of formulation with following three (03) sections to M/s Pharman Pharmaceuticals

1.	Tablet (General)
2.	Capsule (General)
3.	Oral Liquid Section (General)

Accordingly, firm has applied for following products for consideration by Drug Registration Board

Tablet (General)
03 Molecules/ 04 Products

350.	Name, address of Applicant / Marketing Authorization Holder	M/s Pharman Pharmaceuticals 6-km Bohmaan Baath Road, Kalasky Gujranwala, Pakistan
	Name, address of Manufacturing site.	M/s Pharman Pharmaceuticals 6-km Bohmaan Baath Road, Kalasky Gujranwala, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2395 dated 25-01-2023
	Details of fee submitted	PKR 30,000/-: Deposit slip # 3839876908
	The proposed proprietary name / brand name	CIPHARM 250mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin HCl…250mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Antibiotic (fluoroquinolone)
	Reference to Finished product specifications	USP
	Proposed Pack size	1×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ciprofloxacin 250mg film coated tablet. Manufactured M/s Aurobindo Phrma-Milpharm Ltd. MHRA Approved.
	For generic drugs (me-too status)	NOVIDAT 250mg tab by M/s Sami Pharma #011836
	GMP status of the Finished product manufacturer	New DML issued on 30/05/2022
	Name and address of API manufacturer.	Citi Pharma (Pvt.) Ltd. 3.5 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Ciprofloxacin Hydrochloride is present in USP . The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (CPH1402007, CPH1402008, CPH1402009)

	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Novidat 250mg tablet BY SAMI Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Ciprofloxacin 250mg tablet Tablet by SAMI Pharma in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Citi Pharma (Pvt.) Ltd. 3.5 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan.		
API Lot No.	CPH211111		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CP22-001	CP22-002	CP22-003
Batch Size	2000	2000	2000
Manufacturing Date	14-05-22	14-05-22	14-05-22
Date of Initiation	17-05-22	17-05-22	17-05-22
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by DRAP on the basis of Evaluation conducted on 17-12-2020 and valid for 2 years.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted Data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator: Dissolution value in all the sheets for accelerated and Real for 3 batches same i.e 98%, 98.5%, 97%

S.No	Section	Shortcomings Communicated
1.	2.3.R.1.1	Overage is used in manufacturing of stability batches without any scientific justification.
2.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.
3.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.
5.	3.2.P.1	Overage of drug substance in manufacturing of drug product without any scientific justification.
6.	3.2.S.2.2.1	Submit correct F2 calculation.
7.	3.2.P.5.4	COA's of three different batches having same values of Assay and dissolution
8.	3.2.P.6	Submit COA of reference standard Ciprofloxacin Ethylenediamine Analoge.
9.	3.2.P.8	• Purchase documents for Ciprofloxacin HCl • COA's of all time points does not match with stability summary sheets and raw data. Clarification is required. • In batch# CP22-00 and CP22-003 how value of Assay at 0 month for Real time stability studies and Accelerated stability studies are changed. Clarification is required. • Submit complete raw data for dissolution. • Raw data sheets for dissolution shows dissolution limits NLT 75% while USP states NLT 80% (Q). Clarification is required.

Firm Response:
It is submitted that we want to withdraw our product development & stability data only as the said data was mistakenly not properly arranged in order & in some cases was mixed up.
It is requested to hold the above submitted data & we will re-submit properly arranged.

Decision:

- **Registration Board acceded the firm's request of withdrawal and declared the instant application as disposed off.**
- **Registration Board decided that firm shall formulate new trial batches and submit its stability data for both accelerated and long term conditions along with full fee of registration i.e., Rs. 30,000/- for correction/pre-approval change in stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Registration Board further noted that firm's quota of priority consideration against the new DML will also be deducted in leiu of the consideration of instant application.**

351.	Name, address of Applicant / Marketing Authorization Holder	M/s Pharman Pharmaceuticals 6-km Bohmaan Baath Road, Kalasky Gujranwala, Pakistan
	Name, address of Manufacturing site.	M/S Pharman Pharmaceuticals 6-km Bohmaan Baath Road, Kalasky Gujranwala, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2396 dated 25-01-2023
	Details of fee submitted	PKR 30,000/-: Deposit slip # 701724321
	The proposed proprietary name / brand name	CIPHARM 500mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ciprofloxacin HCl…500mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Antibiotic (fluoroquinolone)
	Reference to Finished product specifications	USP
	Proposed Pack size	1×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ciprofloxacin 500mg film coated tablet. Manufactured M/s Aurobindo Phrma-Milpharm Ltd. MHRA Approved.
	For generic drugs (me-too status)	NOVIDAT 250mg tab by M/s Sami Pharma #011836
	GMP status of the Finished product manufacturer	New DML issued on 30/05/2022
	Name and address of API manufacturer.	Citi Pharma (Pvt.) Ltd. 3.5 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Ciprofloxacin Hydrochloride is present in USP . The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (CPH1402007, CPH1402008, CPH1402009)

	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Novidat 500mg tablet BY SAMI Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Ciprofloxacin 500mg tablet Tablet by SAMI Pharma in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Citi Pharma (Pvt.) Ltd. 3.5 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan.		
API Lot No.	CPH2111119		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CP22-004	CP22-005	CP22-006
Batch Size	2000	2000	2000
Manufacturing Date	14-05-22	14-05-22	14-05-22
Date of Initiation	17-05-22	17-05-22	17-05-22
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by DRAP on the basis of Evaluation conducted on 17-12-2020 and valid for 2 years.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted Data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator: Dissolution value in all the sheets for accelerated and Real for 3 batches same i.e 98%, 98.5%, 97%

S.No	Section	Shortcomings Communicated
1.	2.3.R.1.1	Overage is used in manufacturing of stability batches without any scientific justification.
2.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.
3.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.
5.	3.2.P.1	Overage of drug substance in manufacturing of drug product without any scientific justification.
6.	3.2.S.2.2.1	Submit correct F2 calculation
7.	3.2.P.5.4	COA's of three different batches having same values of Assay and dissolution
8.	3.2.P.6	Submit COA of reference standard Ciprofloxacin Ethylenediamine Analoge
9.	3.2.P.8	• Purchase documents for Ciprofloxacin HCl • COA's of all time points does not match with stability summary sheets and raw data. Clarification is required. • In batch# CP22-004 and CP22-005 how value of Assay at 0 month for Real time stability studies and Accelerated stability studies are changed. Clarification is required. • Submit complete raw data for dissolution. • Raw data sheets for dissolution shows dissolution limits NLT 75% while USP states NLT 80% (Q). Clarification is required.

Firm Response:
It is submitted that we want to withdraw our product development & stability data only as the said data was mistakenly not properly arranged in order & in some cases was mixed up.
It is requested to hold the above submitted data & we will re-submit properly arranged.

Decision:

- **Registration Board acceded the firm's request of withdrawal and declared the instant application as disposed off.**
- **Registration Board decided that firm shall formulate new trial batches and submit its stability data for both accelerated and long term conditions along with full fee of registration i.e., Rs. 30,000/- for correction/pre-approval change in stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Registration Board further noted that firm's quota of priority consideration against the new DML will also be deducted in leiu of the consideration of instant application.**

352.	Name, address of Applicant / Marketing Authorization Holder	M/S Pharman Pharmaceuticals 6-km Bohmaan Baath Road, Kalasky Gujranwala, Pakistan
	Name, address of Manufacturing site.	M/S Pharman Pharmaceuticals 6-km Bohmaan Baath Road, Kalasky Gujranwala, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2396 dated 25-01-2023
	Details of fee submitted	PKR 30,000/-: Deposit slip # 701724321
	The proposed proprietary name / brand name	PARASOL 500mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Paracetamol…500mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Analgesic and anti pyretic
	Reference to Finished product specifications	USP
	Proposed Pack size	20×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Paracetamol IPCA 500mg Tablet by IPCA Laboratories (**MHRA** Approved)
	For generic drugs (me-too status)	
	GMP status of the Finished product manufacturer	New DML issued on 30/05/2022
	Name and address of API manufacturer.	Citi Pharma (Pvt.) Ltd. 3.5 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Paracetamol is present in USP/BP . The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (PGP14-37, PGP14-38, PGP14-39)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls,

		impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Panadol 500mg capsules BY GSK Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is PARACETAMOL TABLET 500MG capsule by GSK in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Citi Pharma (Pvt.) Ltd. 3.5 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan.		
API Lot No.	PGP22-286		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PR22-001	PR22-002	PR22-003
Batch Size	2000	2000	2000
Manufacturing Date	16-05-22	16-05-22	16-05-22
Date of Initiation	13-05-22	13-05-22	13-05-22
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by DRAP on the basis of Evaluation conducted on 17-12-2020 and valid for 2 years.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator: Dissolution value in all the sheets for accelerated and Real for 3 batches same i.e 98%, 98.5%, 97%

S.No	Section	Shortcomings Communicated
1.	1.5.6	Specification claimed are USP while in Section 3.2.P.5.1 BP specifications mentioned.
2.	1.5.9	Evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form and dosage form (**film coated Tablet**) in one of the reference regulatory authority specified by Registration Board
3.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.
4.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.
5.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.
6.	3.2.S.4.4	COA limits of Assay as per USP while claimed BP Manufacturing of paracetamol in July 2022 while finished product manufactured in May 2022
7.	3.2.P.1	• Methyl paraben and Propyl paraben as preservatives in Tablet dosage form • Sugar is added in paracetamol Tablet. • Provide reference product of which Formulation followed for manufacturing.
8.	3.2.S.2.2.1	Applied as film coated tablet while pharmaceutical equivalence and CDP conducted with uncoated tablet.
9.	3.2.P.5.1	Claimed Specifications are BP while Specification limits applied are not according to BP (Specification assay, dissolution limits are as per USP but time 15 minutes) Analytical testing method is as per BP
10.	3.2.P.5.2	Analytical testing method of finished product instead of prints of monograph of paracetamol
11.	3.2.P.5.4	COA's of three different batches having same values of Assay and dissolution
12.	3.2.P.8	• Purchase documents for Paracetamol • Before manufacturing of product how stability studies initiated.(Manufacturing 16-05-22 stability initiation 13-05-22) • COA's of all time points does not match with stability summary sheets and raw data. Clarification is required. • COA's of all time points of 3 batches have same values. Clarification is required. • In stability summary sheets in all the three batches how value of Assay at 0 month Real time stability studies and Accelerated stability studies are changed. Clarification is required. • Submit Raw data for dissolution • UV spectra for assay are without dates. • All the Raw data sheets not match with summary sheets.

Firm Response:
It is submitted that we want to withdraw our product development & stability data only as the said data was mistakenly not properly arranged in order & in some cases was mixed up.
It is requested to hold the above submitted data & we will re-submit properly arranged.

Decision:

- **Registration Board acceded the firm's request of withdrawal and declared the instant application as disposed off.**
- **Registration Board decided that firm shall formulate new trial batches and submit its stability data for both accelerated and long term conditions along with full fee of registration i.e., Rs.**

	30,000/- for correction/pre-approval change in stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • **Registration Board further noted that firm's quota of priority consideration against the new DML will also be deducted in leiu of the consideration of instant application.**	
353.	Name, address of Applicant / Marketing Authorization Holder	M/S Pharman Pharmaceuticals 6-km Bohmaan Baath Road, Kalasky Gujranwala, Pakistan
	Name, address of Manufacturing site.	M/S Pharman Pharmaceuticals 6-km Bohmaan Baath Road, Kalasky Gujranwala, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2392 dated 25-01-2023
	Details of fee submitted	PKR 30,000/-: Deposit slip # 683957894
	The proposed proprietary name / brand name	Ibufen 200mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ibuprofen…200mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	NSAIDS
	Reference to Finished product specifications	USP
	Proposed Pack size	10×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ibuprofen 200 MG film coated tablet of MHRA Approved.
	For generic drugs (me-too status)	Brufen 200mg Tablet of M/s Abbott Laboratories
	GMP status of the Finished product manufacturer	New DML issued on 30/05/2022
	Name and address of API manufacturer.	Citi Pharma (Pvt.) Ltd. 3.5 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Ibuprofen is present in BP. The firm as submitted detail of nomenclature,

		structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (IB1806001, IB1806002, IB1806003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Neo-Butinal 200mg tab of Schazoo Zaka tablet by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is IBUPROFEN 500mg tablet Tablet by in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Citi Pharma (Pvt.) Ltd. 3.5 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan.		
API Lot No.	**IBP2212036**		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	BP22-001	BP22-002	BP22-003
Batch Size	2000	2000	2000
Manufacturing Date	18-05-22	18-05-22	18-05-22
Date of Initiation	21-05-22/18-05-2022	21-05-22/18-05-2022	21-05-22/18-05-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by DRAP on the basis of Evaluation conducted on 17-12-2020 and valid for 2 years.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator: Dissolution value in all the sheets for accelerated and Real for 3 batches same i.e 98%, 98.5%, 97%

S.No	Section	Shortcomings Communicated
1.	3.2.S.4.1	Copies of the drug substance specifications by Drug Product manufacturer is required.
2.	3.2.S.4.2	Analytical procedures used for routine testing of the drug substance by substance Drug Product manufacturer is required.
3.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.
4.	3.2.S.4.4	Assay specification 98.5% to 102 % while BP specifications 98.5% to 101 %. Clarify.
5.	3.2.P.1	Provide Reference product of which formulation followed for manufacturing . In section 1.5.2 Film coated applied while in 3.2.P. 1 and batch formula sugar coated applied.
6.	3.2.P.2.2.1	Submit F2 calculations.
7.	3.2.P.5.1	USP monograph States dissolution time 60 minutes while in applied formulation dissolution time is 15 minutes.
8.	3.2.P.5.2	Submit analytical testing method instead of presenting USP monograph.
9.	3.2.P.5.2	In AMV Repeatability not done
10.	3.2.P.5.4	COA's of three different batches having same values.
11.	3.2.P.8	• Purchase documents for Ibuprofen • COA's of all time points does not match with stability summary sheets and raw data. Clarification is required. • Specifications in stability summary sheets change from 3.2.P.5.1 (Dissolution NLT 80% in 30 minutes in accelerated and in Real time NLT 75% in 30 minutes while Assay 95-105 % disintegration test include, average weight included.) • Stability data of at accelerated condition for 3 batches same values • In stability summary sheets in all the three batches how value of Assay at 0 month for Real time stability studies and Accelerated stability studies are changed. Clarification is required. • Dissolution value in 6 sheets are same. • Initiation date on accelerated 21-05-2022 while in real time 18-05-2022 • Stability summary sheets 30°C ± 2°C / 65% ± 5%RH and 25°C ± 2°C / 60% ± 5%RH both are submitted with same values,.

Firm Response:

It is submitted that we want to withdraw our product development & stability data only as the said data was mistakenly not properly arranged in order & in some cases was mixed up. It is requested to hold the above submitted data & we will re-submit properly arranged.		
Decision: • **Registration Board acceded the firm's request of withdrawal and declared the instant application as disposed off.** • **Registration Board decided that firm shall formulate new trial batches and submit its stability data for both accelerated and long term conditions along with full fee of registration i.e., Rs. 30,000/- for correction/pre-approval change in stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Registration Board further noted that firm's quota of priority consideration against the new DML will also be deducted in leiu of the consideration of instant application.**		
Capsule (General) **01 Molecules/ 02 Products**		
354.	Name, address of Applicant / Marketing Authorization Holder	M/S Pharman Pharmaceuticals 6-km Bohmaan Baath Road, Kalasky Gujranwala, Pakistan
	Name, address of Manufacturing site.	M/S Pharman Pharmaceuticals 6-km Bohmaan Baath Road, Kalasky Gujranwala, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2397 dated 25-01-2023
	Details of fee submitted	PKR 30,000/-: Deposit slip # 14485162419
	The proposed proprietary name / brand name	Omeprazole 20mg capsules
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard gelatin capsule contains: Enteric coated pellets containing Omeprazole ..20mg
	Pharmaceutical form of applied drug	capsule
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size	2×7's & 10 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Omeprazole 20mg capsules Manufactured Vision Pharma FDA Approved.
	For generic drugs (me-too status)	Faast 20mg Capsule by M/s by CCL pharmaceuticals
	GMP status of the Finished product manufacturer	New DML issued on 30/05/2022
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers,

		description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Omeprazole is present in USP . The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (OMP883, OMP514, OMP671)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is FAAST **20mg Capsule** BY CCL Laboratories by performing quality tests (Description, Identification, Assay, Uniformity of dosage form).
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad		
API Lot No.	OMP1147		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	OM22-001	OM22-002	OM22-003
Batch Size	2000	2000	2000
Manufacturing Date	11-05-22	11-05-22	11-05-22
Date of Initiation	08-05-22	08-05-22	08-05-22
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate on the basis of evaluation conducted on 14-06-2022 and valid for 02 years.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator: Dissolution value in all the sheets for accelerated and Real for 3 batches same i.e 98%, 98.5%, 97%

S.No	Section	Shortcomings Communicated
1.	2.3.R.1.1	Calculation for fill weight with respect to assay of pellets by drug product manufacturer is not done
2.	3.2.S.4.1	Copies of the Omeprazole Pellets specifications by Drug Product manufacturer is required.
3.	3.2.S.4.2	Analytical procedures used for routine testing of the Omeprazole Pellets by substance Drug Product manufacturer is required.
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for Omeprazole Pellets shall be submitted.
5.	3.2.S.4.4	Dissolution testing for pellets not done by drug product manufacturer
6.	3.2.P.2.2.1	In CDP in pH 1.2 time points are up to 60 minutes while USP pharmacopeia specify 2 hour in acidic medium.
7.	3.2.P.5.1	Submit Complete specifications as per USP monograph
8.	3.2.P.5.4	• COA's of three different batches having same values of Assay and dissolution • Dissolution specifications in COA's are different than USP.
9.	3.2.P.8	• Purchase documents for Omeprazol pellets • COA's of all time points does not match with stability summary sheets and raw data. Clarification is required. • In stability summary sheets in all the three batches how value of Assay at 0 month for Real time stability studies and Accelerated stability studies are changed. Clarification is required. • Dissolution values in 6 sheets are same. • Raw data for dissolution not submitted.

Firm Response:
It is submitted that we want to withdraw our product development & stability data only as the said data was mistakenly not properly arranged in order & in some cases was mixed up.
It is requested to hold the above submitted data & we will re-submit properly arranged.

Decision:

- **Registration Board acceded the firm's request of withdrawal and declared the instant application as disposed off.**

• **Registration Board decided that firm shall formulate new trial batches and submit its stability data for both accelerated and long term conditions along with full fee of registration i.e., Rs. 30,000/- for correction/pre-approval change in stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Registration Board further noted that firm's quota of priority consideration against the new DML will also be deducted in leiu of the consideration of instant application.**		
355.	Name, address of Applicant / Marketing Authorization Holder	M/S Pharman Pharmaceuticals 6-km Bohmaan Baath Road, Kalasky Gujranwala, Pakistan
	Name, address of Manufacturing site.	M/S Pharman Pharmaceuticals 6-km Bohmaan Baath Road, Kalasky Gujranwala, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2398 dated 25-01-2023
	Details of fee submitted	PKR 30,000/-: Deposit slip # 15580570295
	The proposed proprietary name / brand name	Omeprazole 40mg capsules
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each hard gelatin capsule contains: Enteric coated pellets containing Omeprazole ..40mg
	Pharmaceutical form of applied drug	capsule
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size	2×7's & 10 x 10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Omeprazole 40mg capsules Manufactured Vision Pharma FDA Approved.
	For generic drugs (me-too status)	Faast 40mg Capsule by M/s by CCL pharmaceuticals
	GMP status of the Finished product manufacturer	New DML issued on 30/05/2022
	Name and address of API manufacturer.	Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Omeprazole is present in USP . The firm as submitted detail of nomenclature,

		structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (OMP1066, OMP893, OMP748)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad		
API Lot No.	OMP1158		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	OM22-004	OM22-005	OM22-006
Batch Size	2000	2000	2000
Manufacturing Date	11-05-22	11-05-22	11-05-22
Date of Initiation	08-05-22	08-05-22	08-05-22
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate on the basis of evaluation conducted on 14-06-2022 and valid for 02 years.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator: Dissolution value in all the sheets for accelerated and Real for 3 batches same i.e 98%, 98.5%, 97%

S.No	Section	Shortcomings Communicated
1.	2.3.R.1.1	Calculation for fill weight with respect to assay of pellets by drug product manufacturer is not done
2.	3.2.S.4.1	Copies of the Omeprazole Pellets specifications by Drug Product manufacturer is required.
3.	3.2.S.4.2	Analytical procedures used for routine testing of the Omeprazole Pellets by substance Drug Product manufacturer is required.
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for Omeprazole Pellets shall be submitted.
5.	3.2.S.4.4	Dissolution testing for pellets not done
6.	3.2.P.2.2.1	Pharmaceutical equivalence of 20mg strength submitted. In CDP in pH 1.2 time points are up to 60 minutes while USP pharmacopeia specify 2 hour in acidic medium
7.	3.2.P.5.1	Submit Complete specifications as per USP monograph
8.	3.2.P.5.4	• COA's of three different batches having same values of Assay and dissolution and having same value of 20mg capsule • Dissolution specifications in COA's are different than USP
9.	3.2.P.8	• Purchase documents for Omeprazol pellets • COA's of all time points does not match with stability summary sheets and raw data. Clarification is required. • In stability summary sheets in all the three batches how value of Assay at 0 month for Real time stability studies and Accelerated stability studies are changed. Clarification is required. • Dissolution values in 6 sheets is same. • Raw data for dissolution not submitted.

Firm Response:

It is submitted that we want to withdraw our product development & stability data only as the said data was mistakenly not properly arranged in order & in some cases was mixed up.

It is requested to hold the above submitted data & we will re-submit properly arranged**.**

Decision:

- **Registration Board acceded the firm's request of withdrawal and declared the instant application as disposed off.**
- **Registration Board decided that firm shall formulate new trial batches and submit its stability data for both accelerated and long term conditions along with full fee of registration i.e., Rs. 30,000/- for correction/pre-approval change in stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Registration Board further noted that firm's quota of priority consideration against the new DML will also be deducted in leiu of the consideration of instant application.**

Oral Liquid (General)
02 Molecules/ 02 Products

356.	Name, address of Applicant / Marketing Authorization Holder	M/S Pharman Pharmaceuticals 6-km Bohmaan Baath Road, Kalasky Gujranwala, Pakistan
	Name, address of Manufacturing site.	M/S Pharman Pharmaceuticals 6-km Bohmaan Baath Road, Kalasky Gujranwala, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2396 dated 25-01-2023
	Details of fee submitted	PKR 30,000/-: Deposit slip # 701724321
	The proposed proprietary name / brand name	PARASOL SUSPENSION
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each bottle contains: Paracetamol…160mg
	Pharmaceutical form of applied drug	Suspension
	Pharmacotherapeutic Group of (API)	Analgesic and anti pyretic
	Reference to Finished product specifications	BP
	Proposed Pack size	1 x 90ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	
	For generic drugs (me-too status)	
	GMP status of the Finished product manufacturer	New DML issued on 30/05/2022
	Name and address of API manufacturer.	Citi Pharma (Pvt.) Ltd. 3.5 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Paracetamol is present in USP/BP . The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (PGP14-37, PGP14-38, PGP14-39)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Citi Pharma (Pvt.) Ltd. 3.5 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan.		
API Lot No.	PGP22-286		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2×10's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PC22-001	PC22-002	PC22-003
Batch Size	16 BOTTLES	16 BOTTLES	16 BOTTLES
Manufacturing Date	16-05-22	16-05-22	16-05-22
Date of Initiation	16-05-22	16-05-22	16-05-22
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by DRAP on the basis of Evaluation conducted on 17-12-2020 and valid for 2 years.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator: pH all the sheets for accelerated and Real for 3 batches same

S.No	Section	Shortcomings Communicated
1.	1.5.2	Provide Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit
2.	1.5.9	Evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form and dosage form in any one of the reference regulatory authority specified by Registration Board in its 275th meeting for further evaluation of application.
3.	1.5.10	Explain applied dosage form either suspension, liquid, elixir
4.	2.3.R.1.1	• Batch size of 2 L and fill volume of 120ml while applied as 90ml • BMR of chlopheniramine submitted.
5.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.
6.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.
7.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.
8.	3.2.S.4.4	• COA limits of Assay as per USP while claimed BP • Manufacturing in July 2022 while finished product manufactured in May 2022
9.	3.2.P.1	• Qualitative composition is different from the reference product, since reference product has not used potassium sorbate and pregelatinized starch.
10.	3.2.P.2.2.1	Pharmaceutical equivalence not done
11.	3.2.P.5.1	Claimed Specifications are BP while Specification limits applied are not according to BP (Specification assay as USP) Deliverable volume not performed
12.	3.2.P.5.4	COA's of three different batches having same values of Assay
13.	3.2.P.8	• Purchase documents for Paracetamol • Before manufacturing of product how stability studies initiated. • In stability summary sheets pH is mentioned however B.P monograph not mentioned • COA's of all time points does not match with stability summary sheets and raw data. Clarification is required. • COA's of all time points of 3 batches have same values. Clarification is required. • In stability summary sheets in all the three batches how value of Assay at 0 month for Real time stability studies and Accelerated stability studies were changed. Clarification is required. • Data logger at 25°C ± 2°C / 60% ± 5%RH

Firm Response:
It is submitted that we want to withdraw our product development & stability data only as the said data was mistakenly not properly arranged in order & in some cases was mixed up.
It is requested to hold the above submitted data & we will re-submit properly arranged.

Decision:

- **Registration Board acceded the firm's request of withdrawal and declared the instant application as disposed off.**

• **Registration Board decided that firm shall formulate new trial batches and submit its stability data for both accelerated and long term conditions along with full fee of registration i.e., Rs. 30,000/- for correction/pre-approval change in stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Registration Board further noted that firm's quota of priority consideration against the new DML will also be deducted in leiu of the consideration of instant application.**		
357.	Name, address of Applicant / Marketing Authorization Holder	M/S Pharman Pharmaceuticals 6-km Bohmaan Baath Road, Kalasky Gujranwala, Pakistan
	Name, address of Manufacturing site.	M/S Pharman Pharmaceuticals 6-km Bohmaan Baath Road, Kalasky Gujranwala, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2391 dated 25-01-2023
	Details of fee submitted	PKR 30,000/-: Deposit slip # 21919307498
	The proposed proprietary name / brand name	Ibufen 100mg suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each bottle contains: Ibuprofen…100mg/5ml
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	NSAIDS
	Reference to Finished product specifications	BP
	Proposed Pack size	90ml & 120ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ibuprofen Suspension of MHRA Approved.
	For generic drugs (me-too status)	Brufen suspension of M/s Abbott Laboratories Reg# 004595
	GMP status of the Finished product manufacturer	New DML issued on 30/05/2022
	Name and address of API manufacturer.	Citi Pharma (Pvt.) Ltd. 3.5 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.

	Module III (Drug Substance)	Official monograph of Ibuprofen is present in BP. The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (IB1806001, IB1806002, IB1806003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	
	Analytical method validation/verification of product	Method verification studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Citi Pharma (Pvt.) Ltd. 3.5 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan.		
API Lot No.	**IBP2212036**		
Description of Pack (Container closure system)	Transparent pet bottle		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	BP22-001	BP22-002	BP22-003
Batch Size	2L	2L	2L
Manufacturing Date	15-05-22	15-05-22	15-05-22
Date of Initiation	15-05-22	15-05-22	15-05-22
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by DRAP on the basis of Evaluation conducted on 17-12-2020 and valid for 2 years.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator: pH values same

S.No	Section	Shortcomings Communicated
1.	2.3.R.1.1	• Overage is added • Micronized mentioned with ibuprofen while COA of Ibuprofen submitted for same which is used for tablet • Batch size mentioned is 2 liter while in manufacturing method 16 L mentioned.
2.	3.2.S.4.1	Copies of the drug substance specifications by Drug Product manufacturer is required.
3.	3.2.S.4.2	Analytical procedures used for routine testing of the drug substance by substance Drug Product manufacturer is required.
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.
5.	3.2.S.4.4	Assay specification 98.5% to 102 % while BP specifications are 98.5% to 101 %. Clarify
6.	3.2.P.1	Overage of ibuprofen
7.	3.2.P.2.2.1	Pharmaceutical equivalence not done
8.	3.2.P.5.1	Claimed Specifications are BP while Specification limits applied are not according to BP (Specification assay as USP)
9.	3.2.P.5.3	In AMV Repeatability not done
10.	3.2.P.5.4	COA's of three different batches having same values
11.	3.2.P.8	• Purchase documents for Ibuprofen • COA's of all time points does not match with stability summary sheets and raw data. Clarification is required. • Specifications in stability summary sheets change from 3.2.P.5.1 • In stability summary sheets in all the three batches how value of Assay at 0 month for Real time stability studies and Accelerated stability studies are changed. Clarification is required. • pH values in 6 sheets are same. • Stability summary sheets at 25°C ± 2°C / 60% ± 5%RH submitted

Firm Response:

It is submitted that we want to withdraw our product development & stability data only as the said data was mistakenly not properly arranged in order & in some cases was mixed up.

It is requested to hold the above submitted data & we will re-submit properly arranged.

Decision:

- **Registration Board acceded the firm's request of withdrawal and declared the instant application as disposed off.**
- **Registration Board decided that firm shall formulate new trial batches and submit its stability data for both accelerated and long term conditions along with full fee of registration i.e., Rs. 30,000/- for correction/pre-approval change in stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**
- **Registration Board further noted that firm's quota of priority consideration against the new DML will also be deducted in leiu of the instant application.**

M/s Variant Pharmaceuticals (Pvt) Ltd **. (New DML)**
CLB in its 273rd meeting held on 15th January 2020 has considered and approved the grant of Drug Manufacturing License by way of formulation with following four (04) sections to M/S Variant Pharmaceuticals (Pvt.) Ltd

1. Tablet (General)
2. Capsule (General)
3. Sachet Section (General)
4. General Dry Powder Injection Section (Pre-Lyophilized) Vial

Sr. No	Section	Molecules for consideration in 329th meeting	Products for consideration in 329th meeting
1	Capsule (General)	01	01

358.	Name, address of Applicant / Marketing Authorization Holder	M/s Variant Pharmaceuticals (Pvt.) Ltd Plot # 5, M-2, Pharmazone, 26 Km Main Sharaqpur Road District Sheikhupura.Pakistan
	Name, address of Manufacturing site.	M/s Variant Pharmaceuticals (Pvt.) Ltd Plot # 5, M-2, Pharmazone, 26 Km Main Sharaqpur Road District Sheikhupura.Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 6362 dated 06-03-2023
	Details of fee submitted	PKR 30,000/-: Deposit slip # 255565603
	The proposed proprietary name / brand name	THIOVAR 4mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Thiocolchicoside ……4mg
	Pharmaceutical form of applied drug	Hard gelatin capsule
	Pharmacotherapeutic Group of (API)	Analgesic and Anti-inflammatory
	Reference to Finished product specifications	As per innovator's specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MIOREL 4mg CAPSULES by Laboratotio FARMACEUTICO SIT SRL. ANSM France Approved.
	For generic drugs (me-too status)	Muscoril 4 mg cap by M/s Sanofi-aventis Pakistan Ltd..., Reg. No. 015502
	GMP status of the Finished product manufacturer	Last inspection conducted on 01-06-2021 for grant of additional section and report concludes that overall Evaluation of inspection is Good.
	Name and address of API manufacturer.	SARV BioLabs (Pvt.) Ltd. Plot No.2, Trilokpur Road

		(Behind IITT College of Engg.) Kala Amb-173 030 Himachal Pradesh, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Thiocolchicoside is not present in any pharmacopeia.. The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 18 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (7000-P-11001, 7000-P-11002, 7000-P-11003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the the brand leader that is MUSCORIL 4mg Capsule by M/s Sanofi-aventis Pakistan Ltd..., Reg. No. 015502 ,by performing quality tests (description, Disintegration Assay, Dissolution). CDP has been performed against the same brand that is MUSCORIL 4mg Capsule by M/s Sanofi-aventis Pakistan Ltd , in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8).
	Analytical method validation/verification of product	Method validation studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	SARV BioLabs (Pvt.) Ltd. Plot No.2, Trilokpur Road (Behind IITT College of Engg.) Kala Amb-173 030 Himachal Pradesh, India
API Lot No.	7000-B-20046
Description of Pack (Container closure system)	Alu-Alu Blisters.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9 (Months)		
Batch No.	4BT-001	4BT-002	4BT-003
Batch Size	2000	2000	2000
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	09-03-2022	14-03-2022	14-03-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of cGMP certificate # HFW-H(Drugs)47/08 issued by Health & Family Welfare Department Himachel pradesh and valid until 16-06-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Form 6 and invoice (invoice# Ex/20077) dated: 04-08-2021 attested by DRAP Lahore dated: 07-10-2021 specifying import 0.030Kg of Thiocolchicoside (Batch# 7000-B-20046)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted Data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator:

S.No	Section	Shortcomings Communicated	Reply
1.	3.2.S.4.1	Copies of the Drug substance specifications by Drug Product manufacturer is required.	Copies of the Drug substance specifications by Drug Product manufacturer are submitted.
2.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer are submitted.
3.	3.2.P.2.2.1	• One measurement should be considered after 85% dissolution of both the products according to FDA guidance for industry and EMA guidelines of Comparative dissolution. Provide reference of time points selected. • f2 calculations not submitted.	• The drug release at 30 minutes in all three dissolution media is already above than 85% as evident in the provided data therefore, we did not take further time points. • f2 calculations submitted.

4.	3.2.P.5.1	You have not performed uniformity of dosage unit by content uniformity, as recommended by USP General Chapter <905>. Justification shall be submitted in this regard.	Performance of content uniformity test submitted.

Decision: Approved with innovator's specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

a. New/Additional section(s)

M/s Titlis Pharma (Pvt) Limited . **(New Section)**
CLB in its 287th meeting held on 24th June 2022, has approved the following 03 additional sections of M/s Titlis Pharma (Pvt) Limited .

1) Tablet Section II (General)
2) Dry Powder Suspension Section
3) Dry Powder Sachet Section (General)

Sr. No	Section	Molecules for consideration in 329th meeting	Products for consideration in 329th meeting
1	Tablet Section II (General)	01	01

359.	Name, address of Applicant / Marketing Authorization Holder	M/s Titlis Pharma (Pvt) Limited 528-A, Sundar Industrial Estate, Raiwind Road, Lahore.
	Name, address of Manufacturing site.	M/s Titlis Pharma (Pvt) Limited 528-A, Sundar Industrial Estate, Raiwind Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4038 dated 13-02-2023
	Details of fee submitted	PKR 30,000/-: Deposit slip # 3161162095
	The proposed proprietary name / brand name	IVASET-M 50mg/5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet contains: Metoprolol Tartrate …….50mg Ivabradine HCl equivalent to Ivabradine…..5mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Antiarrhythmic agents
	Reference to Finished product specifications	Manufacturer's specification
	Proposed Pack size	2×7's

	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Implicor 50mg/5mg film coated tablet France approved
	For generic drugs (me-too status)	Implicor Tablets 50mg/5mg of M/s Servier Research and Pharmaceuticals Pakistan Reg# 099006
	GMP status of the Finished product manufacturer	GMP certificate issued on 15-12-2022
	Name and address of API manufacturer.	**Metoprolol Tartrate:** KOPRAN RESEARCH LABORITORIES LIMITED **Address** K-4/4, Additional MIDC, Post Birwadi, Tal. Mahad, Dist, Raigad, 402302 Maharashtr State, India **Ivabradine as HCl:** BEIJING LIANBEN PHARMA-CHEMICALS TECH. CO., LTD **Address:** 2nd Zhongshan Road, Chemicals Park, Binhai economic Development Zone, Binhai County, Yancheng, Jiangsu, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	**Metoprolol Tartrate:** Official monograph of **Metoprolol Tartrate** is present in USP.. The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Ivabradine HCl:** Official monograph of Ivabradine HCl is not present in any pharmacopeia.. The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	**Metoprolol Tartrate:** Stability study conditions:

		Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (MTT/P1706003, MTT/P1706004, MTT/P1706005) **Ivabradine HCl:** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: : (180601, 180602, 180603)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the Implicor Tablet 50/5mg of Servier Pharmaceuticals France by performing quality tests (disintegration, weight variation, Assay, Dissolution, of dosage form). CDP has been performed against the same brand that is Implicor Tablet 50/5mg of Servier Pharmaceuticals France in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8).
	Analytical method validation/verification of product	Method validation studies have submitted including accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	**Metoprolol Tartrate:** KOPRAN RESEARCH LABORITORIES LIMITED **Address** K-4/4, Additional MIDC, Post Birwadi, Tal. Mahad, Dist, Raigad, 402302 Maharashtr State, India **Ivabradine as HCl:** BEIJING LIANBEN PHARMA-CHEMICALS TECH. CO., LTD **Address:** 2nd Zhongshan Road, Chemicals Park, Binhai economic Development Zone, Binhai County, Yancheng, Jiangsu, China.		
API Lot No.	**Metoprolol Tartrate:** MTT/P1810002 **Ivabradine as HCl:** 191201		
Description of Pack (Container closure system)	Alu-Alu Blisters.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	T-091	T-092	T-093
Batch Size	1,333 tab	1,333 tab	1,333 tab
Manufacturing Date	May-2020	May-2020	May-2020

Date of Initiation	15-05-2020	15-05-2020	15-05-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Metoprolol Tartrate:** Copy of GMP certificate No# NEW-WHO-GMP/CERT/KD/89275/2020/11/33788 issued by Food and Drug Control Administration Gandhinagar, Gujrat state India. valid until 19-10-2023 **Ivabradine HCl:** *Copy of DML No# Kat 20170317 issued by National Medical products Adminstration China for. Jijlan Huikang Pharmaceuticals Co., Ltd valid until 08-11-2027* • Copy of GMP certificate No# BJ20160106 issued for BEIJING LIANBEN PHARMA-CHEMICALS TECH. CO., LTD. valid until 24-11-2021
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Metoprolol Tartrate:** Firm has submitted copy of invoice (invoice# KRLL/SAMPLE/10) dated: 08-05-2019 attested by DRAP Lahore dated: 08-05-2019 specifying import of Metoprolol Tartrate (Batch# MTT/P1810002) **Ivabradine HCl:** Firm has submitted copy of Form 3 form 7 and invoice (invoice# 20SJ01001) dated: 31-12-2019 attested by DRAP Lahore dated: 07-01-2020 specifying import of Ivabradine HC**l** (Batch# 191201)
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	The firm has submitted Data of stability batches supported by attested respective documents like chromatograms, raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	The firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).

Remarks of Evaluator:

S.No	Section	Shortcomings Communicated	Reply
1.	1.6.5	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance Ivabradine HCl manufacturer issued by relevant regulatory authority of country of origin	*Copy of DML No# Kat 20170317 issued by National Medical products Adminstration China for. Jijlan Huikang Pharmaceuticals Co., Ltd valid until 08-11-2027* Beijing Lianben Pharma-Co has informed us that they are now manufacturing their Ivabradine HCl from their group company i.e Jilin Huikang Pharmaceutical., Co Ltd; and the Valid Drug Manufacturing License of Jilin Huikang Pharmaceutical., Co Ltd along with duly signed/stamped agreement by both companies is attached herewith.

2.	3.2.S.4.1	• Copies of the Drug substance .(Metoprolol Tartrate**)** specifications by both drug substance manufacturer and Drug Product manufacturer is required. • Copies of the Drug substance (Ivabradine HCl) specifications Drug Product manufacturer is required.	• Copies of the Drug substance .(Metoprolol Tartrate**)** specifications by both drug substance manufacturer and Drug Product manufacturer are submitted. • Copies of the Drug substance (Ivabradine HCl) specifications Drug Product manufacturer are submitted.
3.	3.2.S.4.2	• Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient (Metoprolol Tartrate**)** by both drug substance manufacturer and Drug Product manufacturer is required. • Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient (Ivabradine HCl) by Drug Product manufacturer is required.	• Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient (Metoprolol Tartrate**)** by both drug substance manufacturer and Drug Product manufacturer are submitted. • Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient (Ivabradine HCl) by Drug Product manufacturer are submitted.
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) (Metoprolol Tartrate and Ivabradine HCl) shall be submitted.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both drug substance(s) (Metoprolol Tartrate and Ivabradine HCl) are submitted.
5.	3.2.P.8	• Documents for the procurement of API (Metoprolol Tartrate) with approval from DRAP. • As per reference product public assessment report "During storage an increase in the specified degradation products from Ivabradine is observed, under all storage conditions(PVC/PVDC blisters and in HDPE bottles), all staying within specification up to 18 months under long term conditions." You have conducted stability studies for 24th month and not conducted degradation products from Ivabradine. Clarify.	• Documents for the procurement of API (Metoprolol Tartrate) with approval from DRAP submitted. • We conducted Accelerated and Long Run Studies of Ivaset-M 50mg/5mg Tablet covering all sampling and testing points at • Accelerated:0, 3,6 • Long Run: 0,3,6,9,12,18 & 24 • Utilizing validated analytical method, our assay limits are with in limits at all said testing points. • We have performed stability studies (Long Run) on our Ivaset-M 50mg/5mg Tablet sample at the 36th month mark. The results indicate that the level of impurities is well within the limits (i.e. individual impurity NMT 0.5% and total impurities NMT 1.0%). This demonstrates that the degradation of Ivabradine in our product remains well within the acceptable limits even at the 36th month of storage at 30°C ± 2°C, 65% RH ± 5% RH.

			Based on the result, it is claimed that Ivaset-M 50mg/5mg Tablet is stable even for 36 months at 30°C and 65% humidity provided the product is kept in undamaged original packing. (Reports and chromatographs are attached

Decision: Registeration Bard deferred the case following

- **Registration Board decided that firm shall formulate new trial batches and submit its stability data for both accelerated and long term conditions with new souce of drug substance (Ivabradine Hcl) along with full fee of registration i.e., Rs. 30,000/- for correction/pre-approval change in stability data as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021OR Submit Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance Ivabradine HCl manufacturer issued by relevant regulatory authority of country of origin**
- **In case of new data Registration Board further noted that firm's quota of priority consideration against the new sections will also be deducted keeping the fact of the consideration of instant application.**

Case no. 05 Registration applications of categories to be considered on priority

a. Export facilitation

Export Facilitation: Applications was received through letter No.F.1-6/2019-PR-I (EFD)
"M/s AGP Limited.B-23, S.I.T.E. Karachi have achieved benchmark OF USD 1,549.120.69 as defined in the Board's decision during fiscal year 2021-2022. In this regard, please find the (1 molecule) 03 products applications submitted by the firm."

360.	Name and address of manufacturer / Applicant	M/s AGP Limited.B-23, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Dotril 10mg Sachet
	Composition	Each sachet contains: Racecadotril……..10mg
	Diary No. Date of R& I & fee	Dy No. 15146: 24.04.2018 PKR 50,000 +10,000/-: 23.04.2018 (For Dotril 10mg Sachet + Dotril 30mg Sachet + Dotril 100mg Capsule)
	Pharmacological Group	Other antidiarrheals
	Type of Form	Form 5
	Finished product Specifications	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	16's; Rs. 875
	Approval status of product in Reference Regulator Authorities	TIORFAN 10 mg INFANTS, oral powder in sachet-dose. ANSM Approved HIDRASEC INFANTS 10 mg, Granules for oral suspension. MHRA approved (the pharmaceutical form is Granules for oral suspension White powder with characteristic apricot smell)
	Me-too status	Could not be confirmed.
	GMP status	GMP granted on the basis of inspection dated 16.10.2018
	Remarks of the Evaluator.	
	Previous Decision: Deferred for submission and evaluation of Stability study data **. (M-289)**	

STABILITY STUDY DATA

Drug	Dotril 10mg Sachet

Name of Manufacturer	M/s AGP Limited.B-23, S.I.T.E. Karachi		
Manufacturer of API	M/s Shandong Qidu Pharmaceuticals C0., LTd. No.17 Hongda Road, Linzi District, Zibo City, Shandong, China.		
API Lot No.	200605		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton along with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	22/024-STB/RAC-SAC/01	22/025-STB/RAC-SAC/02	22/026-STB/RAC-SAC/03
Batch Size	400 Sachet	400 Sachet	400 Sachet
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	25-04-2022	25-04-2022	25-04-2022
No. of Batches	03		
Date of Submission	30-12-2022 (39564)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if available)	Firm has referred to onsite inspection report of their product for "Daplazole 30mg and 60mg (Dexlansoprazole) Capsules on 19-03-2020. Further, the said panel inspection report was discussed in 295th Drug Registration Board meeting held on 8-11 June, 2020. The case was approved and the inspection report confirms following points: • The HPLC software is 21CFR Compliant as per record available with the firm. • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (Batch#200605) of API from M/s M/s Shandong Qidu Pharmaceuticals C0., LTd. No.17 Hongda Road, Linzi District, Zibo City, Shandong, China.China and M/s AGP Limited Karachi are submitted.
3.	Method used for analysis of API from both API Manufacturer and Finished Product manufacturer	Methods used for analysis of API from both API Manufacturer and Finished Product Manufacturer are provided by the firm
4.	Stability study data of API from API manufacturer	The firm has submitted copy of **accelerated, 06 Months** (40°C ± 2°C & 75±5%RH) & **long term, 24 Months** (25°C ± 2°C & 60±5%RH) stability study reports of 03 batches. Batches: (140401, 140501, 140502)
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate (SD20180700) of M/s Shandong Qidu Pharmaceuticals C0., LTd. No.17 Hongda Road, Linzi District, Zibo City, Shandong, China.

<table>
<tr><td></td><td></td><td>issued on dated 23-05-2018 by National Medical Product Administration valid till 22-05-2023.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of form 3, 6 and Form 7 and Commercial Invoice No:20200730 Dated: 30-07-2020 from M/s Shandonq Qidu Phamaceuticals Co., Ltd. attested by AD DRAP (Karachi) dated ; 09-09-2020 for Racecadotril batch No# # 200605</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Yes</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Yes</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies</td><td>Firm has submitted that same excipients has been used as used by innovator. Therefore, Drug-excipients compatibility studies were not performed.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Trial batch manufacturing record.
Details are as under:
<table>
<tr><td colspan="3">Dotril 10mg Sachet</td></tr>
<tr><td>Batch No.</td><td>Bach size</td><td>Mfg. Started</td></tr>
<tr><td>22/024-STB/RAC-SAC/01</td><td>400 Sachet</td><td>03-2022</td></tr>
<tr><td>22/025-STB/RAC-SAC/02</td><td>400 Sachet</td><td>03-2022</td></tr>
<tr><td>22/026-STB/RAC-SAC/03</td><td>400 Sachet</td><td>03-2022</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution</td><td>Firm has submitted Comparative dissolution study of their product with Innovator’s Brand “Hidrasec® 10mg” Sachet ”.
The details are as follows:
<table>
<tr><td>Feature</td><td>Reference product</td><td>Product of Abbott</td></tr>
<tr><td>Brand name</td><td>Dotril 10mg Sachet</td><td>Hidrasec® 10mg” Sachet</td></tr>
<tr><td>Batch No.</td><td>22/024-STB/RAC-SAC/02</td><td>SXN757</td></tr>
</table>
Comparative dissolution studies have been performed in following mediums:
pH 1.2 HCl buffer
pH 4.5 Acetate buffer
pH 6.8 Phosphate buffer</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Submitted</td></tr>
</table>

14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

REMARKS OF EVALUATOR

S.NO	Shortcomings communicated	Reply
1.	Reference of previous approval of applications with stability study data of the firm.	Daplazole 30mg and 60mg (Dexlansoprazole) Capsules submitted.
2.	Method used for analysis of API from Finished Product manufacturer	Method used for analysis of API from Finished product manufacturer is submitted.
3.	Real time Stability study data of API from API manufacturer as per Zone IV of 3 batches is required.	Real time Stability study data of API performed on 25ºC±2C/60%±5% RH by manufacturer. Therefore, record of data logger of API for the storage conditions throughout the transportation attached. As per Decision of 297th DRB, we have conducted degradation studies during stability program of finished product. The organic impurities were analyzed at initial stage, 6 months (Accelerated Conditions) and 24 months on long term condition. Data is attached.
4.	Protocols followed for conduction of stability study	Protocols followed for conduction of stability study.
5.	Method used for analysis of FPP	Method used for analysis of FPP
6.	Submit details of product against which CDP conducted with procurement documents.	Details of product with pack image, against which CDP is conducted are attached. Hidrasec® 10mg" Sachet Batch # SXN757 Manufactured:1/2022 EXP :12/2023 Manufactured by Abbott Laboratories

Decision: Approved with Innovator's specifications. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

- **Manufacturer will place first three production batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**

361.	Name and address of manufacturer / Applicant	M/s AGP Limited.B-23, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Dotril 30mg Sachet
	Composition	Each sachet contains: Racecadotril……..30mg
	Diary No. Date of R& I & fee	Dy No. 15146: 24.04.2018 PKR 50,000 +10,000/-: 23.04.2018 (For Dotril 10mg Sachet + Dotril 30mg Sachet + Dotril 100mg Capsule)
	Pharmacological Group	Other antidiarrheals
	Type of Form	Form 5
	Finished product Specifications	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	16's; Rs. 875
	Approval status of product in Reference Regulator Authorities	TIORFAN 30 mg CHILDREN, oral powder in sachet-dose. ANSM Approved HIDRASEC CHILDREN 30 mg, Granules for oral

		suspension. MHRA approved (the pharmaceutical form is Granules for oral suspension White powder with characteristic apricot smell)
	Me-too status	Could not be confirmed.
	GMP status	GMP granted on the basis of inspection dated 16.10.2018
	Remarks of the Evaluator.	Provide complete finished product specifications in line with general chapters (list of tests, reference to analytical procedures, and proposed acceptance criteria), including tests for granules
	Previous Decision: Deferred for submission and evaluation of Stability study data **. (M-289)**	

STABILITY STUDY DATA

Drug	Dotril 30mg Sachet		
Name of Manufacturer	M/s AGP Limited.B-23, S.I.T.E. Karachi		
Manufacturer of API	M/s Shandong Qidu Pharmaceuticals C0., LTd. No.17 Hongda Road, Linzi District, Zibo City, Shandong, China.		
API Lot No.	200605		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton along with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, 9, 12 (months)		
Batch No.	22/044-STB/RAC-SAC/04	22/045-STB/RAC-SAC/05	22/046-STB/RAC-SAC/06
Batch Size	400 Sachet	400 Sachet	400 Sachet
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	09-05-2022	09-05-2022	09-05-2022
No. of Batches	03		
Date of Submission	30-12-2022 (39563)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if available)	Firm has referred to onsite inspection report of their product for "Daplazole 30mg and 60mg (Dexlansoprazole) Capsules on 19-03-2020. Further, the said panel inspection report was discussed in 295th Drug Registration Board meeting held on 8-11 June, 2020. The case was approved and the inspection report confirms following points: • The HPLC software is 21CFR Compliant as per record available with the firm. • Audit trail on the testing reports is available. • Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Copies of COAs (Batch#200605) of API from M/s M/s Shandong Qidu Pharmaceuticals C0., LTd. No.17 Hongda Road, Linzi District, Zibo City, Shandong, China.China and M/s AGP Limited Karachi are submitted.

<table>
<tr><td>3.</td><td>Method used for analysis of API from both API Manufacturer and Finished Product manufacturer</td><td>Methods used for analysis of API from both API Manufacturer and Finished Product Manufacturer are provided by the firm</td></tr>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 24 Months (25°C ± 2°C & 60±5%RH) stability study reports of 03 batches. Batches: (140401, 140501, 140502)</td></tr>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>The firm has submitted copy of GMP certificate (SD20180700) of M/s Shandong Qidu Pharmaceuticals C0., LTd. No.17 Hongda Road, Linzi District, Zibo City, Shandong, China. issued on dated 23-05-2018 by National Medical Product Administration valid till 22-05-2023.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of form 3, 6 and Form 7 and Commercial Invoice No:20200730 Dated: 30-07-2020 from M/s Shandonq Qidu Phamaceuticals Co., Ltd. attested by AD DRAP (Karachi) dated ; 09-09-2020 for Racecadotril batch No# # 200605</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Yes</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Yes</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies</td><td>Firm has submitted that same excipients has been used as used by innovator. Therefore, Drug-excipients compatibility studies were not performed.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Trial batch manufacturing record.
Details are as under:
<table>
<tr><td colspan="3">Dotril 30mg Sachet</td></tr>
<tr><td>Batch No.</td><td>Bach size</td><td>Mfg. Started</td></tr>
<tr><td>22/044-STB/RAC-SAC/04</td><td>400 Sachet</td><td>03-2022</td></tr>
<tr><td>22/045-STB/RAC-SAC/05</td><td>400 Sachet</td><td>03-2022</td></tr>
<tr><td>22/046-STB/RAC-SAC/06</td><td>400 Sachet</td><td>03-2022</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution</td><td>Firm has submitted Comparative dissolution study of their product with Innovator’s Brand “Hidrasec® 30mg” Sachet ”.
The details are as follows:
<table>
<tr><td>Feature</td><td>Reference product</td><td>Product of Abbott</td></tr>
<tr><td>Brand name</td><td>Dotril 30mg Sachet</td><td>Hidrasec® 30mg” Sachet</td></tr>
<tr><td>Batch No.</td><td>22/044-STB/RAC-SAC/05</td><td>SXE2758</td></tr>
</table>
Comparative dissolution studies have been performed in following mediums:
1. pH 1.2 HCl buffer</td></tr>
</table>

		2. pH 4.5 Acetate buffer 3. pH 6.8 Phosphate buffer
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

REMARKS OF EVALUATOR

S.NO	Shortcomings communicated	Reply
1.	Reference of previous approval of applications with stability study data of the firm.	Daplazole 30mg and 60mg (Dexlansoprazole) Capsules submitted.
2.	Method used for analysis of API from Finished Product manufacturer	Method used for analysis of API from Finished product manufacturer is submitted.
3.	Real time Stability study data of API from API manufacturer as per Zone IV of 3 batches is required.	Real time Stability study data of API performed on 25ºC±2C/60%±5% RH by manufacturer. Therefore, record of data logger of API for the storage conditions throughout the transportation attached. As per Decision of 297th DRB, we have conducted degradation studies during stability program of finished product. The organic impurities were analysed at initial stage, 6 months (Accelerated Conditions) and 24 months on long term condition. Data is attached .
4.	Protocols followed for conduction of stability study	Protocols followed for conduction of stability study.
5.	Method used for analysis of FPP	Method used for analysis of FPP
6.	Submit details of product against which CDP conducted with procurement documents.	Details of product with pack image, against which CDP is conducted are attached. Hidrasec® 30mg" Sachet Batch # SXE2758 Manufactured:4/2022 EXP :03/2024 Manufactured by Abbott Laboratories
7.	Stability summary sheets for Accelerated stability studies and Real time stability.	Stability summary sheets for Accelerated stability studies and Real time stability are submitted.

Decision: Approved with Innovator's specifications. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

- **Manufacturer will place first three production batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**

362.	Name and address of manufacturer / Applicant	M/s AGP Limited.B-23, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Dotril 100mg Capsule
	Composition	Each Capsule contains: Racecadotril……..100mg

	Diary No. Date of R& I & fee	Dy No. 15147: 24.04.2018 PKR 50,000 +10,000/-: 23.04.2018 (For Dotril 10mg Sachet + Dotril 30mg Sachet + Dotril 100mg Capsule)
	Pharmacological Group	Other antidiarrheals
	Type of Form	Form 5
	Finished product Specifications	The firm has claimed manufacturer‘s specifications
	Pack size & Demanded Price	10‘s; Rs. 654
	Approval status of product in Reference Regulator Authorities	HIDRASEC 100 mg hard capsules. MHRA approved
	Me-too status	Could not be confirmed.
	GMP status	GMP granted on the basis of inspection dated 16.10.2018
	Remarks of the Evaluator.	
	Previous Decision: Deferred for submission and evaluation of Stability study data **. (M-289)**	

STABILITY STUDY DATA

Drug	Dotril 100mg Capsule		
Name of Manufacturer	M/s AGP Limited.B-23, S.I.T.E. Karachi		
Manufacturer of API	M/s Shandong Qidu Pharmaceuticals C0., LTd. No.17 Hongda Road, Linzi District, Zibo City, Shandong, China.		
API Lot No.	200605		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton along with leaflet.		
Stability Storage Condition	Real time: 30˚C ± 2˚ C / 75% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6, 9 (months)		
Batch No.	TR-675	TR-677	TR-678
Batch Size	4000 Capsule	4000 Capsule	4000 Capsule
Manufacturing Date	02-2021	03-2021	03-2021
Date of Initiation	25-03-2021	25-03-2021	25-03-2021
No. of Batches	03		
Date of Submission	15-04-2022 (9663)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm (if available)	Firm has referred to onsite inspection report of their product for “Daplazole 30mg and 60mg (Dexlansoprazole) Capsules on 19-03-2020. Further, the said panel inspection report was discussed in 295th Drug Registration Board meeting held on 8-11 June, 2020. The case was approved and the inspection report confirms following points: • The HPLC software is 21CFR Compliant as per record available with the firm. • Audit trail on the testing reports is available.

<table>
<tr><td></td><td></td><td>• Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well.</td></tr>
<tr><td>2.</td><td>Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Copies of COAs (Batch#200605) of API from M/s M/s Shandong Qidu Pharmaceuticals C0., LTd. No.17 Hongda Road, Linzi District, Zibo City, Shandong, China.China and M/s AGP Limited Karachi are submitted.</td></tr>
<tr><td>3.</td><td>Method used for analysis of API from both API Manufacturer and Finished Product manufacturer</td><td>Methods used for analysis of API from both API Manufacturer and Finished Product Manufacturer are provided by the firm</td></tr>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 24 Months (25°C ± 2°C & 60±5%RH) stability study reports of 03 batches.
Batches: (140401, 140501, 140502)</td></tr>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>The firm has submitted copy of GMP certificate (SD20180700) of M/s Shandong Qidu Pharmaceuticals C0., LTd. No.17 Hongda Road, Linzi District, Zibo City, Shandong, China. issued on dated 23-05-2018 by National Medical Product Administration valid till 22-05-2023.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of form 3, 6 and Form 7 and Commercial Invoice No:20200730 Dated: 30-07-2020 from M/s Shandonq Qidu Phamaceuticals Co., Ltd. attested by AD DRAP (Karachi) dated ; 09-09-2020 for Racecadotril batch No# # 200605</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Yes</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Yes</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies</td><td>Firm has submitted that same excipients has been used as used by innovator. Therefore, Drug-excipients compatibility studies were not performed.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Trial batch manufacturing record.
Details are as under:
<table>
<tr><td colspan="3">Dotril 100mg Capsule</td></tr>
<tr><td>Batch No.</td><td>Bach size</td><td>Mfg. Started</td></tr>
<tr><td>TR-675</td><td>4000 Capsule</td><td>26-02-2021</td></tr>
<tr><td>TR-677</td><td>4000 Capsule</td><td>16-03-2021</td></tr>
<tr><td>TR-678</td><td>4000 Capsule</td><td>16-03-2021</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution</td><td>Firm has submitted Comparative dissolution study of their product with Innovator’s Brand “Hidrasec100mg” Capsule ”.
The details are as follows:
<table>
<tr><td>Feature</td><td>Reference product</td><td>Product of Abbott</td></tr>
</table></td></tr>
</table>

		<table><tr><td>Brand name</td><td>Dotril 100mg Capsule</td><td>Hidrasec 100mg Capsule</td></tr><tr><td>Batch No.</td><td>TR-677</td><td>SX587</td></tr></table> ● Comparative dissolution studies have been performed in following mediums: 1. pH 1.2 HCl buffer 2. pH 4.5 Acetate buffer 3. pH 6.8 Phosphate buffer
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

REMARKS OF EVALUATOR

S.NO	Shortcomings communicated	Reply
1.	Reference of previous approval of applications with stability study data of the firm.	Daplazole 30mg and 60mg (Dexlansoprazole) Capsules submitted.
2.	Method used for analysis of API from Finished Product manufacturer	Method used for analysis of API from Finished product manufacturer is submitted.
3.	Real time Stability study data of API from API manufacturer as per Zone IV of 3 batches is required.	Real time Stability study data of API performed on 25ºC±2C/60%±5% RH by manufacturer. Therefore, record of data logger of API for the storage conditions throughout the transportation attached. As per Decision of 297th DRB, we have conducted degradation studies during stability program of finished product. The organic impurities were analyzed at initial stage, 6 months (Accelerated Conditions) and 24 months on long term condition. Data is attached. Furthermore, force degradation studies of Drug Product (Dotril 100mg Capsule) is also attached.
4.	Protocols followed for conduction of stability study	Protocols followed for conduction of stability study.
5.	Submit details of product against which CDP conducted with procurement documents.	Details of product with pack image, against which CDP is conducted are attached. Hidrasec® 100mg" Capsule Batch # SX587 Manufactured:03/2021 EXP :02/2023 Manufactured by Abbott Laboratories

Decision: Approved with Innovator's specifications. Firm shall submit the fee of Rs. 7,500 for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

- **Manufacturer will place first three production batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**

Case no. 06 Registration applications of import cases

c. Deferred cases

i. Human

363.	Name, address of Applicant / Importer	**M/s Lab Diagnostic Systems (SMC) Pvt Ltd** **Address:** 36-A, PSIC, SIE, Taxila Rawalpindi
	Details of Drug Sale License of importer	**License No:** 01-374-0006-96845D **Address:** 36-A, PSIC, SIE, Taxila Rawalpindi **Address of Godown:** NA **Validity:** 04/08/2024 **Status:** License to sell drugs as distributor **Renewal:** n/a
	Name and address of marketing authorization holder (abroad)	NAPROD LIFE SCIENCES PVT. LTD. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, INDIA
	Name, address of manufacturer(s)	NAPROD LIFE SCIENCES PVT. LTD. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, INDIA
	Name of exporting country	India
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Original legalized COPP (Certificate# COPP/CERT/KD/114093/2022/11/41431/203263) Valid up to 27-04-2025 by , Food and Drug control administration Gujrat state India. **Free sale:** Free sale of the product in exporting country: Yes confirms from COPP GMP certificate: Yes confirms as recommended by WHO confirms from COPP and Periodicity of inspections is mentioned Yearly. (Section of Liquid Injection cytotoxic mentioned in GMP certificate)
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of authorization certificate from NAPROD LIFE SCIENCES PVT. LTD. (304, Town Center-1 Andheri Kurla Road, Andheri , Mumbai on the request of Facilitator M/s Miles International (2/34, Tardeo Air-Conditioned Market, Tardeo Road, Mumbai – 400034, India specifies that the Facilitator appoints M/s Lab Diagnostic Systems (SMC) Pvt Ltd to register their products in Pakistan. Issued on : 06-09-2022
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale

		☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 26940 dated: 23-09-2022
	Details of fee submitted	PKR 150,000/- deposit Slip # 29422105532
	The proposed proprietary name / brand name	**CARBOLAB 150mg/15ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Carboplatin BP……... 10 mg
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Pyrimidine analogue ATC Code : L01XA02 carboplatin Injection is indicated for the initial treatment of advanced ovarian carcinoma in established combination with other approved chemotherapeutic agents)
	Reference to Finished product specifications	BP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	PARAPLATIN of USFDA approved
	For generic drugs (me-too status)	Brand Name CARBOPLATINO 150MG INJECTION Generic Name: CARBOPLATIN 150MG Importer Name: GHAZALI BROTHERS Registration Number: 043036
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance..
	Name, address of drug substance manufacturer	Sun pharmaceutical industries ltd., A-7/A-8, M.I.D.C., Industrial Area, Ahmednagar – 414 111, Maharashtra, India.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 72 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months

		Batches: (AH-8-41169, AH-8-41168, AH-3-08249, AH-3-08247) And at 30°C ± 2°C / 65 ± 5% RH for 72 months Batches: (AH-5-18252, AH-5-18253, AH-5-18254)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	20ml Amber colour Type-I Glass vial with grey bromo butyl rubber stopper with aluminium
	Stability study data of drug product, shelf life and storage conditions	

Remarks of Evaluator: On COPP 5ml, 15ml and 45 ml mentioned.

S.No	Section	Shortcomings Communicated	Reply
1.	3.2.P.2.2.1	• Pharmaceutical equivalence of the applied drug of same strength/fill volume shall be established with same strength of the innovator / reference / comparator product and results of all the quality tests (mentioned in any official pharmacopoeia or section 3.2.P.5.1 of this application) of the developed formulation and the innovator / reference / comparator product shall be submitted and discussed. • Details and origin of Reference product against which Pharmaceutical Equivalence was established and.	We, Naprod Life Sciences Pvt Ltd hereby declare that Pharmaceutical Equivalenc of Carboplatin 150mg/15ml is same as Carboplatin Injection 450mg/45ml and the basic strength of product is 10mg/ml. the change is only in the fill volume, which is as follows. The fill volume for 150mg/15ml is 15.5ml ±0.1 ml The fill volume for 450mg/45ml is 45.5ml ±0.1 ml The product development was performed on higher strength & therefore are requested to consider the same.
2.	3.2.P.5.4	Specifications of applied filled volume as extractable volume of 45ml mentioned.	Revised specifications submitted.
3.	3.2.P.5.4	Certificate of analysis of applied fill volume is required.	Certificate of analysis of applied fill volume is submitted.
4.	3.2.P.8	Submit stability studies of applied fill volume.	We, Naprod life sciences Pvt. Ltd, hereby declare that the carboplatin injection 150mg/15ml & carboplatin injection 450mg/45ml, the bulk solution is of uniform concentration where in each ml contains 10mg of active ingredient, i.e. 10mg/ml.

			The change is only in the fill volume, which is as follows: The fill volume for 150mg/15ml is 15.5ml± 0.1ml The fill volume for 450mg/45ml is 45.5ml ± 0.1ml The stability studies are performed on higher strength, only filled volume is different.

Registration Board was apprised regarding an e. mail received to Director PE&R Division from M/s Miles International India (authorized exclusive representative for the export of products manufactured by Naprod Life Sciences for the Pakistan region), wherein firm has requested to not consider any product registration applications made by any other party other than LDS as they will not be able to supply these products in the future.

Previous Decision (M-324): Deferred for submission of following:

- Stability studies (both accelerated and long term) as per Zone IVa conditions for the applied strength and fill volume.
- Pharmaceutical equivalence studies against the innovator/reference product of relevant strength and fill volume as applied.
- Afresh notarized "Sole Agency Agreement" between M/s Lab Diagnostic System & M/s Naprod Life Sciences Pvt. Ltd before issuance of registration letter

Evaluation by PEC:

S.No	Reason of deferment	Reply
1.	Stability studies (both accelerated and long term) as per Zone IVa conditions for the applied strength and fill volume.	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 75% ± 5% for 24months. Batches: NN3046, NN4146, NN1082
2.	Pharmaceutical equivalence studies against the innovator/reference product of relevant strength and fill volume as applied.	Pharmaceutical Equivalence have been established against Platamine 10mg/ml (Carboplatin Injection) manufactured by Pfizer Laboratories with 10mg/ml of Carbolatin Injection of Naprod Life Sciences by performing quality tests (Description, pH, Particulate matter Assay, Related substances ,).
3.	Afresh notarized "Sole Agency Agreement" between M/s Lab Diagnostic System & M/s Naprod Life Sciences Pvt. Ltd before issuance of registration letter	Firm has submitted notarized "Sole Agency Agreement" or letter of authorization certificate from NAPROD LIFE SCIENCES PVT. LTD. (304, Town Center-1 Andheri Kurla Road, Andheri , Mumbai appoint, M/s Lab Diagnostic Systems (SMC) Pvt Ltd and M/s Miles International to register their product (Carboplatin Injection 150mg/15ml) in Pakistan . Issued on : 13-03-2023

Decision: Approved with BP specifications as per Policy for inspection of Manufacturer abroad.

364.	Name, address of Applicant / Importer	M/s Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area, Karachi
	Details of Drug Sale License of importer	**License No:** 565 **Address:** Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area, Karachi. **Address of Godown:** (a) 1st floor, Plot no. 211, Sector 23 Korangi Industrial Area, Karachi

		(b) Plot No 32, Sector 16, Korangi Industrial Area, Karachi **Validity:** 16-06-2024 **Status:** License to sell Drugs by way of Wholesale **Renewal:** Yes Submitted valid till 16-06-2022
	Name and address of marketing authorization holder (abroad)	ANFARM HELLAS S.A. 61st km NAT.RD. ATHENS-LAMIA, Schimatari Viotias 32009, Greece.
	Name, address of manufacturer(s)	ANFARM HELLAS S.A. 61st km NAT.RD. ATHENS-LAMIA, Schimatari Viotias 32009, Greece.
	Name of exporting country	Greece
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP (**certificate no. 67769**) dated **27-06-2022** issued by National Organization for Medicines (EOF), 284 Mesogeion Ave. 155 62 Holargos Attica, Greece. The CoPP confirms status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 3 years. The name of importing country on CoPP is mentioned as Pakistan. **Free sale in country of origin:** NO Manufacturing Authorization in Greece only for Export.
	Details of letter of authorization / sole agency agreement	Firm has submitted original, legalized sole agency agreement (letter of authorization) as product registration holder. The letter specifies that the manufacturer **ANFARM HELLAS S.A., located at 4 Achaias Str. & Trizinias, 14564, Kifisia Attiki Greece** (administration office as per COPP) appoints M/s Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area, Karachi to register their products in Pakistan. The authorization letter is issued on 09-05-2022
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☐ Finished Pharmaceutical product import ☒ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 27409 dated: 27-09-2022
	Details of fee submitted	PKR 150,000/- deposit Slip # 434916593
	The proposed proprietary name / brand name	DOWPENEM INJECTION 2g IV
	Strength / concentration of drug of Active	**Each vial contains:**

	Pharmaceutical ingredient (API) per unit	Meropenem trihydrate 2280mg equivalent to Meropenem…….2000mg (with sodium carbonate)
	Pharmaceutical form of applied drug	Powder for Solution for Infusion
	Pharmacotherapeutic Group of (API)	Carbapenem Antibiotic
	Reference to Finished product specifications	As per Innovator
	Proposed Pack size	1's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Meropenem 2g Powder for Solution for Infusion of VILLERTON INVEST S.A of (MHRA Approved).
	For generic drugs (me-too status)	
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Name, address of drug substance manufacturer	ACS DOBFAR SpA 2: Addetta Site, Viale Addetta, 2a/12-3/5 20067 Tribiano, Milano - Italy
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API. Stability study conditions: Real time: 25oC ± 2oC and 60% RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Accelerated Batches: (330772 023 0, 330772 025 0, 330772 027 0) Real time Batches: (330772 8001 8, 330772 8001 0, 330772 8038 1)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence against the product MEROPENEM DR. EBERTH 2g by Dr. Friedrich Eberth Arzneimittel GmbH, Am Bahnhof 2, 92289 Ursensollen, Germany Batch no # 22E340
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Colourless glass Vial type III sealed with rubber stopper and aluminium cap with Plastic flip-off seal
	Stability study data of drug product, shelf life and storage conditions	Accelerated stability studies have been conducted at 40ºC ±2ºC / 75%±5% RH for 06 months. Real time stability studies conducted at 30 ºC±2ºC / 65% ± 5% RH for three batch for 24 months Batches of stability studies : [20A293 (20B158), 20A303 (20B159), 20A304 (20B160)]

Evaluation by PEC: Fee submitted on DML

S.No	Shortcomings communicated	Reply
1.	Product is available in USP pharmacopeia while applied formulation is claimed in house specifications.	Kindly refer to attachment herewith, where you may find the comparison between the specifications mentioned in the USP monograph and the specifications set by Anfarm, both at release and during shelf life. It should be noted that based on the comparison, it is evident that: - The limit for Assay set by Anfarm is stricter to the one set by USP. - The limit for Impurities set by Anfarm is in accordance to USP monograph at shelf life and stricter at the release. - The limits for Bacterial endotoxins, Loss on drying, pH, Sterility test, Particulate contamination, and Uniformity of dosage units set by Anfarm are in accordance to the USP monograph. Anfarm Hellas S.A has set extra specifications for the finished product which include “Time of reconstitution” and “Container / closure integrity’’ which shows that the overall specifications of Anfarm are stringent than U Kindly refer to attachment herewith, where you may find the comparison between the specifications mentioned in the USP monograph and the specifications set by Anfarm, both at release and during shelf life. It should be noted that based on the comparison, it is evident that: - The limit for Assay set by Anfarm is stricter to the one set by USP. - The limit for Impurities set by Anfarm is in accordance to USP monograph at shelf life and stricter at the release. - The limits for Bacterial endotoxins, Loss on drying, pH, Sterility test, Particulate contamination, and Uniformity of dosage units set by Anfarm are in accordance to the USP monograph. Anfarm Hellas S.A has set extra specifications for the finished product which include “Time of

reconstitution" and "Container / closure integrity'' which shows that the overall specifications of Anfarm
are stringent than U
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mentioned in the USP monograph and the specifications set by Anfarm, both at release and during
shelf life.
It should be noted that based on the comparison, it is evident that:
- The limit for Assay set by Anfarm is stricter to the one set by USP.
- The limit for Impurities set by Anfarm is in accordance to USP monograph at shelf life and stricter at
the release.
- The limits for Bacterial endotoxins, Loss on drying, pH, Sterility test, Particulate contamination, and
Uniformity of dosage units set by Anfarm are in accordance to the USP monograph.
Anfarm Hellas S.A has set extra specifications for the finished product which include "Time of
reconstitution" and "Container / closure integrity'' which shows that the overall specifications of Anfarm
are stringent than U
Kindly refer to attachment herewith, where you may find the comparison between the specifications mentioned in the USP monograph and the specifications set by Anfarm, both at release and during shelf life.
It should be noted that based on the comparison, it is evident that:
- The limit for Assay set by Anfarm is stricter to the one set by USP.
- The limit for Impurities set by Anfarm is in accordance to USP monograph at shelf life and stricter at the release.
- The limits for Bacterial endotoxins, Loss on drying, pH, Sterility test, Particulate contamination, and Uniformity of dosage units set by Anfarm are in accordance to the USP monograph.
Anfarm Hellas S.A has set extra specifications for the finished product which include "Time of reconstitution" and "Container / closure integrity'' which shows that the overall specifications of Anfarm are stringent than USP.
Firm claimed that in-house specifications are more stringent than USP specifications.

Controls	**USP monograph of Meropenem Injection**	**Anafarm's Release specification**
Assay	90%-120%	95%-105%
Content of sodium	80%-120%	…
Sodium carbonate content	….	14.7%-16.1%
Bacterial Endotoxin	NMT 0.12 EU/mg	NMT 0.12 EU/mg

		Loss on Drying	9.0%-12.0%	9.0%-12.0%
		pH	7.3-8.3	7.3-8.3
		Sterility test	Sterile	Sterile
		Particulate contaminants	Meets the requirements for SVP injections	Meets the requirements for SVP injections
		Uniformity of dosage unit	Meets the requirement	Meets the requirement
2.	Justification of not performing test of Sodium content test by M/s Anfarm as recommended by USP monograph.	Kindly note that Anfarm Hellas S.A. has performed test for Sodium Carbonate Content, instead of Sodium Content. However, the following should be taken into account: As per the finished product composition, the % content of sodium carbonate is calculated to be equal to 15.4%; i.e. equal to 6.7% (w/w) sodium. ➢ USP limit of Sodium content = 80-120%; i.e. 80-120% of 6.7% sodium = (5.3-8.0%) w/w ➢ Anfarm's Limit of 14.7-16.1% of Sodium carbonate corresponds to sodium (6.4-7.0%) w/w. Thus, Anfarm's limit of sodium content is 6.4-7.0%, which is stricter to USP limit 5.3-8.0%.	
3.	Submit Analytical method verification studies of drug substance performed by M/s Anfarm.	The analytical methods for Assay, Related substances, Sodium carbonate content, Sterility and Bacterial Endotoxins have been validated, confirming their suitability for its intended purpose. The validation studies were performed at the manufacturing site of Anfarm Hellas. Also, please note that the validation studies are the same for the Drug Substance (Meropenem Sterile Bulk) and the Final Product (Meropenem Sterile Vials), as the limit is the same and the final product is the active substance (Meropenem Sterile Bulk) filled in vials.		
4.	Details of Diluent is not submitted.	According to MERREM FDA approved label, the concentration of solution for IV infusion ranges from 1mg/ml to 20mg/ml and there is limited safety data available to support use of a 40mg/kg (maximum of 2g) **bolus dose.** Therefore, for 2g Meropenem, at least 100ml of solution for IV infusion (0.9% NS or 5% Dextrose) should be used and drug should be administered by IV infusion over a period of 15-30 minutes. The Summary of Product Characteristics of MHRA Approved product Meropenem 2g powder for solution for infusion (Attached herewith) also claims that "***There is limited safety data available to support the administration of a 2g dose in adults as an intravenous bolus injection."*** Considering that Meropenem Injection 2g is not recommended to be given as bolus dose, hence it can only be administered in In-Patient/Hospital Setups. So, the diluent is not required to be provided along with the product.		

5.	Submit details and origin of product against which Pharmaceutical equivalence have been established.	The Pharmaceutical equivalence have been established against the Reference Product **MEROPENEM DR. EBERTH 2g** by **Dr. Friedrich Eberth Arzneimittel GmbH, Am Bahnhof 2, 92289 Ursensollen, Germany** (Approved by Federal Institute for Drugs and Medical Devices, Germany).

Previous Decision (M-324): Registration Board deferred the application for further deliberation regarding pharmaceutical and clinical features of the innovator product approved by the reference regulatory authorities adopted by Registration Board in its 275th meeting along with clarification of "Manufacturing Authorization in country of origin i.e., Greece" for Export only purpose.

Evaluation:

S.No	Reason o deferment	Reply
1.	Pharmaceutical and clinical features of the innovator product approved by the reference regulatory authorities adopted by Registration Board in its 275th meeting.	The innovator product available on FDA is Merrem by Pfizer holding NDA no. 050706. This NDA has been approved on the basis of extensive clinical and non-clinical studies conducted by the MA holder. These studies revealed that Meropenem is indicated in the following conditions: • Complicated skin and skin structure infections (adult patients and pediatric patients 3 months of age and older only). • Complicated intra-abdominal infections (adult and pediatric patients). • Bacterial meningitis (pediatric patients 3 months of age and older only). Moreover, the data of Merrem available on FDA also proposes a dosing schedule for pediatric patients 3 months of age and older with Normal renal functions, which shows that Meropenem is recommended for Meningitis up to 2g every 8 hours, which reflects the safety and efficacy of Meropenem in 2g doses. The complete label of Merrem approved by FDA is also attached as Annexure 1.1 for your reference

Recommended MERREM IV Dosage Schedule for Pediatric Patients 3 Months of Age and Older with Normal Renal Function (2.3)

Type of Infection	Dose (mg/kg)	Up to a Maximum Dose	Dosing Interval
Complicated skin and skin structure*	10	500 mg	Every 8 hours
Intra-abdominal	20	1 gram	Every 8 hours
Meningitis	40	2 gram	Every 8 hours

- Intravenous infusion is to be given over approximately 15 minutes to 30 minutes.
- Intravenous bolus injection (5 mL to 20 mL) is to be given over approximately 3 minutes-5 minutes.
- There is no experience in pediatric patients with renal impairment.

*20 mg/kg (or 1 gram for pediatric patients weighing over 50 kg) every 8 hours is recommended when treating complicated skin and skin structure

The above-mentioned data establishes the clinical features of the innovator product which show that Meropenem molecule is safe and efficacious when given in doses of 2g.

Based on the above, following 8 reference products are available from the reference regulatory authorities adopted by Registration Board in its 275th meeting held on 25-27th October, 2017 as the evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form and dosage form

S. No.	Reference Regulatory Authority	Product	MA Holder	Au

			1.	Medicines and Healthcare Regulatory Agency (MHRA), **UK**	Meropenem Injection 2g	VILLERTON INVEST S.A, Luxembourg	10.
			2.	National Agency for the Safety of Medicine and Health Products (ANSM), **France**.	MEROPENEM VENUS PHARMA 2 g powder for solution for injection/infusion	VENUS PHARMA GMBH	05.
			3.	Federal Institute for Drugs and Medical Devices, **Germany**.	Meropenem Dr. Eberth 2 g powder for solution for injection/infusion	dr Friedrich Eberth Arzneimittel GmbH	22.
			4.	Federal Institute for Drugs and Medical Devices, **Germany**	Meropenem Venus Pharma 2 g powder for solution for injection/infusion	Venus Pharma GmbH	03.
			5.	Austrian Agency for Health and Food Safety. **Austria**.	Meropenem AptaPharma 2000 mg Pulver zur Herstellung einer Infusionslösung	Apta Medica Internacional doo	07.
			6.	Austrian Agency for Health and Food Safety. **Austria**.	Meropenem Dr. F. Eberth 2 g powder for solution for injection/infusion	Dr. Friedrich Eberth Arzneimittel GmbH	05.
			7.	Federal Agency for Medicines and Health Products, **Belgium**.	Meropenem Venus Pharma 2 g inj./inf. opl. (pdr.) i.v. flac.	VENUS PHARMA GMBH	02.
			8.	Health Products Regulatory Authority (HPRA), **Ireland**.	Meropenem 2 g powder for solution for injection/infusion	Hikma Farmacêutica (Portugal) S.A.	18-
2.	Clarification of Manufacturing Authorization in country of origin i.e., Greece	MA from Greece is attached. M.A No# 137498/09-12-2022 Product code:2860603 Verified from www.eof.gr					

Decision: Registertion Board deferred the case for following:

- **Submission of specification with sodium content test as recommended by USP.**
- **Submission of stability data including performance of test for "Sodium content" as recommended by USP monograph for applied formulation.**
- **Evidence of atomic absoption spectrophotometer.**

365.	Name, address of Applicant / Importer	M/s Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area, Karachi
	Details of Drug Sale License of importer	**License No:** 565 **Address:** Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area, Karachi. **Address of Godown:** (a) 1st floor, Plot no. 211, Sector 23 Korangi Industrial Area, Karachi (b) Plot No 32, Sector 16, Korangi Industrial Area, Karachi **Validity:** 16-06-2024

		Status: License to sell Drugs by way of Wholesale **Renewal:** Yes Submitted valid till 16-06-2022
	Name and address of marketing authorization holder (abroad)	ANFARM HELLAS S.A. 61st km NAT.RD. ATHENS-LAMIA, Schimatari Viotias 32009, Greece.
	Name, address of manufacturer(s)	ANFARM HELLAS S.A. 61st km NAT.RD. ATHENS-LAMIA, Schimatari Viotias 32009, Greece. **Local repacking by:** Global Pharmaceuticals Private Limited. Plot No. 204 – 205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan
	Name of exporting country	Greece
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP (**certificate no. 72204**) dated **11-08-2021** issued by National Organization for Medicines (EOF), 284 Mesogeion Ave. 155 62 Holargos Attica, Greece. The CoPP confirms status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 3 years. The name of importing country on CoPP is mentioned as Pakistan. **Free sale in country of origin:** Yes
	Details of letter of authorization / sole agency agreement	Firm has submitted original, legalized sole agency agreement (letter of authorization) as product registration holder. The letter specifies that the manufacturer **ANFARM HELLAS S.A., located at 4 Achaias Str. & Trizinias, 14564, Kifisia Attiki Greece** (administration office as per COPP) appoints M/s Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area, Karachi to register their products in Pakistan. The authorization letter is issued on 28-06-2021
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☐ Finished Pharmaceutical product import ☒ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 28326 dated: 14-10-2021
	Details of fee submitted	PKR 100,000/- Deposit slip # 97617572626
	The proposed proprietary name / brand name	DOWPENEM INJECTION 500g IV
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each vial of Powder contains:** Meropenem trihydrate equivalent to Meropenem…….500mg

		(with sodium carbonate) **Diluent:** **Each ampoule contains:** Sterilized water for injection…….10ml
	Pharmaceutical form of applied drug	Powder for Injection/ Infusion
	Pharmacotherapeutic Group of (API)	Carbapenem Antibiotic
	Reference to Finished product specifications	In House
	Proposed Pack size	1's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Merrem (Meropenem) Injection 500mg IV **(USFDA** Approved).
	For generic drugs (me-too status)	Meroget Injection of Getz Pharma Pvt. Ltd. (Reg # 083174)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Name, address of drug substance manufacturer	ACS DOBFAR SpA 2: Addetta Site, Viale Addetta, 2a/12-3/5 20067 Tribiano, Milano - Italy
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API. Stability study conditions: Real time: 25oC ± 2oC and 60% RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Accelerated Batches: (330772 023 0, 330772 025 0, 330772 027 0) Real time Batches: (330772 8001 8, 330772 8001 0, 330772 8038 1)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation report, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence against the innovator product Meronem 500mg by AstraZeneca Batch no # 14047 C

	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Colourless glass Vial type III sealed with rubber stopper and aluminium cap with Plastic flip-off seal
	Stability study data of drug product, shelf life and storage conditions	Accelerated stability studies have been conducted at 40°C ±2°C / 75%±5% RH for 06 months. Real time stability studies conducted at 30 °C±2°C / 65% ± 5% RH for one batch for 36 months ((24410) and two batches 24 months (36474, 33994) Batches of stability studies : (24410, 36474, 33994)

Evaluation by PEC: Fee submitted on DML

Sr.no.	Obseravtions/Shortcoming	Reply of the Firm
1.	Letter of Authorization by ANFARM HELLAS S.A does not mentioned that label vials will be imported.	Firm replied that the letter for Authorization provided in the submitted dossier states that Martin Dow Limited has expreseed its willingness to import the products Dowpenem Injection 500mg &1g in full compliance with the relevant local and international guidelines and cGMP standards which actually corresponds to the labelled vials. We, hereby clarify that we are importing the product in the form of labelled vials and final packaging along with diluents will be done by Global Pharmaceuticals.
2.	Product is available in USP pharmacopeia while applied formulation is claimed in house specifications. Clarify. Firm claimed that in-house specifications are more stringent than USP specifications.	

Controls	**USP monograph of Meropenem Injection**	**Anafarm's Release specification**
Assay	90%-120%	95%-105%
Content of sodium	80%-120%	…
Sodium carbonate content	….	14.7%-16.1%
Bacterial Endotoxin	NMT 0.12 EU/mg	NMT 0.12 EU/mg
Loss on Drying	9.0%-12.0%	9.0%-12.0%
pH	7.3-8.3	7.3-8.3
Sterility test	Sterile	Sterile
Particulate contaminants	Meets the requirements for SVP injections	Meets the requirements for SVP injections
Uniformity of dosage unit	Meets the requirement	Meets the requirement

Further firm stated that Anafarm do not test sodium content ,however the percentage of sodium carbonate is calculated to be equal to 15.4% i.e. equal to 6.7% (w/w) sodium, so the limits are between 6.7-7.0%.

3.	Certificate of analysis by both drug substance manufacturer and drug product manufacturer not submitted.	Firm submitted a declaration letter from ANFARM HELLAS S.A in which it is stated that we,Anafarm S.A. receives Meropenem sterile bulk and not the API Meropenem trihydrate.Thus no analysis on the API is performed and thus no method verification is performed.
4.	Manufacturing process does not show blending of Sodium carbonate with meropenem trihydrate neither by API manufacturer nor by ANFARM HELLAS S.A	Firm submitted the reply in which it is stated that the mixing of the excipient Sodium carbonate lyophilized sterile with the API meropenem trihydrate sterile is considered as the first step of the manufacturing process of the sterile bulk.

5.	Data of compatibility studies has been submitted with ANFARM HELLAS S.A diluent while in this case diluent will be locally purchased and no compatibility studies conducted. Justify.	Firm submit commitment that they perform compatibility studies of the product with the locally purchased diluent before marketing of the product.
6.	Stability studies provided by drug product manufacturer ANFARM HELLAS S.A while product will be imported as labelled vials and final packaging will be done by Global Pharmaceuticals. Justify.	Firm submit commitment that stability studies for the final product packaged by Global Pharmaceuticals will be performed for the first three consecutive batches of commercial scale.
7.	Please specify final quality control release site.	Firm claimed that final quality release site will be Global Pharmaceuticals and the finished product specification are according to USP.
8.	Steps of packaging not mentioned performed in the global pharmaceuticals.	Submitted

Previous Decision (M-322): Deferred for following:

- Justification of not performing test of Sodium content test by M/s Anfarm as recommended by USP monograph.
- Analytical method verification studies of drug substance performed by M/s Anfarm.
- Details regarding Packaging, Quality control analysis and batch release activities to be conducted by M/s Global pharmaceuticals**.**

S.No	Reason of deferment	Reply
1.	Justification of not performing test of Sodium content test by M/s Anfarm as recommended by USP monograph.	Kindly refer to table attached herewith, where you may find the comparison between the specifications mentioned in the USP monograph and the specifications set by Anfarm, both at release and during shelf life. Based on the provided table, please take into account the following: Anfarm has performed test for Sodium Carbonate Content instead of Sodium Content for which equivalency is provided below: As per the finished product composition, the % content of sodium carbonate is calculated to be equal to 15.4% i.e., equal to 6.7% (w/w) sodium. • USP limit of Sodium Content = 80-120%; i.e., 80-120% of 6.7% sodium = (5.3-8.0%) w/w. • Anfarm's Limit of 14.7-16.1% of Sodium carbonate corresponds to sodium (6.4-7.0%) w/w. Thus, Anfarm's limit of sodium content is **6.4-7.0%** which is stringent than USP limit **5.3-8.0%.**
2.	Analytical method verification studies of drug substance performed by M/s Anfarm	The analytical methods for Assay, Related substances, Sodium carbonate content, Sterility and Bacterial Endotoxins have been validated, confirming their suitability for its intended purpose. The validation studies were performed at the manufacturing site of Anfarm Hellas. Also, please note that the validation studies are the same for the Drug Substance (Meropenem Sterile Bulk) and the Final Product (Meropenem Sterile Vials), as the limit

		is the same and the final product is the active substance (Meropenem Sterile Bulk) filled in vials. For reference, Analytical Method Validation is attached.
3.	Details regarding Packaging, Quality control analysis and batch release activities to be conducted by M/s Global pharmaceuticals.	Please note that Quality Control Analysis and Batch Release activities of products **Dowpenem Injection 500mg and 1g** will be conducted by **M/s Global Pharmaceuticals (Pvt.) Ltd.** on the basis of specifications given by the manufacturer "Anfarm Hellas" for which Undertaking from M/s Global Pharmaceuticals (Pvt.) Ltd. is attached herewith. Also please find attached herewith, the steps of packaging and handling performed by M/s Global Pharmaceuticals (Pvt.) Ltd.

Previous Decision (M-324): Deferred for following

- Submission of stability data including performance of test for "Sodium content" as recommended by USP monograph for applied formulation .
- Details of the manufacturing steps (including packaging and batch analysis) to be conducted at the site of M/s Global Pharmaceuticals (Pvt.) Ltd. Islamabad.

Evaluation

<table>
<tr><th>S. NO</th><th>Reason of deferment</th><th>Reply</th></tr>
<tr><td>1.</td><td>Submission of stability data including performance of test for "Sodium content" as recommended by USP monograph for applied formulation</td><td>we would like to inform the authority that the manufacturer has performed all the quality tests as per the in-house specifications which are more stringent than that of USP. The comparison of manufacturer's specifications with that of USP is given below:
<table>
<tr><th colspan="4">FINISHED PRODUCT SPECIFICATIONS</th></tr>
<tr><th>Controls</th><th>USP monograph Meropenem for Injection</th><th>Anfarm's Release specifications</th><th>Remarks</th></tr>
<tr><td>Assay</td><td>90%-120%</td><td>95.0% - 105.0%</td><td>The limit for Assay set by Anfarm is stricter to this set by USP.

More Stringent</td></tr>
<tr><td>Content of Sodium *</td><td>80%-120% of the labelled amount of sodium</td><td>-</td><td rowspan="2">*Anfarm tests Sodium Carbonate Content, not Sodium Content.
However please consider the following:
As per the finished product composition, the % content of sodium carbonate is calculated to be
equal to 15.4%; i.e. equal to 6.7% (w/w) sodium.

➢ USP limit of Sodium content =80-120%; i.e. 80-120% of 6.7% sodium = (5.3-8.0%) w/w
➢ Anfarm's Limit of 14.7-16.1% of Sodium carbonate corresponds to sodium (6.4-7.0%)
w/w.</td></tr>
<tr><td>Sodium carbonate Content *</td><td>-</td><td>14.7% - 16.1%</td></tr>
</table></td></tr>
</table>

						Thus, Anfarm's limit of sodium content is 6.4-7.0%, which is stricter to USP limit 5.3-8.0%. **More Stringent**
		Related substances:				
		- UK - 1	Meropenem Impurity I: NMT 0.8%	UK – 1 (USP Meropenem Impurity I): NMT 0.5%	**More Stringent**	
		- UK - 2	Meropenem Impurity II: NMT 0.6%	UK – 2 (USP Meropenem Impurity II): NMT 0.5%	**More Stringent**	
		- Single unspecified impurity	NMT 0.10%	NMT 0.10%	**Complied**	
		- Total impurities	NMT 2.0%	NMT 1.3%	**More Stringent**	
		Bacterial endotoxins	NMT 0.125 EU/mg	NMT 0.125 EU/mg	**Complied**	
		Loss on drying	9.0% - 12.0%	9.0% - 12.0%	**Complied**	
		pH	7.3 – 8.3	7.3 – 8.3	**Complied**	
		Sterility test	Sterile	Sterile	**Complied**	
		Particulate contamination	Meets the requirements for small volume injections	Complies	**Complied**	
		Uniformity of dosage units	Meets the requirements	Complies	**Complied**	
		Time of reconstitution	-	NMT 2 min	**Additional test**	
		Container /	-	Tight after immers	**Additional test**	

		closure integrity		ion for 300 sec at 160mm Hg in 1% methyl ene blue		

In light of the above, it is evident that Anfarm's specifications are more stringent than USP specifications, and as per DRAP's notification No. F.3 -512020-l &V II (M-297) dated 26th July 2021, paragraph ii. ***"The manufacturers/ importers having stringent/ equivalent product specifications for all parameters than official pharmacopeial specifications, shall apply to registration board for its approval"***, we hereby request the authority to approve manufacturer's specifications for our applied products.

Moreover, we would like to add here that based on the stricter limits set by the products' manufacturer i.e., Anfarm, our products already comply with USP, however if the authority still requires us to submit the stability data with test of "Sodium content" as recommended by USP, then the manufacturer will first have to file a post-registration variation with their respective authority and wait for approval, which might take 3-6 months. After which, the manufacturer will have to produce new batches and charge on stability studies which might take further 3-6 months depending on their production plan and wait for completion of 2 years of stability data, resulting in an overall delay of approximately 2.5 to 3 years.

Considering the above-mentioned foreseeable delay and that our products already comply within USP specifications, kindly consider our products for approval on manufacturer's specifications

2.	Details of the manufacturing steps (including packaging and batch analysis) to be conducted at the site of M/s Global Pharmaceuticals (Pvt.) Ltd. Islamabad.	Details of manufacturing steps (including packaging and batch release) to be conducted at the site of M/s Global Pharmaceuticals (Pvt.) Ltd. Islamabad are attached.

Decision: Registertion Board deferred the case for following:

- **Submission of specification with sodium content test as recommended by USP.**
- **Submission of stability data including performance of test for "Sodium content" as recommended by USP monograph for applied formulation .**
- **Evidence of atomic absoption spectrophotometer.**

366.	Name, address of Applicant / Importer	M/s Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area, Karachi
	Details of Drug Sale License of importer	**License No:** 565 **Address:** Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area, Karachi. **Address of Godown:** (a) 1st floor, Plot no. 211, Sector 23 Korangi Industrial Area, Karachi (b) Plot No 32, Sector 16, Korangi Industrial Area, Karachi

		Validity: 16-06-2024 **Status:** License to sell Drugs by way of Wholesale **Renewal:** Yes Submitted valid till 16-06-2022
	Name and address of marketing authorization holder (abroad)	ANFARM HELLAS S.A. 61st km NAT.RD. ATHENS-LAMIA, Schimatari Viotias 32009, Greece.
	Name, address of manufacturer(s)	ANFARM HELLAS S.A. 61st km NAT.RD. ATHENS-LAMIA, Schimatari Viotias 32009, Greece. **Local repacking by:** Global Pharmaceuticals Private Limited. Plot No. 204 – 205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan
	Name of exporting country	Greece
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized CoPP (**certificate no. 72204**) dated **11-08-2021** issued by National Organization for Medicines (EOF), 284 Mesogeion Ave. 155 62 Holargos Attica, Greece. The CoPP confirms status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 3 years. The name of importing country on COPP is mentioned as Pakistan. **Free sale in country of origin:** Yes
	Details of letter of authorization / sole agency agreement	Firm has submitted original, legalized sole agency agreement (letter of authorization) as product registration holder. The letter specifies that the manufacturer **ANFARM HELLAS S.A., located at 4 Achaias Str. & Trizinias, 14564, Kifisia Attiki Greece** (administration office as per COPP) appoints M/s Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area, Karachi to register their products in Pakistan. The authorization letter is issued on 28-06-2021
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the t hese	☐ Finished Pharmaceutical product import ☒ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 29009 dated: 25-10-2021
	Details of fee submitted	PKR 150,000/- deposit Slip # 5765002081
	The proposed proprietary name / brand name	DOWPENEM INJECTION 1g IV

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each vial of Powder contains:** Meropenem trihydrate equivalent to Meropenem……1000mg (with sodium carbonate) **Diluent:** **Each ampoule contains:** Sterilized water for injection…….20ml
	Pharmaceutical form of applied drug	Powder for Injection/ Infusion
	Pharmacotherapeutic Group of (API)	Carbapenem Antibiotic
	Reference to Finished product specifications	In House
	Proposed Pack size	1's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Merrem (Meropenem) Injection 1000mg IV **(USFDA** Approved).
	For generic drugs (me-too status)	Meroget Injection of Getz Pharma Pvt. Ltd. (Reg # 083175)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Name, address of drug substance manufacturer	ACS DOBFAR SpA 2: Addetta Site, Viale Addetta, 2a/12-3/5 20067 Tribiano, Milano - Italy
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API. Stability study conditions: Real time: 25oC ± 2oC and 60% RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Accelerated Batches: (330772 023 0, 330772 025 0, 330772 027 0) Real time Batches: (330772 8001 8, 330772 8001 0, 330772 8038 1)
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation report, control of excipients, control of drug product, specifications, analytical procedures,

		validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence against the innovator product Meronem 500mg by AstraZeneca Batch no # 14047 C. Firm submitted justification "The manufacturer of Meropenem injection 500mg and 1g ha performed the pharmaceutical Equivalence on the same Powder of Merpenem trihydrate that is filled in the vials of both 500mg and 1g. Hence, Pharmaceutical equivalence of one strength (500mg) with the Innovator brand shall be considered as as pharmaceutical equivalence of the other strength (1g) That is why the manufacturer has covered the same pharmaceutical equivalence under the heading of both strengths. Moreover, the parameters covering in pharmaceutical equivalence of Meropenm injection 500mg are general and can be used for bulk powder testing. Hence confirming the point of equivalence for meropenem injection"
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Colourless glass Vial type III sealed with rubber stopper and aluminium cap with Plastic flip-off seal
	Stability study data of drug product, shelf life and storage conditions	Accelerated stability studies have been conducted at 40oC ±2oC / 75%±5% RH for 06 months. Real time stability studies conducted at 30 oC±2oC / 65% ± 5% RH for one batch for 36 months (317121) and two batches 24 months (31523, 31813) Batches of stability studies : (317121, 31523, 31813)

Evaluation by PEC: Fee submitted on DML

Sr.no.	Obseravtions/Shortcoming	Reply of the Firm
1.	Letter of Authorization by ANFARM HELLAS S.A does not mentioned that label vials will be imported.	Firm replied that the letter for Authorization provided in the submitted dossier states that Martin Dow Limited has expreseed its willingness to import the products Dowpenem Injection 500mg &1g in full compliance with the relevant local and international guidelines and cGMP standards which actually corresponds to the labelled vials. We, hereby clarify that we are importing the product in the form of labelled vials and final packaging along with diluents will be done by Global Pharmaceuticals.
2.	Product is available in USP pharmacopeia while applied formulation is claimed in house specifications. Clarify. Firm claimed that in-house specifications are more stringent than USP specifications.	

Controls	USP monograph of Meropenem Injection	Anafarm's Release specification
Assay	90%-120%	95%-105%
Content of sodium	80%-120%	…
Sodium carbonate content	….	14.7%-16.1%
Bacterial Endotoxin	NMT 0.12 EU/mg	NMT 0.12 EU/mg
Loss on Drying	9.0%-12.0%	9.0%-12.0%

	pH	7.3-8.3	7.3-8.3
	Sterility test	Sterile	Sterile
	Particulate contaminants	Meets the requirements for SVP injections	Meets the requirements for SVP injections
	Uniformity of dosage unit	Meets the requirement	Meets the requirement
	Further firm stated that Anafarm do not test sodium content ,however the percentage of sodium carbonate is calculated to be equal to 15.4% i.e. equal to 6.7% (w/w) sodium, so the limits are between 6.7-7.0%.		
3.	Certificate of analysis by both drug substance manufacturer and drug product manufacturer not submitted.	Firm submitted a declaration letter from ANFARM HELLAS S.A in which it is stated that we,Anafarm S.A. receives Meropenem sterile bulk and not the API Meropenem trihydrate.Thus no analysis on the API is performed and thus no method verification is performed.	
4.	Manufacturing process does not show blending of Sodium carbonate with meropenem trihydrate neither by API manufacturer nor by ANFARM HELLAS S.A	Firm submitted the reply in which it is stated that the mixing of the excipient Sodium carbonate lyophilized sterile with the API meropenem trihydrate sterile is considered as the first step of the manufacturing process of the sterile bulk.	
5.	Data of compatibility studies has been submitted with ANFARM HELLAS S.A diluent while in this case diluent will be locally purchased and no compatibility studies conducted. Justify.	Firm submit commitment that they perform compatibility studies of the product with the locally purchased diluent before marketing of the product.	
6.	Stability studies provided by drug product manufacturer ANFARM HELLAS S.A while product will be imported as labelled vials and final packaging will be done by Global Pharmaceuticals. Justify.	Firm submit commitment that stability studies for the final product packaged by Global Pharmaceuticals will be performed for the first three consecutive batches of commercial scale.	
7.	Please specify final quality control release site.	Firm claimed that final quality release site will be Global Pharmaceuticals and the finished product specification are according to USP.	
8.	Steps of packaging not mentioned performed in the global pharmaceuticals.	Submitted	

Previous Decision (M-322): Deferred for following:

- Justification of not performing test of Sodium content test by M/s Anfarm as recommended by USP monograph.
- Analytical method verification studies of drug substance performed by M/s Anfarm.
- Details regarding Packaging, Quality control analysis and batch release activities to be conducted by M/s Global pharmaceuticals**.**

S.No	Reason of deferment	Reply
1.	Justification of not performing test of Sodium content test by M/s Anfarm as recommended by USP monograph.	Kindly refer to table attached herewith, where you may find the comparison between the specifications mentioned in the USP monograph and the specifications set by Anfarm, both at release and during shelf life. Based on the provided table, please take into account the following: Anfarm has performed test for Sodium Carbonate Content instead of Sodium Content for which equivalency is provided below:

		As per the finished product composition, the % content of sodium carbonate is calculated to be equal to 15.4% i.e., equal to 6.7% (w/w) sodium. • USP limit of Sodium Content = 80-120%; i.e., 80-120% of 6.7% sodium = (5.3-8.0%) w/w. • Anfarm's Limit of 14.7-16.1% of Sodium carbonate corresponds to sodium (6.4-7.0%) w/w. Thus, Anfarm's limit of sodium content is **6.4-7.0%** which is stringent than USP limit **5.3-8.0%.**
2.	Analytical method verification studies of drug substance performed by M/s Anfarm	The analytical methods for Assay, Related substances, Sodium carbonate content, Sterility and Bacterial Endotoxins have been validated, confirming their suitability for its intended purpose. The validation studies were performed at the manufacturing site of Anfarm Hellas. Also, please note that the validation studies are the same for the Drug Substance (Meropenem Sterile Bulk) and the Final Product (Meropenem Sterile Vials), as the limit is the same and the final product is the active substance (Meropenem Sterile Bulk) filled in vials. For reference, Analytical Method Validation is attached.
3.	Details regarding Packaging, Quality control analysis and batch release activities to be conducted by M/s Global pharmaceuticals.	Please note that Quality Control Analysis and Batch Release activities of products **Dowpenem Injection 500mg and 1g** will be conducted by **M/s Global Pharmaceuticals (Pvt.) Ltd.** on the basis of specifications given by the manufacturer "Anfarm Hellas" for which Undertaking from M/s Global Pharmaceuticals (Pvt.) Ltd. is attached herewith. Also please find attached herewith, the steps of packaging and handling performed by M/s Global Pharmaceuticals (Pvt.) Ltd.

Decision: Deferred for the submission of stability data including performance of test for "Sodium content" as recommended by USP monograph for applied formuation .

Previous Decision (M-324): Deferred for following

- Submission of stability data including performance of test for "Sodium content" as recommended by USP monograph for applied formulation .
- Details of the manufacturing steps (including packaging and batch analysis) to be conducted at the site of M/s Global Pharmaceuticals (Pvt.) Ltd. Islamabad.

Evaluation

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<tr><td>3.</td><td>Submission of stability data including performance of test for "Sodium content" as recommended by USP monograph for applied formulation</td><td>we would like to inform the authority that the manufacturer has performed all the quality tests as per the in-house specifications which are more stringent than that of USP. The comparison of manufacturer's specifications with that of USP is given below:
<table>
<tr><th colspan="4">FINISHED PRODUCT SPECIFICATIONS</th></tr>
<tr><th>Controls</th><th>USP monograph Meropenem for Injection</th><th>Anfarm's Release specifications</th><th>Remarks</th></tr>
<tr><td>Assay</td><td>90%-120%</td><td>95.0% - 105.0%</td><td>The limit for Assay set by Anfarm is stricter to this set by USP.</td></tr>
</table>
</td></tr>
</table>

					More Stringent
		Content of Sodium*	80%-120% of the labelled amount of sodium	-	*Anfarm tests Sodium Carbonate Content, not Sodium Content. However please consider the following: As **per the finished product composition, the % content of sodium carbonate is calculated to be equal to 15.4%; i.e. equal to 6.7% (w/w) sodium.** **➢ USP limit of Sodium content =80-120%; i.e. 80-120% of 6.7% sodium = (5.3-8.0%) w/w** **➢ Anfarm's Limit of 14.7-16.1% of Sodium carbonate corresponds to sodium (6.4-7.0%) w/w.** **Thus, Anfarm's limit of sodium content is 6.4-7.0%, which is stricter to USP limit 5.3-8.0%.** **More Stringent**
		Sodium carbonate Content*	-	14.7% - 16.1%	
		Related substances :			
		- UK - 1	Meropenem Impurity I: NMT 0.8%	UK – 1 (USP Meropenem Impurity I): NMT 0.5%	**More Stringent**
		- UK - 2	Meropenem Impurity II: NMT 0.6%	UK – 2 (USP Meropenem Impurity II): NMT 0.5%	**More Stringent**
		- Single unspecified impurity	NMT 0.10%	NMT 0.10%	**Complied**
		- Total impurities	NMT 2.0%	NMT 1.3%	**More Stringent**
		Bacterial endotoxins	NMT 0.125 EU/mg	NMT 0.125 EU/mg	**Complied**
		Loss on drying	9.0% - 12.0%	9.0% - 12.0%	**Complied**
		pH	7.3 – 8.3	7.3 – 8.3	**Complied**
		Sterility test	Sterile	Sterile	**Complied**
		Particulate contamination	Meets the requirements for	Complies	**Complied**

			small volume injections		
		Uniformity of dosage units	Meets the requirements	Complies	**Complied**
		Time of reconstitution	-	NMT 2 min	**Additional test**
		Container / closure integrity	-	Tight after immersion for 300 sec at 160mmHg in 1% methylene blue	**Additional test**

In light of the above, it is evident that Anfarm's specifications are more stringent than USP specifications, and as per DRAP's notification No. F.3 - 512020-l &V II (M-297) dated 26th July 2021, paragraph ii. ***"The manufacturers/ importers having stringent/ equivalent product specifications for all parameters than official pharmacopeial specifications, shall apply to registration board for its approval"***, we hereby request the authority to approve manufacturer's specifications for our applied products.

Moreover, we would like to add here that based on the stricter limits set by the products' manufacturer i.e., Anfarm, our products already comply with USP, however if the authority still requires us to submit the stability data with test of "Sodium content" as recommended by USP, then the manufacturer will first have to file a post-registration variation with their respective authority and wait for approval, which might take 3-6 months. After which, the manufacturer will have to produce new batches and charge on stability studies which might take further 3-6 months depending on their production plan and wait for completion of 2 years of stability data, resulting in an overall delay of approximately 2.5 to 3 years.

Considering the above-mentioned foreseeable delay and that our products already comply within USP specifications, kindly consider our products for approval on manufacturer's specifications

4.	Details of the manufacturing steps (including packaging and batch analysis) to be conducted at the site of M/s Global Pharmaceuticals (Pvt.) Ltd. Islamabad.	Details of manufacturing steps (including packaging and batch release) to be conducted at the site of M/s Global Pharmaceuticals (Pvt.) Ltd. Islamabad are attached.

Decision: Registertion Board deferred the case for following:

- **Submission of specification with sodium content test as recommended by USP.**
- **Submission of stability data including performance of test for "Sodium content" as recommended by USP monograph for applied formulation.**
- **Evidence of atomic absoption spectrophotometer.**

Case No. I: Routine applications submitted on Form-5F for local manufacturing
Deferred Cases

367.	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma (pvt.) Ltd. 44-45B Korangi creek road, Karachi.
	Name, address of Manufacturing site.	M/s Genix Pharma (pvt.) Ltd. 44-45B Korangi creek road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 9894 dated 30/04/2021
	Details of fee submitted	PKR 50,000/-: dated 30/11/2020
	The proposed proprietary name / brand name	Carlep 200mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Eslicarbazepine acetate……200mg
	Pharmaceutical form of applied drug	Oblong, White colored, biconvex core tablet plain from both sides
	Pharmacotherapeutic Group of (API)	Anti-epileptic
	Reference to Finished product specifications	Inhouse Specification
	Proposed Pack size	10's, 20's & 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	APTIOM tablets 200mg by Sunovion Pharmaceuticals Inc. USFDA Approved.
	For generic drugs (me-too status)	Not available
	GMP status of the Finished product manufacturer	**GMP inspection : 28/10/2019** Tablet (General & Psychotropic) section approved.
	Name and address of API manufacturer.	Ami Lifesciences Pr,t. Limited Plot No. 8218, ECP channel Road At & post Karakhadi, Dist. Vadodara -391 450 State Gujarat, INDIA Phone: +9 | -2662-27 3 40 | I 27 33 12 Fax: * 9l-2662-273401
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is

		submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 72 months Batches: (ECA/50030515, ECA/50040515, ECA/50050515) Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (ECA/50020111, ECA/50030111 ECA/50040111)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Aptiom 200mg tablet by Sunovion Pharmaceuticals Inc.by performing quality tests (Appearance, Identification, DT ,Assay, Dissolution). CDP has been performed against the same brand that is Aptiom 200mg tablet by Sunovion Pharmaceuticals Inc in 0.1N HCL, Acetate buffer 4.5 and Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity & Range, robustness, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Ami Lifesciences Pr,t. Limited Plot No. 8218, ECP channel Road At & post Karakhadi, Dist. Vadodara -391 450 State Gujarat, INDIA		
API Lot No.	ECA/50010117		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (10's, 20's & 30's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 1,2,3,4 & 6 (months) Real Time: 0, 3, 6 (Months)		
Batch No.	19SB-159-01	19SB-160-02	19SB-161-03
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	08-2019	08-2019	08-2019

Date of Initiation	08-2021	08-2021	08-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	A Panel Inspection for the verification of authenticity of Stability Data of product on Form-5D "Wymly Tablet 25mg" for Tablet Section has been conducted on 06 April, 2018. Inspection Report included in the 281th DRB meeting held on 11-13th April, 2018.. The firm has 21CFR compliant system and adequate monitoring and control for stability chamber.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 19041306 issued by FOOD AND DRUG CONTROL ADMINISTRATION valid till 24/04/2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Form 6 Dated:27/04/2017 is submitted, wherein the permission to import API Eslicarbazepine acetate for the purpose of test/analysis and stability studies is granted. • Invoice No & Date: EXP/A/007/2017-18 dated 13/04/2017. • Batch No:ECA/50010117
4.	Data of stability batches will be supported by attested respective documents like chromatograms,Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S. No	Sections	Observations/Deficiencies/ Short-comings	Reply
1.	1.3.5.	Evidence of approval of relevant section from Licensing Authority is required as you have provided approval of master layout plan.	Firm has provided grant of additional/revised section Tablet (General) – Revised letter dated 30 Sep 2021.
2.	2.3.S.6	The container closure system mentions material of construction as food grade quality material ,clarification is required.	Firm has used food grade LDPE as primary packing material for drug substance.
3.	2.3.P.2.2.1	Provide Summary of the results of comparative dissolution profile.	The summary of CDP is of Carlep 400mg.
4.	2.3.P.3.2	Provide List of all components of the Drug Product to be used in the manufacturing process and their amounts per proposed commercial batch as	First trail batch of 1000 tablets were manufactured and parameters found unsatisfactory. In order to obtain best and optimized product formulation was designed with change in quantitative composition that is Trail 2 in which all physical and chemical parameters were found satisfactory.

		provided data is of Trial batch. Moreover, the batch size mentioned in this section is 1000 tablets and BMR mentions batch size of 1500 Tablets. The quantity of individual components per tablet mentioned in Trail batch formula is different than stability batch formula.	As per CTD guidelines three stability batch sizes 1500 Tablet as mentioned in BMR with same formulation were manufactured as that of passed trail 2.
5.	2.3.P.5.6	Provide justification of specifications for all the tests specified in section 2.3.P.5.1.	Justification for specification not provided only inhouse has been mentioned.
6.	2.3.R.1.2	Provide blank master production document / batch manufacturing record to be used during the commercial manufacturing of the applied product.	BMR has not been signed.
7.	3.2.S.4.4	A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer like residual solvents.	**Firms Response** We follow suppliers COA for residual solvents.
8.	3.2.P.3.3	The maximum holding time for bulk product prior to final packaging shall be stated.	Firm has submitted the SOP for withholding time.
9.	3.2.P.5.1	The innovator proposes two point dissolution according to chemistry review.	**Firms Response** We have set our specification single point in 15 minutes.
10.	3.2.P.5.2	Dissolution testing conducted by test 1 or test 2 of USP monograph by Drug product manufacturer.	**Firms Response** USP Type II Paddle apparatus are used.
11.	3.2.P.8.3	The formulation was previously applied on Form 5 D which was rejected in 289th meeting wherein 7kg API was imported vide invoice dated 27-04-2017 and 3kg vide invoice dated 24-02-2017 for manufacturing of trial batches of Carlep 200mg, 400mg and 800mg. Approximately, 6.4 kg was consumed in manufacturing of trial batches. Now, you have applied same formulation on Form 5 F wherein the submitted commercial invoice is same dated 27-04-2017. Please justify/clarify the quantity of API in manufacturing of	**Firms Response** **Provided at the end of 800mg strength.**

		current trial batches of **Carlep 200mg, 400mg and 800mg** applied on Form-5F.	

368.	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma (pvt.) Ltd. 44-45B Korangi creek road, Karachi.
	Name, address of Manufacturing site.	M/s Genix Pharma (pvt.) Ltd. 44-45B Korangi creek road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 9893 dated 30/03/2021
	Details of fee submitted	PKR 50,000/-: dated 30/11/2021
	The proposed proprietary name / brand name	Carlep 400mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Eslicarbazepine acetate……400mg
	Pharmaceutical form of applied drug	Oblong shape, white color, biconvex tablet, engraved 'GENIX" on one side and plain on other side.
	Pharmacotherapeutic Group of (API)	Anti-epileptic
	Reference to Finished product specifications	Inhouse Specification
	Proposed Pack size	10's, 20's & 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	APTIOM tablets 400mg by Sunovion Pharmaceuticals Inc. USFDA Approved.
	For generic drugs (me-too status)	Not available
	GMP status of the Finished product manufacturer	GMP granted on 28/10/2019 Tablet (General & Psychotropic) section approved.
	Name and address of API manufacturer.	Ami Lifesciences Pr,t. Limited Plot No. 8218, ECP channel Road At & post Karakhadi, Dist. Vadodara -391 450 State Gujarat, INDIA Phone: +9 | -2662-27 3 40 | I 27 33 12 Fax: * 9l-2662-273401
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is

		submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 72 months Batches: (ECA/50030515, ECA/50040515, ECA/50050515) Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (ECA/50020111, ECA/50030111 ECA/50040111)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Aptiom 400mg tablet by Sunovion Pharmaceuticals Inc.by performing quality tests (Appearance, Identification, DT ,Assay, Dissolution). CDP has been performed against the same brand that is Aptiom 200mg tablet by Sunovion Pharmaceuticals Inc in 0.1N HCL, Acetate buffer 4.5 and Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity & Range, robustness, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Ami Lifesciences Pr,t. Limited Plot No. 8218, ECP channel Road At & post Karakhadi, Dist. Vadodara -391 450 State Gujarat, INDIA		
API Lot No.	ECA/50010117		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (10's, 20's & 30's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 1,2,3,4 & 6 (months) Real Time: 0, 3, 6 (Months)		
Batch No.	19SB-162-01	19SB-163-02	19SB-164-03
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	08-2019	08-2019	08-2019

Date of Initiation	10-09-2019	10-09-2019	10-09-2019
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	A Panel Inspection for the verification of authenticity of Stability Data of product on Form-5D "Wymly Tablet 25mg" for Tablet Section has been conducted on 06 April, 2018. Inspection Report included in the 281th DRB meeting held on 11-13th April, 2018.. The firm has 21CFR compliant system and adequate monitoring and control for stability chamber.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 19041306 issued by FOOD AND DRUG CONTROL ADMINISTRATION valid till 24/04/2022
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Form 6 Dated:27/04/2017 is submitted, wherein the permission to import API Eslicarbazepine acetate for the purpose of test/analysis and stability studies is granted. • Invoice No & Date: EXP/A/007/2017-18 dated 13/04/2017.
4.	Data of stability batches will be supported by attested respective documents like chromatograms,Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S. No	Sections	Observations/Deficiencies/ Short-comings	Reply
1.	1.3.5.	Evidence of approval of relevant section from Licensing Authority is required as you have provided approval of master layout plan.	Firm has provided grant of additional/revised section Tablet (General) – Revised letter dated 30 Sep 2021.
2.	2.3.S.6	The container closure system mentions material of construction as food grade quality material ,clarification is required.	Firm has used food grade LDPE as primary packing material for drug substance.
3.	2.3.P.3.2	Provide List of all components of the Drug Product to be used in the manufacturing process and their amounts per proposed commercial batch as provided data is of Trial batch. Moreover, the batch size mentioned in this section is 1000 tablets and BMR mentions batch size of 1500 Tablets. The quantity of	First trail batch of 1000 tablets were manufactured and parameters found unsatisfactory . In order to obtain best and optimized product formulation was designed with change in quantitative composition that is Trail 2 in which all physical and chemical parameters were found satisfactory. As per CTD guidelines three stability batch sizes 1500 Tablet as mentioned in BMR with same formulation were manufactured as that of passed trail 2.

		individual components per tablet mentioned in Trail batch formula is different than stability batch formula.	
4.	2.3.P.5.6	Provide justification of specifications for all the tests specified in section 2.3.P.5.1.	Justification for specification not provided only inhouse has been mentioned.
5.	2.3.R.1.2	Provide blank master production document / batch manufacturing record to be used during the commercial manufacturing of the applied product.	BMR has not been signed.
6.	3.2.S.4.4	A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer like residual solvents.	Firms Response We follow suppliers COA for residual solvents.
7.	3.2.P.3.3	The maximum holding time for bulk product prior to final packaging shall be stated.	Firm has submitted the SOP for withholding time.
8.	3.2.P.5.1	The innovator proposes two point dissolution according to chemistry review.	Firms Response We have set our specification single point in 15 minutes.
9.	3.2.P.5.2	Dissolution testing conducted by test 1 or test 2 of USP monograph by Drug product manufacturer.	USP Type II Paddle apparatus are used.
10.	3.2.P.8.3	The formulation was previously applied on Form 5 D which was rejected in 289th meeting wherein 7kg API was imported vide invoice dated 27-04-2017 and 3kg vide invoice dated 24-02-2017 for manufacturing of trial batches of Carlep 200mg, 400mg and 800mg. Approximately, 6.4 kg was consumed in manufacturing of trial batches. Now, you have applied same formulation on Form 5 F wherein the submitted commercial invoice is same dated 27-04-2017. Please justify/clarify the quantity of API in manufacturing of current trial batches of **Carlep 200mg, 400mg and 800mg** applied on Form-5F.	**Firms Response** **Provided at the end of 800mg strength.**

369.	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma (pvt.) Ltd. 44-45B Korangi creek road, Karachi.
	Name, address of	M/s Genix Pharma (pvt.) Ltd.

	Manufacturing site.	44-45B Korangi creek road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No.9895 dated 30/03/2021
	Details of fee submitted	PKR 50,000/-: dated 30/11/2021
	The proposed proprietary name / brand name	Carlep 800mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Eslicarbazepine acetate……800mg
	Pharmaceutical form of applied drug	Oblong shape, white color, biconvex tablet, engraved 'GENIX" on one side and break line on other side.
	Pharmacotherapeutic Group of (API)	Anti-epileptic
	Reference to Finished product specifications	Inhouse Specification
	Proposed Pack size	10's, 20's & 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	APTIOM tablets 800mg by Sunovion Pharmaceuticals Inc. USFDA Approved.
	For generic drugs (me-too status)	Not available
	GMP status of the Finished product manufacturer	GMP granted on 28/10/2019 Tablet (General & Psychotropic) section approved.
	Name and address of API manufacturer.	Ami Lifesciences Pr,t. Limited Plot No. 8218, ECP channel Road At & post Karakhadi, Dist. Vadodara -391 450 State Gujarat, INDIA Phone: +9 | -2662-27 3 40 | I 27 33 12 Fax: * 9l-2662-273401
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance

	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 72 months Batches: (ECA/50030515, ECA/50040515, ECA/50050515) Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (ECA/50020111, ECA/50030111 ECA/50040111)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Aptiom 800mg tablet by Sunovion Pharmaceuticals Inc.by performing quality tests (Appearance, Identification, DT ,Assay, Dissolution). CDP has been performed against the same brand that is Aptiom 200mg tablet by Sunovion Pharmaceuticals Inc in 0.1N HCL, Acetate buffer 4.5 and Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity & Range, robustness, accuracy, precision, specificity.

STABILITY STUDY DATA				
Manufacturer of API		Ami Lifesciences Pr,t. Limited Plot No. 8218, ECP channel Road At & post Karakhadi, Dist. Vadodara -391 450 State Gujarat, INDIA		
API Lot No.		ECA/50010117		
Description of Pack (Container closure system)		Alu-Alu blister packed in unit carton (10's, 20's & 30's)		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 1,2,3,4 & 6 (months) Real Time: 0, 3, 6 (Months)		
Batch No.		19SB-165-01	19SB-166-02	19SB-167-03
Batch Size		1500 tab	1500 tab	1500 tab
Manufacturing Date		08-2019	08-2019	08-2019
Date of Initiation		10-09-2019	10-09-2019	10-09-2019
No. of Batches		03		
Administrative Portion				
7.	Reference of previous approval of applications with stability study data of the firm (if any)	A Panel Inspection for the verification of authenticity of Stability Data of product on Form-5D "Wymly Tablet 25mg" for Tablet Section has been conducted on 06 April, 2018. Inspection Report included in the 281th DRB meeting held on 11-13th April, 2018.. The firm has 21CFR compliant system and adequate monitoring and control for stability chamber.		

8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 19041306 issued by FOOD AND DRUG CONTROL ADMINISTRATION valid till 24/04/2022
9.	Documents for the procurement of API with approval from DRAP (in case of import).	• Form 6 Dated:27/04/2017 is submitted, wherein the permission to import API Eslicarbazepine acetate for the purpose of test/analysis and stability studies is granted. • Invoice No & Date: EXP/A/007/2017-18 dated 13/04/2017.
10.	Data of stability batches will be supported by attested respective documents like chromatograms,Raw data sheets, COA, summary data sheets etc.	Submitted
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S. No	Sections	Observations/Deficiencies/ Short-comings	Reply
1.	1.3.5.	Evidence of approval of relevant section from Licensing Authority is required as you have provided approval of master layout plan.	Firm has provided grant of additional/revised section Tablet (General) – Revised letter dated 30 Sep 2021.
2.	2.3.S.6	The container closure system mentions material of construction as food grade quality material ,clarification is required.	Firm has used food grade LDPE as primary packing material for drug substance.
3.	2.3.P.3.2	Provide List of all components of the Drug Product to be used in the manufacturing process and their amounts per proposed commercial batch as provided data is of Trial batch. Moreover, the batch size mentioned in this section is 1000 tablets and BMR mentions batch size of 1500 Tablets. The quantity of individual components per tablet mentioned in Trail batch formula is different than stability batch formula.	First trail batch of 1000 tablets were manufactured and parameters found unsatisfactory . In order to obtain best and optimized product formulation was designed with change in quantitative composition that is Trail 2 in which all physical and chemical parameters were found satisfactory. As per CTD guidelines three stability batch sizes 1500 Tablet as mentioned in BMR with same formulation were manufactured as that of passed trail 2.
4.	2.3.P.5.6	Provide justification of specifications for all the tests specified in section 2.3.P.5.1.	Justification for specification not provided only inhouse has been mentioned.
5.	2.3.R.1.2	Provide blank master production document / batch manufacturing record to be used during the commercial	BMR has not been signed.

		manufacturing of the applied product.	
6.	3.2.S.4.4	A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer like residual solvents.	Firms Response We follow suppliers COA for residual solvents.
7.	3.2.P.3.3	The maximum holding time for bulk product prior to final packaging shall be stated.	Firm has submitted the SOP for withholding time.
8.	3.2.P.5.1	The innovator proposes two point dissolution according to chemistry review.	Firms Response We have set our specification single point in 15 minutes.
9.	3.2.P.5.2	Dissolution testing conducted by test 1 or test 2 of USP monograph by Drug product manufacturer.	USP Type II Paddle apparatus are used.
10.	3.2.P.8.3	The formulation was previously applied on Form 5 D which was rejected in 289th meeting wherein 7kg API was imported vide invoice dated 27-04-2017 and 3kg vide invoice dated 24-02-2017 for manufacturing of trial batches of Carlep 200mg, 400mg and 800mg. Approximately, 6.4 kg was consumed in manufacturing of trial batches. Now, you have applied same formulation on Form 5 F wherein the submitted commercial invoice is same dated 27-04-2017. Please justify/clarify the quantity of API in manufacturing of current trial batches of **Carlep 200mg, 400mg and 800mg** applied on Form-5F.	

Carlep Tablets Range		
Eslicarbazepine Acetate		
API Consumption for Trial Batches		
API	Eslicarbazepine Acetate	
RM #	1912	
Potency	99.20 %	
Quantity Received	03 kg	
Carlep Tablets 200mg		
Potency Adjustment	Potency of Eslicarbazepine Acetate = 99.2 % Required Quantity = Standard Qty. x 100 / Potency = 200mg x 100/99.2 =201.6 mg/Tab	
Trail Batch	Trail Batch 01	Trail Batch 02
	1000 Tablets 201.6 mg x 1000 Tablets = 201.6 g	1000 Tablets 201.6 mg x 1000 Tablets = 201.6 g
	Total = 201.6 g + 201.6 g = 403.2 g	
Carlep Tablets 400mg		
Potency Adjustment	Potency of Eslicarbazepine Acetate = 99.2 % Required Quantity = Standard Qty. x 100 / Potency = 400mg x 100/99.2 =403.2 mg/Tab	
Trail Batch	Trail Batch 01	Trail Batch 02
	1000 Tablets 403.2 mg x 1000 Tablets = 403.2 g	1000 Tablets 403.2 mg x 1000 Tablets = 403.2 g
	Total = 403.2 g + 403.2 g	

	= 806.4 g		
Carlep Tablets 800mg			
Potency Adjustment	Potency of Eslicarbazepine Acetate = 99.2 % Required Quantity = Standard Qty. x 100 / Potency = 800mg x 100/99.2 =806.4 mg/Tab		
Trail Batch	Trail Batch 01	Trail Batch 02	
	1000 Tablets 806.4 mg x 1000 Tablets = 806.4 g	1000 Tablets 806.4 mg x 1000 Tablets = 806.4 g	
	Total = 806.4 g + 806.4 g = 1612.8 g		
Quantity used in trial batches = 403.2 g + 806.4 g + 1612.8 g **= 2.8224 kg** **Quantity used in testing = 10.0 g** **Total = 2.8324 kg**			
Carlep Tablets Range			
Eslicarbazepine Acetate			
API Consumption for Stability Batches			
API	Eslicarbazepine Acetate		
RM #	2108		
Potency	99.00 %		
Quantity Received	07 kg		
Carlep Tablets 200mg			
Potency Adjustment	Potency of Eslicarbazepine Acetate = 99.0 % Required Quantity = Standard Qty. x 100 / Potency = 200mg x 100/99.0 = 202 mg/Tab		
Stability Batch	Stability Batch 01	Stability Batch 02	Stability Batch 03
	1500 Tablets 202mg x 1500 Tablets = 303.0 g	1500 Tablets 202mg x 1500 Tablets = 303.0 g	1500 Tablets 202mg x 1500 Tablets = 303.0 g
	Total = 303.0 g + 303.0 g + 303.0 g = 909.0 g		
Carlep Tablets 400mg			
Potency Adjustment	Potency of Eslicarbazepine Acetate = 99.0 % Required Quantity = Standard Qty. x 100 / Potency = 400mg x 100/99.0 = 404 mg/Tab		
Stability Batch	Stability Batch 01	Stability Batch 02	Stability Batch 03
	1500 Tablets 404 mg x 1500 Tablets = 606.0 g	1500 Tablets 404 mg x 1500 Tablets = 606.0 g	1500 Tablets 404 mg x 1500 Tablets = 606.0 g
	Total = 606.0 g + 606.0 g + 606.0 g = 1818.0 g		
Carlep Tablets 800mg			
Potency Adjustment	Potency of Eslicarbazepine Acetate = 99.0 % Required Quantity = Standard Qty. x 100 / Potency = 800mg x 100/99.0 = 808 mg/Tab		
Stability Batch	Stability Batch 01	Stability Batch 02	Stability Batch 03

	1500 Tablets 808mg x 1500 Tablets = 1212.0 g	1500 Tablets 808mg x 1500 Tablets = 1212.0 g	1500 Tablets 808mg x 1500 Tablets = 1212.0 g
	Total = 1212.0 g + 1212.0 g + 1212.0 g = 3636.0 g		

Quantity used in Stability batches = 909.0 g + 1818.0 g + 3636.0 g **= 6.363 kg**
Quantity used in testing = 10.0 g
Total = 6.373 kg

Total consumption of API		
Trial Batches of Carlep Tablets Range + Q.C. Testing	**RM # 1912**	**2.8324 kg**
Stability Batches of Carlep Tablets Range + Q.C. Testing	**RM # 2108**	**6.373 kg**

Also note that:
Formulation applied on form 5-D in which all results meet as per pre-defined specifications and no out of trends results were found. Furthermore, all physical and chemical parameters found satisfactory. Therefore, same formulation applied on form 5-F.

Evaluation by PEC
The firm has changed the batch size and number of batches for product applied in M-289 to justify the quantity of API.

	Minutes 289 meeting Form 5 D			Firms Response		
Strength	Carlep Tablet 200mg	Carlep Tablet 400mg	Carlep Tablet 800mg	Carlep Tablet 200mg	Carlep Tablet 400mg	Carlep Tablet 800mg
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets	1000 Tablets	1000 Tablets	1000 Tablets
Batch No.	TR001	TR001	TR001	TR001	TR001	TR001
	TR002	TR002	TR002	TR002	TR002	TR002
	TR003	TR003	TR003			

Well along the firm further submitted on 30-12-2021.
"We request Evaluation cell to consider our product Carlep Tablet Range in Registration Board once we submit additional data of the product in support of already submitted data to registration board."
Evaluation by PEC
Since 30-12-2021 firm has not submitted any additional data in order to support already submitted data .The Registration Board may decide accordingly.

Previous Decision of 322nd meeting: Deferred for the reconciliation record of the quantity drug substance imported against the quantity required for the manufacturing of stability batches of each strength.

Firms Response:
Regarding Submission of additional data for below mentioned products, deferred in 322 DRB for the reconciliation record of the quantity drug substance imported against the quantity required for the manufacturing of stability batches of each strength, we would like to inform that we have imported new quantity of drug substance and fresh batches were manufactured, accordingly this data is submitted in DRAP for consideration. We hereby request to ignore previously submitted data and consider the recent one for your kind perusal.

Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma (pvt.) Ltd. 44-45B Korangi creek road, Karachi.
Name, address of Manufacturing site.	M/s Genix Pharma (pvt.) Ltd. 44-45B Korangi creek road, Karachi.
Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 7082 dated 10/03/2023
	Details of fee submitted	PKR 75,000/-: dated 08/03/2023
	The proposed proprietary name / brand name	Carlep 200mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Eslicarbazepine acetate……200mg
	Pharmaceutical form of applied drug	White color, oval shape ,biconvex core tablet, engraved Genix on one side and plain from the other side.
	Pharmacotherapeutic Group of (API)	Anti-epileptic
	Reference to Finished product specifications	Inhouse Specification
	Proposed Pack size	10's, 20's & 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	APTIOM tablets 200mg by Sunovion Pharmaceuticals Inc. USFDA Approved.
	For generic drugs (me-too status)	Not available
	GMP status of the Finished product manufacturer	**GMP inspection : 28/10/2019** Tablet (General & Psychotropic) section approved.
	Name and address of API manufacturer.	Ami Lifesciences Pvt. Limited Plot No. 8218, ECP channel Road At & post Karakhadi, Dist. Vadodara -391 450 State Gujarat, INDIA Phone: +9 | -2662-27 3 40 | I 27 33 12 Fax: * 9l-2662-273401
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 72 months Batches: (ECA/50030515, ECA/50040515, ECA/50050515) Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (ECA/50020111, ECA/50030111 ECA/50040111)

		……..
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Aptiom 200mg tablet by Sunovion Pharmaceuticals Inc.by performing quality tests (Appearance, Identification, DT ,Assay, Dissolution). CDP has been performed against the same brand that is Aptiom 200mg tablet by Sunovion Pharmaceuticals Inc in 0.1N HCL, Acetate buffer 4.5 and Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity & Range, robustness, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Ami Lifesciences Pr,t. Limited Plot No. 8218, ECP channel Road At & post Karakhadi, Dist. Vadodara -391 450 State Gujarat, INDIA		
API Lot No.	ESA/30011221		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (10's, 20's & 30's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 1,2,3,4 & 6 (months) Real Time: 0, 3, 6 (Months)		
Batch No.	22SB-208-01	22SB-209-02	22SB-210-03
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	21-06-2022	21-06-2022	21-06-2022
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	A Panel Inspection for the verification of authenticity of Stability Data of product on Form-5D "Wymly Tablet 25mg" for Tablet Section has been conducted on 06 April, 2018. Inspection Report included in the 281th DRB meeting held on 11-13th April, 2018.. The firm has 21CFR compliant system and adequate monitoring and control for stability chamber.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 22043267 issued by FOOD AND DRUG CONTROL ADMINISTRATION valid till 17/04/2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Invoice No & Date: EXP/I/21-22/0880 dated 29/01/2022. • Batch No:ESA/30011221 • QTY=10KG
4.	Data of stability batches will be supported by attested respective documents like chromatograms,Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Decision: Approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma (pvt.) Ltd. 44-45B Korangi creek road, Karachi.
Name, address of Manufacturing site.	M/s Genix Pharma (pvt.) Ltd. 44-45B Korangi creek road, Karachi.
Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
Dy. No. and date of submission	Dy. No. 7082 dated 10/03/2023
Details of fee submitted	PKR 75,000/-: dated 08/03/2023
The proposed proprietary name / brand name	Carlep 400mg Tablet
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Eslicarbazepine acetate……400mg
Pharmaceutical form of applied drug	Oblong shape, white color, biconvex tablet, plain from both sides.
Pharmacotherapeutic Group of (API)	Anti-epileptic
Reference to Finished product specifications	Inhouse Specification

	Proposed Pack size	10's, 20's & 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	APTIOM tablets 400mg by Sunovion Pharmaceuticals Inc. USFDA Approved.
	For generic drugs (me-too status)	Not available
	GMP status of the Finished product manufacturer	GMP granted on 28/10/2019 Tablet (General & Psychotropic) section approved.
	Name and address of API manufacturer.	Ami Lifesciences Pvt. Limited Plot No. 8218, ECP channel Road At & post Karakhadi, Dist. Vadodara -391 450 State Gujarat, INDIA Phone: +9 | -2662-27 3 40 | I 27 33 12 Fax: * 9l-2662-273401
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 72 months Batches: (ECA/50030515, ECA/50040515, ECA/50050515) Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (ECA/50020111, ECA/50030111 ECA/50040111)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Aptiom 400mg tablet by Sunovion Pharmaceuticals Inc.by performing quality tests (Appearance, Identification, DT ,Assay, Dissolution). CDP has been performed against the same brand that is Aptiom 400mg tablet by Sunovion Pharmaceuticals Inc in 0.1N HCL, Acetate buffer 4.5 and Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of	Method verification studies have submitted including

	product	linearity & Range, robustness, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Ami Lifesciences Pvt. Limited Plot No. 8218, ECP channel Road At & post Karakhadi, Dist. Vadodara -391 450 State Gujarat, INDIA		
API Lot No.	ESA/30011221		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (10's, 20's & 30's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 1,2,3,4 & 6 (months) Real Time: 0, 3, 6 (Months)		
Batch No.	22SB-214-01	22SB-215-02	22SB-216-03
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	21-06-2022	21-06-2022	21-06-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	A Panel Inspection for the verification of authenticity of Stability Data of product on Form-5D "Wymly Tablet 25mg" for Tablet Section has been conducted on 06 April, 2018. Inspection Report included in the 281th DRB meeting held on 11-13th April, 2018.. The firm has 21CFR compliant system and adequate monitoring and control for stability chamber.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 22043267 issued by FOOD AND DRUG CONTROL ADMINISTRATION valid till 17/04/2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Invoice No & Date: EXP/I/21-22/0880 dated 29/01/2022. • Batch No:ESA/30011221 • QTY=10KG
4.	Data of stability batches will be supported by attested respective documents like chromatograms,Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator:		
Decision: Approved with innovator's specifications.		

• **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma (pvt.) Ltd. 44-45B Korangi creek road, Karachi.
	Name, address of Manufacturing site.	M/s Genix Pharma (pvt.) Ltd. 44-45B Korangi creek road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 7082 dated 10/03/2023
	Details of fee submitted	PKR 75,000/-: dated 08/03/2023
	The proposed proprietary name / brand name	Carlep 800mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Eslicarbazepine acetate……800mg
	Pharmaceutical form of applied drug	Oblong shape, white color, biconvex tablet, Plain from both sides.
	Pharmacotherapeutic Group of (API)	Anti-epileptic
	Reference to Finished product specifications	Inhouse Specification
	Proposed Pack size	10's, 20's & 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	APTIOM tablets 800mg by Sunovion Pharmaceuticals Inc. USFDA Approved.
	For generic drugs (me-too status)	Not available
	GMP status of the Finished product manufacturer	GMP granted on 28/10/2019 Tablet (General & Psychotropic) section approved.
	Name and address of API manufacturer.	Ami Lifesciences Pr,t. Limited Plot No. 8218, ECP channel Road At & post Karakhadi, Dist. Vadodara -391 450 State Gujarat, INDIA Phone: +9 | -2662-27 3 40 | I 27 33 12 Fax: * 9l-2662-273401
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures

		and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 72 months Batches: (ECA/50030515, ECA/50040515, ECA/50050515) Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (ECA/50020111, ECA/50030111 ECA/50040111)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Aptiom 800mg tablet by Sunovion Pharmaceuticals Inc.by performing quality tests (Appearance, Identification, DT ,Assay, Dissolution). CDP has been performed against the same brand that is Aptiom 800mg tablet by Sunovion Pharmaceuticals Inc in 0.1N HCL, Acetate buffer 4.5 and Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity & Range, robustness, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Ami Lifesciences Pr,t. Limited Plot No. 8218, ECP channel Road At & post Karakhadi, Dist. Vadodara -391 450 State Gujarat, INDIA		
API Lot No.	ESA/30011221		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (10's, 20's & 30's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 1,2,3,4 & 6 (months) Real Time: 0, 3, 6 (Months)		
Batch No.	22SB-211-01	22SB-212-02	22SB-213-03
Batch Size	1000	1000	1000
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	22-06-2022	22-06-2022	22-06-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	A Panel Inspection for the verification of authenticity of Stability Data of product on Form-5D "Wymly Tablet 25mg" for Tablet Section has been conducted on 06 April, 2018. Inspection Report included in the 281th DRB meeting held on 11-13th April, 2018.. The firm has 21CFR compliant system and adequate monitoring and control for stability chamber.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 22043267 issued by FOOD AND DRUG CONTROL ADMINISTRATION valid till 17/04/2025.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Invoice No & Date: EXP/I/21-22/0880 dated 29/01/2022. • Batch No:ESA/30011221 • QTY=10KG
4.	Data of stability batches will be supported by attested respective documents like chromatograms,Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator:		
Decision: Approved with innovator's specifications. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

Agenda of Evaluator PEC-IX

370.	Name and address of manufacturer/ Applicant	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad (DML No.000600) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Lacosa Tablet 200mg
	Composition	Each film-coated tablet contains: Lacosamide……200mg
	Diary No. Date of R & I & fee	Dy. No. 13691 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901273 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	N03AX18 Other antiepileptics
	Type of Form	Form-5
	Finished product Specification	**As per Innovator (found in BP, USP)**
	Pack size & Demanded Price	As per SRO.

	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Lacolep tablet by Hilton
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required.
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspectrion report conuducted within last three years, before issuance of registration letter.	
371.	Name and address of manufacturer/ Applicant	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad (DML No.000600) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Dexole Capsule 30mg
	Composition	Each hard gelatin capsule contains: Dexlansoprazole (Dual Delayed Release Pellets) eq. to Dexlansoprazole……30mg
	Diary No. Date of R & I & fee	Dy. No. 13701 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901284 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	A02BC06 Proton pump inhibitors
	Type of Form	Form-5
	Finished product Specification	**As per Innovator's**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	DEXILANT (dexlansoprazole) delayed-release capsules, for oral use Delayed-release capsules: 30 mg and 60 mg MHRA Approved.
	Me-too status	Daplazole DDR Capsule 30 mg Reg. No. 104251 M/s AGP Ltd. Karachi.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Source of pellets is required to be defined along with submission of required fee. • Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.
	Decision: Registration Board decided to reject the application since the firm has not submitted stability study data of 3 batches of the drug product before the lapse of deadline decided by DRAP Authority i.e. till 31st December 2022.	
372.	Name and address of manufacturer/ Applicant	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad (DML No.000600) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Dexole Capsule 60mg
	Composition	Each hard gelatin capsule contains: Dexlansoprazole (Dual Delayed Release Pellets) eq. to Dexlansoprazole……60mg
	Diary No. Date of R & I & fee	Dy. No. 13702 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901285 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	A02BC06 Proton pump inhibitors
	Type of Form	Form-5
	Finished product Specification	**As per Innovator's**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	DEXILANT (dexlansoprazole) delayed-release capsules, for oral use

		Delayed-release capsules: 30 mg and 60 mg MHRA Approved.
	Me-too status	Remit DR Capsules 60 mg Reg. No. 090301 M/s Scotmann Pharmaceuticals Plot No. 5-D, Sector I-10/3 Islamabad.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Source of pellets is required to be defined along with submission of required fee. • Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.
	Decision: Registration Board decided to reject the application since the firm has not submitted stability study data of 3 batches of the drug product before the lapse of deadline decided by DRAP Authority i.e. till 31st December 2022.	
373.	Name and address of manufacturer/ Applicant	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad (DML No.000600) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Maven MR Capsule 200mg
	Composition	Each hard gelatin capsule contains: Mebeverine HCl (as Modified Release Pellets 50%w/w) eq. to Mebeverine HCl…….……200mg
	Diary No. Date of R & I & fee	Dy. No. 13697 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901280 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	A03AA04 Synthetic anticholinergics, esters with tertiary amino group
	Type of Form	Form-5
	Finished product Specification	**As per Innovator's**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Mebeverine 200 mg modified release capsules (mebeverine hydrochloride) - PL 35533/0095 MHRA Approved.
	Me-too status	Mebever MR 200mg Capsule Reg. No. 050747 M/s Getz Pharma Karachi.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Source of pellets is required to be defined along with submission of required fee.
	Decision: Approved. Firm shall submit source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets) and latest GMP inspection report conducted within last three years, before issuance of registration letter.	
374.	Name and address of manufacturer/ Applicant	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad (DML No.000600) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Clorisone Cream
	Composition	Each gram contains: Hydrocortisone Acetate eq. to Hydrocortisone…….……10mg Clotrimazole……..10mg
	Diary No. Date of R & I & fee	Dy. No. 13698 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901281 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Antifungal preparations with corticosteroids are classified in

		D01A
	Type of Form	Form-5
	Finished product Specification	**BP Specs**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Canesten HC Cream of UK-MHRA
	Me-too status	Hydrozole Cream of GSK Health
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
375.	Name and address of manufacturer/ Applicant	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad (DML No.000600) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Tobrin-D Eye Drops
	Composition	Each ml ophthalmic suspension contains: Tobramycin……3mg Dexamethasone……..1mg
	Diary No. Date of R & I & fee	Dy. No. 13803 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1900296 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	D07CB04 Corticosteroids, moderately potent, combinations with antibiotics
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	TOBRAMYCIN + DEXAMETHASONE (3 MG/ML + 1 MG/ML) EYE DROPS, SUSPENSION - PL 31103/0010 MHRA Approved.
	Me-too status	Tobradex Suspension Reg. No. 017040 M/s Novartis Pharma Karachi.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
376.	Name and address of manufacturer/ Applicant	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad (DML No.000600) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Flora Cream 13.9%
	Composition	Each gram contains: Eflornithine Hydrochloride Monohydrate eq. to. Eflornithine Hydrochloride……..139mg
	Diary No. Date of R & I & fee	Dy. No. 13699 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1900282 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	D11AX16 Other dermatologicals
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Health Canada Approved
	Me-too status	Verona Cream by Rotex Pharma
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.

	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three years, before issuance of registration letter.	
377.	Name and address of manufacturer/ Applicant	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad (DML No.000600) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Diacin Capsule 50mg
	Composition	Each hard gelatin capsule contains: Diacerein……50mg
	Diary No. Date of R & I & fee	Dy. No. 13801 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0814999 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	M01AX21 Other anti-inflammatory and anti-rheumatic agents, non-steroids
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Diacerein Biogaran 50 mg, capsule ANSM Approved
	Me-too status	Diora Capsule by Getz
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required.
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three years, before issuance of registration letter.	
378.	Name and address of manufacturer/ Applicant	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad (DML No.000600) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Amilin Tablet 100mg
	Composition	Each tablet contains: Amisulpride……100mg
	Diary No. Date of R & I & fee	Dy. No. 13696 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901279 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	N05AL05 Benzamides
	Type of Form	Form-5
	Finished product Specification	**BP Specs**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	AMISULPRIDE 100MG TABLETS MHRA Approved
	Me-too status	Amrida 100mg Tablet Reg. No. 105217 of M/s Wnsfeild.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
379.	Name and address of manufacturer/ Applicant	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad (DML No.000600) Section Approval not provided.

	Brand Name + Dosage Form + Strength	Uric Tablet 40mg
	Composition	Each tablet contains: Febuxostat……40mg
	Diary No. Date of R & I & fee	Dy. No. 13682 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901263 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	M04AA03 Preparations inhibiting uric acid production
	Type of Form	Form-5
	Finished product Specification	**As per Innovator's**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Uloric tablets 40 mg. USFDA Approved.
	Me-too status	Adenuric Tablet 40mg Reg. No. 067033 M/s S.J & G. Fazul Ellahie (Pvt) Ltd., E/46 S.I.T.E Karachi.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required.
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three years, before issuance of registration letter.	
380.	Name and address of manufacturer/ Applicant	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad (DML No.000600) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Seon Tablet 100mg
	Composition	Each tablet contains: Sertraline Hydrochloride eq. to Sertraline……100mg
	Diary No. Date of R & I & fee	Dy. No. 13693 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901275 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	N06AB06 Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	**As per Innovator's**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	SERTRALINE 100MG TABLETS MHRA Approved.
	Me-too status	Dysert 100mg Tablet Reg. No. 111686 M/s Dyson Research.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Applied product is uncoated while Innovator is film-coated. Justification and revision along with fee of Rs. 7500/- is required.
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three years, before issuance of registration letter.	
381.	Name and address of manufacturer/ Applicant	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad (DML No.000600) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Minodil Plus Topical Solution 5%
	Composition	Each ml contains:

		Minoxidil……50mg
	Diary No. Date of R & I & fee	Dy. No. 13685 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901266 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	D11AX01 Other dermatologicals
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	MINOXIDIL 5% CUTANEOUS SOLUTION MHRA Approved.
	Me-too status	Collin 5% Topical Solution Reg. No. 107326 M/s Saffron Pharma.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Topical Lotion/Liquid section" from CLB.	
382.	Name and address of manufacturer/ Applicant	M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad (DML No.000600) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Calinol-T Lotion 1%
	Composition	Each ml contains: Clindamycin Phosphate eq. to Clindamycin……10mg
	Diary No. Date of R & I & fee	Dy. No. 13687 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901268 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	D10AF01 Anti-infectives for treatment of acne
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	DALACIN T TOPICAL LOTION MHRA Approved.
	Me-too status	Lindagen 1% w/v Lotion Reg. No. 109303 M/s Biogen Pharma.
	GMP status	Report of 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Topical Lotion/Liquid section" from CLB.	
383.	Name and address of manufacturer/ Applicant	M/s. Elvin Pharmaceuticals (Pvt) Ltd., 35-Km Raiwind Road, Lahore (DML No.000508) Section Approval not provided.
	Brand Name + Dosage Form + Strength	L-Cip Tablet 250mg
	Composition	Each film coated tablet contains: Ciprofloxacin as HCl……250mg
	Diary No. Date of R & I & fee	Dy. No. 16152 dated 07.03.2019. Fee paid Rs. 12,000/- vide Slip No. 0839973 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	J01MA02 Fluoroquinolones
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Novidat Tablet by Sami
	GMP status	Not Provided.

	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Differential fee is required.
	Decision: Registration Board decided to reject the application since firm had not submitted full fee registration at the time of submission of application.	
384.	Name and address of manufacturer/ Applicant	M/s. Elvin Pharmaceuticals (Pvt) Ltd., 35-Km Raiwind Road, Lahore (DML No.000508) Section Approval not provided.
	Brand Name + Dosage Form + Strength	L-Cip Tablet 500mg
	Composition	Each film coated tablet contains: Ciprofloxacin as HCl……500mg
	Diary No. Date of R & I & fee	Dy. No. 16153 dated 07.03.2019. Fee paid Rs. 12,000/- vide Slip No. 0839974 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	J01MA02 Fluoroquinolones
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Novidat Tablet by Sami
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Differential fee is required.
	Decision: Registration Board decided to reject the application since firm had not submitted full fee registration at the time of submission of application.	
385.	Name and address of manufacturer/ Applicant	M/s. Elvin Pharmaceuticals (Pvt) Ltd., 35-Km Raiwind Road, Lahore (DML No.000508) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Elvo Tablet 250mg
	Composition	Each film coated tablet contains: Levofloxacin as Hemihydrate……250mg
	Diary No. Date of R & I & fee	Dy. No. 16139 dated 07.03.2019. Fee paid Rs. 12,000/- vide Slip No. 0839977 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	J01MA12 Fluoroquinolones
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Cravit Tablet by M/s Hilton Pharma
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Differential fee is required.
	Decision: Registration Board decided to reject the application since firm had not submitted full fee registration at the time of submission of application.	
386.	Name and address of manufacturer/ Applicant	M/s. Elvin Pharmaceuticals (Pvt) Ltd., 35-Km Raiwind Road, Lahore (DML No.000508) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Elvo Tablet 500mg
	Composition	Each film coated tablet contains: Levofloxacin as Hemihydrate……500mg

	Diary No. Date of R & I & fee	Dy. No. 16145 dated 07.03.2019. Fee paid Rs. 12,000/- vide Slip No. 0839978 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	J01MA12 Fluoroquinolones
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Cravit Tablet by M/s Hilton Pharma
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Differential fee is required.
	Decision: Registration Board decided to reject the application since firm had not submitted full fee registration at the time of submission of application.	
387.	Name and address of manufacturer/ Applicant	M/s. Elvin Pharmaceuticals (Pvt) Ltd., 35-Km Raiwind Road, Lahore (DML No.000508) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Clarvin Tablet 250mg
	Composition	Each film coated tablet contains: Clarithromycin……250mg
	Diary No. Date of R & I & fee	Dy. No. 16150 dated 07.03.2019. Fee paid Rs. 12,000/- vide Slip No. 0839975 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	J01FA09 Macrolides
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Claramed Tablet by M/s Novartis Pharma
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Differential fee is required.
	Decision: Registration Board decided to reject the application since firm had not submitted full fee registration at the time of submission of application.	
388.	Name and address of manufacturer/ Applicant	M/s. Elvin Pharmaceuticals (Pvt) Ltd., 35-Km Raiwind Road, Lahore (DML No.000508) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Clarvin Tablet 500mg
	Composition	Each film coated tablet contains: Clarithromycin……500mg
	Diary No. Date of R & I & fee	Dy. No. 16151 dated 07.03.2019. Fee paid Rs. 12,000/- vide Slip No. 0839971 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	J01FA09 Macrolides
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Claramed Tablet by M/s Novartis Pharma
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required.

		• Differential fee is required.
	Decision: Registration Board decided to reject the application since firm had not submitted full fee registration at the time of submission of application.	
389.	Name and address of manufacturer/ Applicant	M/s. Elvin Pharmaceuticals (Pvt) Ltd., 35-Km Raiwind Road, Lahore (DML No.000508) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Amyth Tablet 20/120mg
	Composition	Each film coated tablet contains: Artemether……..20mg Lumefantrine…….120mg
	Diary No. Date of R & I & fee	Dy. No. 16155 dated 07.03.2019. Fee paid Rs. 12,000/- vide Slip No. 0839951 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	P01BF01 Artemisinin and derivatives, combinations
	Type of Form	Form-5
	Finished product Specification	**In-house Specs (Available in Intl. Ph.)**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Evidence of formulation as film-coated is required
	Me-too status	Evidence of formulation as film-coated is required
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Differential fee is required. • Evidence of formulation as film-coated both in RRAs & Pakistan is required.
	Decision: Registration Board decided to reject the application since firm had not submitted full fee registration at the time of submission of application.	
390.	Name and address of manufacturer/ Applicant	M/s. Elvin Pharmaceuticals (Pvt) Ltd., 35-Km Raiwind Road, Lahore (DML No.000508) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Amyth Plus Tablet 80/480mg
	Composition	Each film coated tablet contains: Artemether……..80mg Lumefantrine…….480mg
	Diary No. Date of R & I & fee	Dy. No. 16144 dated 07.03.2019. Fee paid Rs. 12,000/- vide Slip No. 0839967 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	P01BF01 Artemisinin and derivatives, combinations
	Type of Form	Form-5
	Finished product Specification	**In-house Specs (Available in Intl. Ph.)**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Evidence of formulation as film-coated is required
	Me-too status	Evidence of formulation as film-coated is required
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Differential fee is required. • Evidence of formulation as film-coated both in RRAs & Pakistan is required.
	Decision: Registration Board decided to reject the application since firm had not submitted full fee of registration at the time of submission of application.	
391.	Name and address of manufacturer/ Applicant	M/s. Elvin Pharmaceuticals (Pvt) Ltd., 35-Km Raiwind Road, Lahore (DML No.000508)

		Section Approval not provided.
	Brand Name + Dosage Form + Strength	BMN Tablet 500mcg
	Composition	Each film coated tablet contains: Mecobalamin…….500mcg
	Diary No. Date of R & I & fee	Dy. No. 16148 dated 07.03.2019. Fee paid Rs. 12,000/- vide Slip No. 0839980 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	B03BA05 Vitamin B12 (cyanocobalamin and analogues)
	Type of Form	Form-5
	Finished product Specification	**In-house Specs (Available in JP)**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Evidence of formulation as film-coated is required
	Me-too status	Evidence of formulation as film-coated is required
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Differential fee is required. • Evidence of formulation as film-coated both in RRAs & Pakistan is required.
	Decision: Registration Board decided to reject the application since firm had not submitted full fee of registration at the time of submission of application.	
392.	Name and address of manufacturer/ Applicant	M/s. Elvin Pharmaceuticals (Pvt) Ltd., 35-Km Raiwind Road, Lahore (DML No.000508) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Pekan Tablet 50mg
	Composition	Each film coated tablet contains: Diclofenac Potassium…….75mg
	Diary No. Date of R & I & fee	Dy. No. 16154 dated 07.03.2019. Fee paid Rs. 12,000/- vide Slip No. 0839970 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	M01AB05 Acetic acid derivatives and related substances
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Clarification of difference of strength in brand name & composition is required.
	Me-too status	Clarification of difference of strength in brand name & composition is required.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Differential fee is required. • Clarification of difference of strength in brand name & composition is required.
	Decision: Registration Board decided to reject the application since firm had not submitted full fee of registration at the time of submission of application.	
393.	Name and address of manufacturer/ Applicant	M/s. Elvin Pharmaceuticals (Pvt) Ltd., 35-Km Raiwind Road, Lahore (DML No.000508) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Naplin Tablet 500mg
	Composition	Each film coated tablet contains: Naproxen Sodium USP 550mg eq. to Naproxen…….500mg
	Diary No. Date of R & I & fee	Dy. No. 16136 dated 07.03.2019. Fee paid Rs. 12,000/- vide Slip No. 0839982 dated 07-03-2019, endorsed on 07.03.2019.

	Pharmacological Group	M01AE02 Propionic acid derivatives
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	NAPROSYN (naproxen) tablets USFDA.
	Me-too status	Proxomir 500mg Tablet of M/s Fahmir Pharma
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Differential fee is required.
	Decision: Registration Board decided to reject the application since firm had not submitted full fee of registration at the time of submission of application.	
394.	Name and address of manufacturer/ Applicant	M/s. Elvin Pharmaceuticals (Pvt) Ltd., 35-Km Raiwind Road, Lahore (DML No.000508) Section Approval not provided.
	Brand Name + Dosage Form + Strength	PCD Tablet 20mg
	Composition	Each tablet contains: Piroxicam β-Cyclodextrin 191.2mg eq. to Piroxicam…….20mg
	Diary No. Date of R & I & fee	Dy. No. 16137 dated 07.03.2019. Fee paid Rs. 12,000/- vide Slip No. 0839986 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	M01AC01 Oxicams
	Type of Form	Form-5
	Finished product Specification	**Not Mentioned**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Applied product is not effervescent. BREXIN 20 mg effervescent tablet ANSM France Approved.
	Me-too status	Straza Tablet Reg. No. 096316 M/s Asian Continental Karachi.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Differential fee is required. • Evidence of approval of applied formulation in RRA is required. • Reference of finished product specifications is required.
	Decision: Registration Board decided to reject the application since firm had not submitted full fee of registration at the time of submission of application.	
395.	Name and address of manufacturer/ Applicant	M/s. Elvin Pharmaceuticals (Pvt) Ltd., 35-Km Raiwind Road, Lahore (DML No.000508) Section Approval not provided.
	Brand Name + Dosage Form + Strength	EST Tablet 50mg
	Composition	Each film-coated tablet contains: Sertraline as Hydrochloride…….50mg
	Diary No. Date of R & I & fee	Dy. No. 16140 dated 07.03.2019. Fee paid Rs. 12,000/- vide Slip No. 0839985 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	N06AB06 Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK

	Me-too status	Ertalin 50 mg Tablets of M/s Genome Pharma, (Reg.#076844)
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Differential fee is required.
	Decision: Registration Board decided to reject the application since firm had not submitted full fee of registration at the time of submission of application.	
396.	Name and address of manufacturer/ Applicant	M/s. Elvin Pharmaceuticals (Pvt) Ltd., 35-Km Raiwind Road, Lahore (DML No.000508) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Elmox Tablet 400mg
	Composition	Each film-coated tablet contains: Moxifloxacin as HCl…….400mg
	Diary No. Date of R & I & fee	Dy. No. 16142 dated 07.03.2019. Fee paid Rs. 12,000/- vide Slip No. 0839981 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	J01MA14 Fluoroquinolones
	Type of Form	Form-5
	Finished product Specification	**In-house Specs (Available in USP)**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Kimoks 400 mg film-coated tablets (moxifloxacin hydrochloride) - PL 34088/0047; UK/H/6473/001/DC MHRA Approved.
	Me-too status	Avelox Tablets Reg. No. 024653 M/s Bayer Pakistan Ltd Karachi.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Differential fee is required.
	Decision: Registration Board decided to reject the application since firm had not submitted full fee of registration at the time of submission of application.	
397.	Name and address of manufacturer/ Applicant	M/s. Elvin Pharmaceuticals (Pvt) Ltd., 35-Km Raiwind Road, Lahore (DML No.000508) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Oflocid Tablet 200mg
	Composition	Each film-coated tablet contains: Ofloxacin…….200mg
	Diary No. Date of R & I & fee	Dy. No. 16149 dated 07.03.2019. Fee paid Rs. 12,000/- vide Slip No. 0839983 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	J01MA01 Fluoroquinolones
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	OFLOXACIN 200MG TABLETS MHRA Approved.
	Me-too status	Ofloper Tablets Reg. No. 111758 M/s Quaper Pvt. Ltd.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Differential fee is required.
	Decision: Registration Board decided to reject the application since firm had not submitted full fee of registration at the time of submission of application.	
398.	Name and address of manufacturer/ Applicant	M/s. Elvin Pharmaceuticals (Pvt) Ltd., 35-Km Raiwind Road, Lahore (DML No.000508)

		Section Approval not provided.
	Brand Name + Dosage Form + Strength	Elvpride Tablet 25mg
	Composition	Each tablet contains: Levosulpiride…….25mg
	Diary No. Date of R & I & fee	Dy. No. 16143 dated 07.03.2019. Fee paid Rs. 12,000/- vide Slip No. 0839979 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	N05AL07 Benzamides
	Type of Form	Form-5
	Finished product Specification	**Innovator's Specs**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Levosulpiride Aristo 25 mg tablets, AIFA Italy approved.
	Me-too status	Sulvoric 25mg Tablet Reg. No.070484 M/s High-Q
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Differential fee is required.
	Decision: Registration Board decided to reject the application since firm had not submitted full fee of registration at the time of submission of application.	
399.	Name and address of manufacturer/ Applicant	M/s. Elvin Pharmaceuticals (Pvt) Ltd., 35-Km Raiwind Road, Lahore (DML No.000508) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Elgem Tablet 320mg
	Composition	Each film-coated tablet contains: Gemifloxacin mesylate eq. to Gemifloxacin…….320mg
	Diary No. Date of R & I & fee	Dy. No. 16146 dated 07.03.2019. Fee paid Rs. 12,000/- vide Slip No. 0839968 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	J01MA15 Fluoroquinolones
	Type of Form	Form-5
	Finished product Specification	**Innovator's Specs**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Discontinued in FDA / applicant withdrawn its application for Marketing authorization in EMA
	Me-too status	Gemixa tablet by Bosch Pharma
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Differential fee is required. • Withdrawn in EMA due to negative risk/benefit ratio.
	Decision: Registration Board decided to reject the application since firm had not submitted full fee of registration at the time of submission of application.	
400.	Name and address of manufacturer/ Applicant	M/s. Elvin Pharmaceuticals (Pvt) Ltd., 35-Km Raiwind Road, Lahore (DML No.000508) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Elvim Tablet 50mg
	Composition	Each film-coated tablet contains: Topiramate…….50mg
	Diary No. Date of R & I & fee	Dy. No. 16138 dated 07.03.2019. Fee paid Rs. 12,000/- vide Slip No. 0839966 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	N03AX11 Other antiepileptics
	Type of Form	Form-5
	Finished product Specification	**USP Specs**

	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	TOPIRAMATE MILPHARM 50 MG FILM-COATED TABLETS MHRA Approved
	Me-too status	Hach 50mg tablet by Zafa Pharma
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Differential fee is required.
	Decision: Registration Board decided to reject the application since firm had not submitted full fee of registration at the time of submission of application.	
401.	Name and address of manufacturer/ Applicant	M/s. Elvin Pharmaceuticals (Pvt) Ltd., 35-Km Raiwind Road, Lahore (DML No.000508) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Visam Tablet 10mg
	Composition	Each film-coated tablet contains: Escitalopram as oxalate (USP)…….10mg
	Diary No. Date of R & I & fee	Dy. No. 16135 dated 07.03.2019. Fee paid Rs. 12,000/- vide Slip No. 0839969 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	N06AB10 Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Escitalopram 5, 10 & 20mg Film-Coated Tablets (PL 36390/0149-51; UK/H/5394/001-3/DC) MHRA Approved.
	Me-too status	Cipralex Film-Coated Tablet 10mg Reg. No. 028467 M/s Lundbeck Pakistan (Pvt.) Ltd. Karachi.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Section Approval is required. • Differential fee is required.
	Decision: Registration Board decided to reject the application since firm had not submitted full fee of registration at the time of submission of application.	
402.	Name and address of manufacturer/ Applicant	M/s. Parkar Pharma, Plot No. 0/7-A, S.I.T.E, Area Kotri, Karachi (DML No.000883) Section Approval letter No. F. 2-4/2005-Lic dated 11-04-2018 for Tablet, Capsule & Syrup Sections.
	Brand Name + Dosage Form + Strength	Linzopar Tablet 400mg
	Composition	Each film-coated tablet contains: Linezolid…….400mg
	Diary No. Date of R & I & fee	Dy. No. 16284 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0839061 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	J01XX08 Other antibacterials
	Type of Form	Form-5
	Finished product Specification	**Innovator Specs**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Zyvox 400mg tablet USFDA Approved.
	Me-too status	LZL Tablet of M/s Daneen Pharma
	GMP status	Grant of DML Report of year 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.

	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
403.	Name and address of manufacturer/ Applicant	M/s. Parkar Pharma, Plot No. 0/7-A, S.I.T.E, Area Kotri, Karachi (DML No.000883) Section Approval letter No. F. 2-4/2005-Lic dated 11-04-2018 for Tablet, Capsule & Syrup Sections.
	Brand Name + Dosage Form + Strength	Linzopar Tablet 600mg
	Composition	Each film-coated tablet contains: Linezolid…….600mg
	Diary No. Date of R & I & fee	Dy. No. 16283 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0839060 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	J01XX08 Other antibacterials
	Type of Form	Form-5
	Finished product Specification	**Innovator Specs**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Zyvox 600mg tablet USFDA Approved.
	Me-too status	LZL Tablet of M/s Daneen Pharma
	GMP status	Grant of DML Report of year 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
404.	Name and address of manufacturer/ Applicant	M/s. Parkar Pharma, Plot No. 0/7-A, S.I.T.E, Area Kotri, Karachi (DML No.000883) Section Approval letter No. F. 2-4/2005-Lic dated 11-04-2018 for Tablet, Capsule & Syrup Sections.
	Brand Name + Dosage Form + Strength	Flurosafe Tablet 100mg
	Composition	Each film-coated tablet contains: Flurbiprofen…….100mg
	Diary No. Date of R & I & fee	Dy. No. 16266 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0839062 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	M01AE09 Propionic acid derivatives
	Type of Form	Form-5
	Finished product Specification	**Innovator Specs (Available in BP & USP)**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Flurbiprofen 100mg Tablet Oral USFDA Approved.
	Me-too status	Ansaid 100mg Tablet Reg. No. 012299 M/s Pfizer Pakistan.
	GMP status	Grant of DML Report of year 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved with USP Specifications. Registration letter shall be issued after submission of fee of Rs. 7500/- as per SRO 496(I)/2023 dated 17.04.2023. by the firm along with latest GMP inspection report conducted within last three years before issuance of registration letter.	
405.	Name and address of manufacturer/ Applicant	M/s. Parkar Pharma, Plot No. 0/7-A, S.I.T.E, Area Kotri, Karachi (DML No.000883) Section Approval letter No. F. 2-4/2005-Lic dated 11-04-2018 for Tablet, Capsule & Syrup Sections.
	Brand Name + Dosage Form + Strength	Parkotron Tablet 8mg
	Composition	Each film-coated tablet contains: Ondansetron as HCl dihydrate…….8mg

	Diary No. Date of R & I & fee	Dy. No. 16268 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0839056 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	A04AA01 Serotonin (5HT3) antagonists
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ondansetron 4 mg & 8 mg (Ondansetron Hydrochloride dihydrate) MHRA Approved.
	Me-too status	Zofran Tablets 8 mg Reg. No. 020668 M/s GSK Karachi.
	GMP status	Grant of DML Report of year 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
406.	Name and address of manufacturer/ Applicant	M/s. Parkar Pharma, Plot No. 0/7-A, S.I.T.E, Area Kotri, Karachi (DML No.000883) Section Approval letter No. F. 2-4/2005-Lic dated 11-04-2018 for Tablet, Capsule & Syrup Sections.
	Brand Name + Dosage Form + Strength	Xincain Tablet 4mg
	Composition	Each film-coated tablet contains: Lornoxicam…….4mg
	Diary No. Date of R & I & fee	Dy. No. 16262 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0839063 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	M01AC05 Oxicams
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Xefo 4mg film-coated tablet (EMA approved)
	Me-too status	Xonica 4mg Tablet by M/s Zephyr Pharmatec (Reg#086984)
	GMP status	Grant of DML Report of year 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved with Innovator's Specifications. Registration letter shall be issued after submission of fee of Rs. 7500/- as per SRO 496(I)/2023 dated 17.04.2023. by the firm along with latest GMP inspection report conducted within last three years before issuance of registration letter.	
407.	Name and address of manufacturer/ Applicant	M/s. Parkar Pharma, Plot No. 0/7-A, S.I.T.E, Area Kotri, Karachi (DML No.000883) Section Approval letter No. F. 2-4/2005-Lic dated 11-04-2018 for Tablet, Capsule & Syrup Sections.
	Brand Name + Dosage Form + Strength	Xincain Tablet 8mg
	Composition	Each film-coated tablet contains: Lornoxicam…….8mg
	Diary No. Date of R & I & fee	Dy. No. 16260 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0839051 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	M01AC05 Oxicams
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Xefo 8mg film-coated tablet (EMA approved)
	Me-too status	Xonica 8mg Tablet by M/s Zephyr Pharmatec (Reg#086983)

	GMP status	Grant of DML Report of year 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved with Innovator's Specifications. Registration letter shall be issued after submission of fee of Rs. 7500/- as per SRO 496(I)/2023 dated 17.04.2023 along with latest GMP inspection report conducted within last three years before issuance of registration letter.	
408.	Name and address of manufacturer/ Applicant	M/s. Parkar Pharma, Plot No. 0/7-A, S.I.T.E, Area Kotri, Karachi (DML No.000883) Section Approval letter No. F. 2-4/2005-Lic dated 11-04-2018 for Tablet, Capsule & Syrup Sections.
	Brand Name + Dosage Form + Strength	Montin Tablet 4mg
	Composition	Each film-coated (dispersible) tablet contains: Montelukast Sodium eq. to Montelukast…….4mg
	Diary No. Date of R & I & fee	Dy. No. 16278 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0848296 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	R03DC03 Leukotriene receptor antagonists
	Type of Form	Form-5
	Finished product Specification	**USP Specs (Available monograph is of chewable tablet)**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	MONTELUKAST 4MG CHEWABLE TABLETS MHRA Approved
	Me-too status	Monti tablet M/s Lisko Pakistan.
	GMP status	Grant of DML Report of year 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Applied formulation is film coated (dispersible) while in RRA and Me-too formulations are chewable tablet.
	Decision: Approved with following label; **Each chewable tablet contains;** **Montelukast Sodium eq. to Montelukast…….4mg** **Registration letter shall be issued after submission of fee of Rs. 30,000/- for revision of dosage form as per SRO 496(I)/2023 dated 17.04.2023 by the firm along with latest GMP inspection report conducted within last three years before issuance of registration letter.**	
409.	Name and address of manufacturer/ Applicant	M/s. Parkar Pharma, Plot No. 0/7-A, S.I.T.E, Area Kotri, Karachi (DML No.000883) Section Approval letter No. F. 2-4/2005-Lic dated 11-04-2018 for Tablet, Capsule & Syrup Sections.
	Brand Name + Dosage Form + Strength	Montin Tablet 5mg
	Composition	Each Chewable tablet contains: Montelukast Sodium eq. to Montelukast…….5mg
	Diary No. Date of R & I & fee	Dy. No. 16270 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0839059 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	R03DC03 Leukotriene receptor antagonists
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	MONTELUKAST 5MG CHEWABLE TABLETS MHRA Approved
	Me-too status	Dewkast Chewable Tablet M/s Seatle Private.
	GMP status	Grant of DML Report of year 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.

	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
410.	Name and address of manufacturer/ Applicant	M/s. Parkar Pharma, Plot No. 0/7-A, S.I.T.E, Area Kotri, Karachi (DML No.000883) Section Approval letter No. F. 2-4/2005-Lic dated 11-04-2018 for Tablet, Capsule & Syrup Sections.
	Brand Name + Dosage Form + Strength	Montin Tablet 10mg
	Composition	Each film-coated tablet contains: Montelukast Sodium eq. to Montelukast…….10mg
	Diary No. Date of R & I & fee	Dy. No. 16279 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0848295 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	R03DC03 Leukotriene receptor antagonists
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	MONTELUKAST 10MG TABLETS MHRA Approved
	Me-too status	Dewkast Tablet M/s Seatle Private.
	GMP status	Grant of DML Report of year 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
411.	Name and address of manufacturer/ Applicant	M/s. Parkar Pharma, Plot No. 0/7-A, S.I.T.E, Area Kotri, Karachi (DML No.000883) Section Approval letter No. F. 2-4/2005-Lic dated 11-04-2018 for Tablet, Capsule & Syrup Sections.
	Brand Name + Dosage Form + Strength	Citrokin Tablet 10mg
	Composition	Each film-coated tablet contains: Cetirizine Hydrochloride…….10mg
	Diary No. Date of R & I & fee	Dy. No. 16263 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0839036 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	R06AE07 Piperazine derivatives
	Type of Form	Form-5
	Finished product Specification	**Innovator Specs (Available in USP, BP & JP)**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	CETIRIZINE HYDROCHLORIDE 10MG TABLETS MHRA Approved
	Me-too status	Stamin Tablet M/s Shaigan.
	GMP status	Grant of DML Report of year 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved with USP Specifications. Registration letter shall be issued after submission of fee of Rs. 7500/- as per SRO 496(I)/2023 dated 17.04.2023. by the firm.	
412.	Name and address of manufacturer/ Applicant	M/s. Parkar Pharma, Plot No. 0/7-A, S.I.T.E, Area Kotri, Karachi (DML No.000883) Section Approval letter No. F. 2-4/2005-Lic dated 11-04-2018 for Tablet, Capsule & Syrup Sections.
	Brand Name + Dosage Form + Strength	Levopar Tablet 5mg
	Composition	Each film-coated tablet contains:

		Levocetirizine Dihydrochloride…….5mg
	Diary No. Date of R & I & fee	Dy. No. 16261 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0839038 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	R06AE09 Piperazine derivatives
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LEVOCETIRIZINE 5MG FILM-COATED TABLETS MHRA Approved
	Me-too status	Algrix Tablet M/s Hi-Q.
	GMP status	Grant of DML Report of year 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved.	
413.	Name and address of manufacturer/ Applicant	M/s. Parkar Pharma, Plot No. 0/7-A, S.I.T.E, Area Kotri, Karachi (DML No.000883) Section Approval letter No. F. 2-4/2005-Lic dated 11-04-2018 for Tablet, Capsule & Syrup Sections.
	Brand Name + Dosage Form + Strength	Levopar Syrup 5mg/5ml
	Composition	Each 5ml contains: Levocetirizine …….2.5mg
	Diary No. Date of R & I & fee	Dy. No. 16264 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0839037 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	R06AE09 Piperazine derivatives
	Type of Form	Form-5
	Finished product Specification	**USP Specs (Not available in USP)**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	XYZAL oral solution 2.5/5mL USFDA Approved.
	Me-too status	Concidol L Syrup by M/s Convell Laboratories Registration No. 079350
	GMP status	Grant of DML Report of year 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required. • Clarification is required as strength of API is mentioned as 5mg/5ml in brand name while as 2.5mg/5ml in composition. • Revised Label Claim as per RRA along with fee of Rs. 30000/- is required. • USP monograph of product is required.
	Decision: Deferred for following: • **Clarification regarding strength of API which is mentioned as 5mg/5ml in brand name and 2.5mg/5ml in composition.** • **Revised Label Claim as per innovator drug product along with fee of Rs. 30000/-.** • **Drug product specifications.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
414.	Name and address of manufacturer/ Applicant	M/s. Parkar Pharma, Plot No. 0/7-A, S.I.T.E, Area Kotri, Karachi (DML No.000883) Section Approval letter No. F. 2-4/2005-Lic dated 11-04-2018 for Tabl. 0et, Capsule & Syrup Sections.

	Brand Name + Dosage Form + Strength	Parkolex Oral Syrup 500mg/5ml
	Composition	Each 5ml contains: Chloral Hydrate…….500mg
	Diary No. Date of R & I & fee	Dy. No. 16282 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0848291 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	N05CC01 Aldehydes and derivatives
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	CHLORAL HYDRATE 500MG/5ML ORAL SOLUTION MHRA Approved.
	Me-too status	CHR Syrup M/s Bio-Mark Pharma.
	GMP status	Grant of DML Report of year 2018 is submitted.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
415.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Slective Tablet 50mg
	Composition	Each tablet contains: Atenolol…….50mg
	Diary No. Date of R & I & fee	Dy. No. 14322 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739969 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	C07AB03 Beta blocking agents, selective
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ATENOLOL 50MG TABLETS MHRA Approved
	Me-too status	Obetenol Tablet M/s Obsons Pharma.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
416.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Slective Tablet 100mg
	Composition	Each tablet contains: Atenolol…….100mg
	Diary No. Date of R & I & fee	Dy. No. 14323 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739970 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	C07AB03 Beta blocking agents, selective
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ATENOLOL 100MG TABLETS MHRA Approved

	Me-too status	Atenolol Tablet M/s City Pharma.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
417.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Teracetam Tablet 500mg
	Composition	Each film-coated tablet contains: Levetiracetam…….500mg
	Diary No. Date of R & I & fee	Dy. No. 14325 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739972 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Other antiepileptics ATC Code: N03AX14
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LEVETIRACETAM RIVOPHARM 500 MG FILM-COATED TABLETS - PL 33155/0026 MHRA Approved.
	Me-too status	Vicet Tablet 500mg Re. No. 061774 M/s Martin Dow Ltd. Karachi.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
418.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Domgen Tablet 10mg
	Composition	Each film-coated tablet contains: Domperidone (as maleate)…….10mg
	Diary No. Date of R & I & fee	Dy. No. 14305 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0749398 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	A03FA03 Propulsives
	Type of Form	Form-5
	Finished product Specification	**BP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	DOMPERIDONE APOTEX domperidone (as maleate) 10mg tablets TGA Approved
	Me-too status	Domlis 10mg Tablet by M/s Lisko Pakistan (Reg#094897)
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
419.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.

	Brand Name + Dosage Form + Strength	Alarza Tablet 50mg
	Composition	Each film-coated tablet contains: Diclofenac Potassium…….50mg
	Diary No. Date of R & I & fee	Dy. No. 14312 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739955 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	M01AB05 Acetic acid derivatives and related substances
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Diclofenac Potassium 50 mg Tablets - PL 20046/0078 MHRA Approved.
	Me-too status	Caflam 50mg Tablet Reg. No. 021528 M/s Novartis Pharma Karachi.
	GMP status	Not Provided.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
420.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Pericid Extended Release Tablet 100mg
	Composition	Each extended release tablet contains: Tramadol HCl…….100mg
	Diary No. Date of R & I & fee	Dy. No. 14339 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739987 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	N02AX02 Other opioids
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TRAMADOL HYDROCHLORIDE KRKA 100 MG PROLONGED-RELEASE TABLETS MHRA Approved.
	Me-too status	Tamarooq XR Tablet Reg. No. 110889 M/s Shrooq Pharma.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
421.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Loft Tablet 100mg
	Composition	Each film-coated tablet contains: Aceclofenac…….100mg
	Diary No. Date of R & I & fee	Dy. No. 14309 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739952 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	M01AB16 Acetic acid derivatives and related substances
	Type of Form	Form-5
	Finished product Specification	**Innovator's Specs**
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Aceclofenac 100 mg Film-coated Tablets, MHRA approved.
	Me-too status	Acenac 100Mg Tablets, S.J & G. Fazul Ellahie, Reg. No. 039336.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
422.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Glen SR Tablet 75mg
	Composition	Each film-coated sustained-release tablet contains: Diclofenac Sodium…….75mg
	Diary No. Date of R & I & fee	Dy. No. 14307 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0749400 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	M01AB05 Acetic acid derivatives and related substances
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Dicloflex 75 mg SR Prolonged-Release Tablets, MHRA approved.
	Me-too status	Dicrays SR Tablet M/s Caraway Pharma.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
423.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Envir Tablet 0.5mg
	Composition	Each film-coated tablet contains: Entecavir as monohydrate…….0.5mg
	Diary No. Date of R & I & fee	Dy. No. 14348 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739996 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	J05AF10 Nucleoside and nucleotide reverse transcriptase inhibitors
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Entecavir Kent 0.5 and 1 mg film-coated tablets (Entecavir monohydrate) - PL 08215/0104-5; UK/H/6427/001-2/DC MHRA Approved
	Me-too status	Previr 0.5mg Tablet Reg. No. 056601 M/s Navegal Laboratories Peshawar.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	

424.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Cling Tablet 40mg
	Composition	Each film-coated tablet contains: Propranolol Hydrochloride…….40mg
	Diary No. Date of R & I & fee	Dy. No. 14327 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739974 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	C07AA05 Beta Blocking agents, non-selective
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	PROPRANOLOL 40MG TABLETS MHRA Approved
	Me-too status	Promount 40mg Tablet Reg. No. 104851 M/s Paramount Pharma.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
425.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Tritop Tablet 50mg
	Composition	Each film-coated tablet contains: Topiramate…….50mg
	Diary No. Date of R & I & fee	Dy. No. 14314 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739958 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	N03AX11 Other antiepileptics
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TOPIRAMATE MILPHARM 50 MG FILM-COATED TABLETS MHRA Approved
	Me-too status	Hach 50mg tablet by Zafa Pharma
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
426.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Cenex Tablet 7.5mg
	Composition	Each uncoated tablet contains: Meloxicam…….7.5mg
	Diary No. Date of R & I & fee	Dy. No. 14313 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739957 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	M01AC06 Oxicams
	Type of Form	Form-5

	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MELOXICAM 7.5 MG TABLETS - PL 14251/0097 MHRA Approved.
	Me-too status	Xobix 7.5mg Tablet Reg. No. 023928 M/s Hilton Pharma Karachi.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
427.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Cenex Tablet 15mg
	Composition	Each uncoated tablet contains: Meloxicam…….15mg
	Diary No. Date of R & I & fee	Dy. No. 14317 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739961 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	M01AC06 Oxicams
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MELOXICAM 15MG TABLETS, MHRA Approved.
	Me-too status	Camzit 15mg Tablet Reg. No. 109367 M/s Rotex Pharma.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
428.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Fresno Tablet 500mg
	Composition	Each extended-release tablet contains: Ranolazine…….500mg
	Diary No. Date of R & I & fee	Dy. No. 14335 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739983 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	C01EB18 Other cardiac preparations
	Type of Form	Form-5
	Finished product Specification	**Innovtor's Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ranexa 500 mg prolonged-release tablets, MHRA Approved.
	Me-too status	Razine ER Tablet Reg. No. 111063 M/s CCL Pharma.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	

429.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Solifen Tablet 5mg
	Composition	Each film-coated tablet contains: Solifenacin Succinate…….5mg
	Diary No. Date of R & I & fee	Dy. No. 14346 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739994 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	G04BD08 Drugs for urinary frequency and incontinence
	Type of Form	Form-5
	Finished product Specification	**Innovtor's Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Solifenacin 5 mg film-coated tablets, MHRA Approved.
	Me-too status	Dynaso 5mg Tablet Reg. No. 108339 M/s Dynatis Pakistan.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
430.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Famto Tablet 40mg
	Composition	Each film-coated tablet contains: Famotidine…….40mg
	Diary No. Date of R & I & fee	Dy. No. 14315 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739959 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	A02BA03 H2-receptor antagonists
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Famotidine 40 mg Film Coated Tablets, MHRA Approved.
	Me-too status	Pepcidine 40mg Tablet Reg. No. 112845 M/s Aspin Pharma.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
431.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Tenovir Tablet 300mg
	Composition	Each film-coated tablet contains: Tenofovir Disoproxil Fumarate 300mg equivalent to Tenofovir Disoproxil……..245mg
	Diary No. Date of R & I & fee	Dy. No. 14347 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739995 dated 07-03-2019, endorsed on 07.03.2019.

	Pharmacological Group	J05AF07 Nucleoside and nucleotide reverse transcriptase inhibitors
	Type of Form	Form-5
	Finished product Specification	**Innovator's Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TENOFOVIR DISOPROXIL ACCORD PHARMA 245MG FILM-COATED TABLETS, MHRA Approved.
	Me-too status	Tenere 300mg Tablet Reg. No. 112699 M/s Hi-Q.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved with International Pharmacopoeia specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three years, before issuance of registration letter.	
432.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Fresno Tablet 1000mg
	Composition	Each extended-release tablet contains: Ranolazine…….1000mg
	Diary No. Date of R & I & fee	Dy. No. 14336 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739984 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	C01EB18 Other cardiac preparations
	Type of Form	Form-5
	Finished product Specification	**Innovtor's Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ranexa™ ranolazine extended-release tablets, USFDA Approved.
	Me-too status	Razine ER Tablet Reg. No. 111064 M/s CCL Pharma.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Section Approval is required. • Latest GMP inspection report/ certificate is required.
	Decision: Approved with Innovator specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three years, before issuance of registration letter.	
433.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Glen Tablet 50mg
	Composition	Each film-coated Tablet contains: Diclofenac Sodium…….50mg
	Diary No. Date of R & I & fee	Dy. No. 14306 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0749399 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	M01AB05 Acetic acid derivatives and related substances
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Diclofenac Sodium 50 mg Tablets, MHRA approved.
	Me-too status	Trifenac Tablet M/s Trillium Pharma.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Section Approval is required. • Latest GMP inspection report/ certificate is required. • Revise label claim as per RRA along with fee of Rs. 30000/- is required.
	Decision: Approved as per following revised label calim: **Each delayed release Tablet contains:** **Diclofenac Sodium…….50mg"** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, along with latest GMP inspection report conducted within last three years before issuance of registration letter.**	
434.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Teracetam Tablet 250mg
	Composition	Each film-coated tablet contains: Levetiracetam…….250mg
	Diary No. Date of R & I & fee	Dy. No. 14319 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739965 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	Other antiepileptics ATC Code: N03AX14
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LEVETIRACETAM 250MG FILM-COATED TABLETS MHRA Approved.
	Me-too status	Torleva Tablet 250mg Re. No. 112594 M/s Safe Pharma.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Section Approval is required. • Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
435.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Myoprex Tablet 250mg
	Composition	Each Extended-release tablet contains: Divalproex sodium eq. to Valproic acid…….250mg
	Diary No. Date of R & I & fee	Dy. No. 14337 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739985 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	N03AG01 Fatty acid derivatives
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	DEPAKOTE® ER USFDA Approved.
	Me-too status	The available Me-too product is delayed release.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Section Approval is required.

		• Latest GMP inspection report/ certificate is required. • Valid evidence of Me-Too product is required.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
436.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Vorif Tablet 200mg
	Composition	Each film-coated tablet contains: Voriconazole…….200mg
	Diary No. Date of R & I & fee	Dy. No. 14342 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739990 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	J02AC03 Triazole and tetrazole derivatives
	Type of Form	Form-5
	Finished product Specification	**Innovator's Specs (Available in JP)**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	VORICONAZOLE 200MG FILM-COATED TABLETS MHRA Approved.
	Me-too status	VCZ 200mg Tablet of M/s Shrooq Pharma.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Section Approval is required. • Latest GMP inspection report/ certificate is required.
	Decision: Approved with JP specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three years, before issuance of registration letter.	
437.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	T-CID Tablet 25mg
	Composition	Each film-coated tablet contains: Quetiapine Fumarate eq. to. Quetiapine…….25mg
	Diary No. Date of R & I & fee	Dy. No. 14303 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739978 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	N05AH04 Diazepines, oxazepines, thiazepines and oxepines
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	QUETIAPINE 25MG FILM-COATED TABLETS MHRA Approved.
	Me-too status	Rekyt 25mg Tablet of M/s Hi-Q Pharma.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Section Approval is required. • Latest GMP inspection report/ certificate is required.
	Decision: Approved with USP specifications. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
438.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844)

		Section Approval not provided.
	Brand Name + Dosage Form + Strength	T-CID Tablet 100mg
	Composition	Each film-coated tablet contains: Quetiapine Fumarate eq. to. Quetiapine…….100mg
	Diary No. Date of R & I & fee	Dy. No. 14331 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739979 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	N05AH04 Diazepines, oxazepines, thiazepines and oxepines
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	QUETIAPINE 100MG FILM-COATED TABLETS MHRA Approved.
	Me-too status	Rekyt 100mg Tablet of M/s Hi-Q Pharma.
	GMP status	Not Provided.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
	Decision: Approved with USP specifications. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
439.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Acovir Tablet 200mg
	Composition	Each tablet contains: Acyclovir…….200mg
	Diary No. Date of R & I & fee	Dy. No. 14340 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739988 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	J05AB01 Nucleosides and nucleotides excl. reverse transcriptase inhibitors
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ACICLOVIR TABLETS BP 200MG MHRA Approved.
	Me-too status	Danclave 200mg Tablet of M/s Daneen Pharma.
	GMP status	Not Provided.
	Remarks of the Evaluator	Latest GMP inspection report/ certificate is required.
	Decision: Approved with USP specifications. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
440.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Vorif Tablet 50mg
	Composition	Each film-coated tablet contains: Voriconazole…….50mg
	Diary No. Date of R & I & fee	Dy. No. 14341 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739989 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	J02AC03 Triazole and tetrazole derivatives
	Type of Form	Form-5
	Finished product Specification	**Innovator's Specs (Available in JP)**
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	VORICONAZOLE 50MG FILM-COATED TABLETS MHRA Approved.
	Me-too status	V.Zde 50mg Tablet of M/s Neutro Pharma.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three years, before issuance of registration letter.	
441.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Purpal Tablet 40mg
	Composition	Each gastro-resistant tablet contains: Esomeprazole (as magnesium dihydrate)…….40mg
	Diary No. Date of R & I & fee	Dy. No. 14303 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0749395 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	A02BC05 Proton pump inhibitors
	Type of Form	Form-5
	Finished product Specification	**Innovator's Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ESOMEPRAZOLE 40 MG GASTRO-RESISTANT TABLETS MHRA Approved.
	Me-too status	Eprazole 40mg Tablet of M/s Fynk Pharma.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three years, before issuance of registration letter.	
442.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Algac Tablet 10mg
	Composition	Each tablet contains: Loratadine…….10mg
	Diary No. Date of R & I & fee	Dy. No. 14316 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739960 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	R06AX13 Other antihistamines for systemic use
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LORATADINE 10MG TABLETS MHRA Approved.
	Me-too status	Salmorat 10mg Tablet of M/s Fedro Pharma.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Section Approval is required. • Latest GMP inspection report/ certificate is required.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	

443.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Pericid Capsule 50mg
	Composition	Each capsule contains: Tramadol HCl…….50mg
	Diary No. Date of R & I & fee	Dy. No. 14320 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739968 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	N02AX02 Other opioids
	Type of Form	Form-5
	Finished product Specification	**USP Specs (Not found in USP, available in BP)**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TRAMADOL HYDROCHLORIDE 50MG CAPSULES MHRA Approved.
	Me-too status	Tramtar 50mg capsule Reg. No. 108558 M/s Star Laboratories.
	GMP status	Not Provided.
	Remarks of the Evaluator	• . • Latest GMP inspection report/ certificate is required.
	Decision: Approved with BP specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three years, before issuance of registration letter.	
444.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Astelin Tablet 20mg
	Composition	Each Film coated tablet contains: Atorvastatin as Calcium Trihydrate…….20mg
	Diary No. Date of R & I & fee	Dy. No. 16429 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901953 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	C10AA05 HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ATORVASTATIN 20 MG TABLETS MHRA Approved.
	Me-too status	Axolt 20mg Tablet of M/s Evolution Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
445.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Fincar Tablet 1mg
	Composition	Each Film coated tablet contains: Finasteride…….1mg
	Diary No. Date of R & I & fee	Dy. No. 15438 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0811896 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	G04CB01 Testosterone-5-alpha reductase inhibitors
	Type of Form	Form-5

	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	FINASTERIDE 1MG FILM-COATED TABLETS MHRA Approved.
	Me-too status	Fincar 1mg Tablet of M/s Genome Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Defferred for the confiormation of steroidal section by the licencing division	
446.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Fincar Tablet 5mg
	Composition	Each Film coated tablet contains: Finasteride…….5mg
	Diary No. Date of R & I & fee	Dy. No. 15437 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0811895 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	G04CB01 Testosterone-5-alpha reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	FINASTERIDE 5MG FILM-COATED TABLETS MHRA Approved.
	Me-too status	Finsocar 5mg Tablet of M/s AGP Limited.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
447.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Nuset Tablet 8mg
	Composition	Each Film coated tablet contains: Ondansetron as Hydrochloride Dihydrate (USP)…….8mg
	Diary No. Date of R & I & fee	Dy. No. 15403 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844304 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	A04AA01 Serotonin (5HT3) antagonists
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ondansetron 8 mg Tablets MHRA Approved.
	Me-too status	Onseget 8mg Tablet of M/s Getz Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
448.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Colvac Tablet 100mg
	Composition	Each Uncoated tablet contains: Cilostazol (USP)…….100mg

	Diary No. Date of R & I & fee	Dy. No. 75463 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0825940 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	B01AC23 Platelet aggregation inhibitors excl. heparin
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	CILOSTAZOL 100 MG TABLETS MHRA Approved.
	Me-too status	Plator 100mg Tablet of M/s Don Valley.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
449.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Montek Tablet 10mg
	Composition	Each Film-coated tablet contains: Montelukast as Sodium (USP)…….10mg
	Diary No. Date of R & I & fee	Dy. No. 15402 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844305 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	R03DC03 Leukotriene receptor antagonists
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MONTELUKAST 10MG FILM-COATED TABLETS MHRA Approved.
	Me-too status	Josef 10mg Tablet of M/s Winlet Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
450.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Sebifin Tablet 125mg
	Composition	Each Uncoated tablet contains: Terbinafine as Hydrochloride (USP)…….125mg
	Diary No. Date of R & I & fee	Dy. No. 15408 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844329 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	D01BA02 Antifungals for systemic use
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TERBINAFINE 125MG TABLETS (TERBINAFINE HYDROCHLORIDE) MHRA Approved
	Me-too status	Brandit Tablet 125 mg Reg. No. 090822 M/s High-Q Pharmaceuticals Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
451.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792)

		Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Sebifin Tablet 250mg
	Composition	Each Uncoated tablet contains: Terbinafine as Hydrochloride (USP)…….250mg
	Diary No. Date of R & I & fee	Dy. No. 15480 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901903 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	D01BA02 Antifungals for systemic use
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TERBINAFINE 250MG TABLETS (TERBINAFINE HYDROCHLORIDE) MHRA Approved
	Me-too status	Brandit Tablet 250 mg Reg. No. 090823 M/s High-Q Pharmaceuticals Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
452.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Letranor Tablet 2.5mg
	Composition	Each Film coated tablet contains: Letrozole…….2.5mg
	Diary No. Date of R & I & fee	Dy. No. 15413 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844324 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	L02BG04 Aromatase inhibitors
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Letrozole 2.5 mg film-coated tablets MHRA Approved
	Me-too status	Letrast Tablet 2.5 mg Reg. No. 101952 M/s Genome Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
453.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	ClotriNor Tablet 500mg
	Composition	Each Vaginal tablet contains: Clotrimazole…….500mg
	Diary No. Date of R & I & fee	Dy. No. 15394 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844313 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	G01AF02 Imidazole derivatives
	Type of Form	Form-5
	Finished product Specification	**USP Specs (Not found in USP, available in BP)**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Clotrimazole 500mg Vaginal Tablet MHRA Approved
	Me-too status	Gylot Vaginal Tablet 500mg Reg. No. 111685

		M/s Dyson Research.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with BP Specifications. Registration letter shall be issued after submission of fee of Rs. 7500/- as per SRO 496(I)/2023 dated 17.04.2023. by the firm.	
454.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Baclof Tablet 10mg
	Composition	Each Un-coated tablet contains: Baclofen…….10mg
	Diary No. Date of R & I & fee	Dy. No. 15464 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0825941 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	M03BX01 Other centrally acting agents
	Type of Form	Form-5
	Finished product Specification	**BP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	BACLOFEN 10MG TABLETS MHRA Approved
	Me-too status	Baclez Tablet 10mg Reg. No. 105469 M/s Avant Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
455.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Tizan Tablet 2mg
	Composition	Each Un-coated tablet contains: Tizanidine as Hydrochloride (USP)…….2mg
	Diary No. Date of R & I & fee	Dy. No. 15483 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901906 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	M03BX02 Other centrally acting agents
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Tizanidine 2 mg Tablets MHRA Approved
	Me-too status	Zandilex Tablet 2mg Reg. No. 104761 M/s Genetics Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
456.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Peta Cyclonor Tablet 20mg
	Composition	Each Un-coated tablet contains: Piroxicam as Piroxicam Beta Cyclodextrin (In-house)…….20mg

	Diary No. Date of R & I & fee	Dy. No. 15406 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844301 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	M01AC01 Oxicams
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Applied product is not effervescent. BREXIN 20 mg effervescent tablet ANSM France Approved.
	Me-too status	Straza Tablet Reg. No. 096316 M/s Asian Continental Karachi.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	Evidence of approval of applied formulation in RRA of is required
	Decision: Deferred for evidence of approval of applied formulation as uncoated pain tablet in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
457.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Pantora Tablet 40mg
	Composition	Each Delayed Release tablet contains: Pantoprazole as Sodium Sesquihydrate (USP)…….40mg
	Diary No. Date of R & I & fee	Dy. No. 15405 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844302 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	A02BC02 Proton pump inhibitors
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Pantoprazole 40 mg gastro-resistant tablets MHRA Approved.
	Me-too status	Sorgner 40mg Tablet Reg. No. 111676 M/s Highnoon Laboratories.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
458.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Etoshine Tablet 60mg
	Composition	Each Film Coated tablet contains: Etorixcoxib (In-house)…….60mg
	Diary No. Date of R & I & fee	Dy. No. 15440 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0811898 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	M01AH05 Coxibs
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Etoricoxib 60 mg film-coated tablets MHRA Approved.

	Me-too status	ETCM Tablet 60mg Reg. No. 113020 M/s Cure Laboratories.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications. Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
459.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	D-Veniz XL Tablet 50mg
	Composition	Each Extended Release Film Coated tablet contains: Desvenlafaxine as succinate (In-house)…….50mg
	Diary No. Date of R & I & fee	Dy. No. 16412 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 01901934 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	N06AX23 Other antidepressants
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	PRISTIQ 50mg Tablet USFDA Approved.
	Me-too status	Pristiq Tablet 50mg Reg. No. 103782 M/s Wyeth Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications. Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
460.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Irole Tablet 0.25mg
	Composition	Each Film Coated tablet contains: Ropinirole as Hydrochloride (USP)…….0.25mg
	Diary No. Date of R & I & fee	Dy. No. 15433 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 01901934 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	N04BC04 Dopamine agonists
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ropinirole 0.25 mg film-coated tablets MHRA Approved.
	Me-too status	Trigleg Tablet 0.25mg Reg. No. 107630 M/s Sigma Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
461.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Zevert Tablet 8mg
	Composition	Each Uncoated tablet contains:

		Betahistine as Dihydrochloride (BP)…….8mg
	Diary No. Date of R & I & fee	Dy. No. 15478 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901901 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	N07CA01 Antivertigo preparations
	Type of Form	Form-5
	Finished product Specification	**BP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Betahistine Dihydrochloride 8 mg Tablets MHRA Approved.
	Me-too status	Dowbet Tablet 8mg Reg. No. 107871 M/s Martin Dow.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	Revised Label Claim as per RRA along with fee of Rs. 30000/- is required.
	Decision: Approved with following label claim; **Each uncoated tablet contains;** **Betahistine Dihydrochloride (BP)…….8mg** **Registration letter shall be issued after submission of fee of Rs. 30000/- for correction/pre-approval change in product composition as per SRO 496(I)/2023 dated 17.04.2023. by the firm.**	
462.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Triposole Tablet 62.233/80mg
	Composition	Each Sugar coated tablet contains: Phloroglucinol as Hydrate……62.233mg Trimethylphloroglucinol…….80mg
	Diary No. Date of R & I & fee	Dy. No. 15481 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901904 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	A03AX12 Other drugs for functional gastrointestinal disorders
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Not Available
	Me-too status	Signinol Tablet 80mg Reg. No. 110900 M/s Welwink.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Evidence of approval of formulation in RRAs is required.
	Decision: Approved with following label claim; **Each Sugar coated tablet contains:** **Phloroglucinol Hydrate…...……80mg** **Trimethylphloroglucinol…….80mg** **Registration letter shall be issued after submission of fee of Rs. 30000/- for correction/pre-approval change in product composition as per SRO 496(I)/2023 dated 17.04.2023. by the firm.**	
463.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Prodep Tablet 10mEq (1080mg)
	Composition	Each Extended Release Tablet contains: Potassium Citrate (USP)…….10mEq (1080mg)
	Diary No. Date of R & I & fee	Dy. No. 15481 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901904 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	A12BA02 MINERAL SUPPLEMENTS

	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Urocit-K Extended Release Tablets USFDA Approved.
	Me-too status	Exocit XR10mEq Tablet Reg. No. 080827 M/s Vision Pharma
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
464.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Lornoxinor Tablet 8mg
	Composition	Each Film-coated Tablet contains: Lornoxicam…….8mg
	Diary No. Date of R & I & fee	Dy. No. 15401 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844306 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	M01AC05 Oxicams
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo 8mg film-coated tablet (EMA approved)
	Me-too status	Xonica 8mg Tablet by M/s Zephyr Pharmatec (Reg#086983)
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications. Registration letter shall be issued after submission of fee of Rs. 7500/- as per SRO 496(I)/2023 dated 17.04.2023. by the firm.	
465.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Liso Tablet 600mg
	Composition	Each Film-coated Tablet contains: Linezolid (USP)…….600mg
	Diary No. Date of R & I & fee	Dy. No. 15399 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844308 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	J01XX08 Other antibacterials
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Zyvox 600mg tablet USFDA Approved.
	Me-too status	LZL Tablet of M/s Daneen Pharma
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications. Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
466.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.

	Brand Name + Dosage Form + Strength	Sertin Tablet 100mg
	Composition	Each Film-coated Tablet contains: Sertraline as Hydrochloride (USP)…….100mg
	Diary No. Date of R & I & fee	Dy. No. 15473 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0825950 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	N06AB06 Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	SERTRALINE 100MG TABLETS MHRA Approved.
	Me-too status	Dysert 100mg Tablet Reg. No. 111686 M/s Dyson Research.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
467.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Pentazoc Tablet 25mg
	Composition	Each Uncoated Tablet contains: Pentazocine Hydrochloride (BO)…….25mg
	Diary No. Date of R & I & fee	Dy. No. 15484 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901907 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	N02AD01 Benzomorphan derivatives
	Type of Form	Form-5
	Finished product Specification	**BP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	PENTAZOCINE TABLETS BP 25mg MHRA Approved.
	Me-too status	Olped Tablet Reg. No. 094012 M/s Pulse Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Liquid injection (Psychotropic) section" from CLB. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
468.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strengths	D-Veniz XL Tablet 100mg
	Composition	Each Extended Release Film Coated tablet contains: Desvenlafaxine as succinate (In-house)…….100mg
	Diary No. Date of R & I & fee	Dy. No. 15441 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0811899 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	N06AX23 Other antidepressants
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	PRISTIQ 100mg Tablet USFDA Approved.
	Me-too status	Desfaxine Tablet 100mg Reg. No. 106542 M/s Bio-Lab.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications. Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
469.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Syncapone Tablet 25mg/100mg
	Composition	Each Uncoated tablet contains: Carbidopa as Monohydrate (USP)……..25mg Levodopa (USP)…….100mg
	Diary No. Date of R & I & fee	Dy. No. 15469 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0825946 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	N04BA02 Dopa and dopa derivatives
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Co-Careldopa 25 mg/100 mg tablets MHRA Approved.
	Me-too status	Cardop Tablet Reg. No. 092663 M/s Hilton Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
470.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Groproide Tablet 50mg
	Composition	Each Film-coated tablet contains: Itopride Hydrochloride (In-house)…….50mg
	Diary No. Date of R & I & fee	Dy. No. 15436 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0811894 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	A03FA07 Propulsives
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ganaton 50mg tablets PMDA Approved.
	Me-too status	Obspride Tablet Reg. No. 083962 M/s OBS Pakistan.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications. Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
471.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.

	Brand Name + Dosage Form + Strength	Syncapone Tablet 25mg/250mg
	Composition	Each Uncoated tablet contains: Carbidopa as Monohydrate (USP)……..25mg Levodopa (USP)…….250mg
	Diary No. Date of R & I & fee	Dy. No. 15467 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0825944 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	N04BA02 Dopa and dopa derivatives
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Co-Careldopa 25 mg/250 mg tablets MHRA Approved.
	Me-too status	Cardop Tablet Reg. No. 086607 M/s Hilton Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
472.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Lamosyn Tablet 50mg
	Composition	Each Uncoated tablet contains: Lamotrigine (USP)…….50mg
	Diary No. Date of R & I & fee	Dy. No. 15470 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0825947 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	N03AX09 Other antiepileptics
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lamotrigine Consilient 50 mg Tablets MHRA Approved.
	Me-too status	Trignin Tablet 50mg Reg. No. 105402 M/s Hi-Q.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
473.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Lamosyn Tablet 100mg
	Composition	Each Uncoated tablet contains: Lamotrigine (USP)…….100mg
	Diary No. Date of R & I & fee	Dy. No. 15468 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0825945 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	N03AX09 Other antiepileptics
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lamotrigine Consilient 100 mg Tablets MHRA Approved.
	Me-too status	Trignin Tablet 100mg Reg. No. 105403 M/s Hi-Q.

	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
474.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Irole Tablet 0.5mg
	Composition	Each Film Coated tablet contains: Ropinirole as Hydrochloride (USP)…….0.5mg
	Diary No. Date of R & I & fee	Dy. No. 15434 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0811892 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	N04BC04 Dopamine agonists
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ROPINIROLE 0.5MG FILM-COATED TABLETS MHRA Approved.
	Me-too status	Rolin Tablet 0.5mg Reg. No. 108605 M/s Mediate Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
475.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Deslonor Tablet 5mg
	Composition	Each Film Coated tablet contains: Desloratadine (USP)…….5mg
	Diary No. Date of R & I & fee	Dy. No. 15423 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844382 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	R06AX27 Other antihistamines for systemic use
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	DESLORATADINE 5MG FILM-COATED TABLETS MHRA Approved.
	Me-too status	Rolin Tablet 0.5mg Reg. No. 108605 M/s Mediate Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
476.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Capsule (general) Section.
	Brand Name + Dosage Form + Strength	Omepranor Capsule 20mg
	Composition	Each Capsule contains: Omeprazole (as Enteric Coated Pellets) eq. to…….20mg
	Diary No. Date of R & I & fee	Dy. No. 15425 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844387 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	A02BC01 Proton pump inhibitors
	Type of Form	Form-5

	Finished product Specification	**In-house Specs (Available in BP & USP)**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Omeprazole 20mg Capsules MHRA Approved.
	Me-too status	Omeprasyn Capsule 20mg Reg. No. 112063 M/s Synchro Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Source of pellets is required. • Revision of specifications as per monograph along with fee is required.
	Decision: Approved with USP Specifications. Registration letter shall be issued after submission of fee of Rs. 7500/- as per SRO 496(I)/2023 dated 17.04.2023. by the firm.	
477.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Capsule (general) Section.
	Brand Name + Dosage Form + Strength	Omepranor Capsule 40mg
	Composition	Each Capsule contains: Omeprazole (as Enteric Coated Pellets) eq. to…….40mg
	Diary No. Date of R & I & fee	Dy. No. 15426 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844388 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	A02BC01 Proton pump inhibitors
	Type of Form	Form-5
	Finished product Specification	**In-house Specs (Available in BP & USP)**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Omeprazole 40mg Capsules MHRA Approved.
	Me-too status	Omeprasyn Capsule 40mg Reg. No. 112064 M/s Synchro Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Source of pellets is required. • Revision of specifications as per monograph along with fee is required.
	Decision: Approved with USP Specifications. Registration letter shall be issued after submission of fee of Rs. 7500/- as per SRO 496(I)/2023 dated 17.04.2023. by the firm.	
478.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Capsule (general) Section.
	Brand Name + Dosage Form + Strength	Diclonor-P SR Capsule 100mg
	Composition	Each Capsule contains: Diclofenac Sodium (as SR Pellets) eq. to Diclofenac…….100mg
	Diary No. Date of R & I & fee	Dy. No. 15426 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901950 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	M01AB05 Acetic acid derivatives and related substances
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Rhumalgan XL 100 mg modified-release capsules MHRA Approved.
	Me-too status	Arthonil Capsule 100mg Reg. No. 110890 M/s Batala Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Source of Pellets is required.

	Decision: Approved with BP specifications. Firm shall submit fee of Rs. 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with documents for source of pellets.	
479.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Capsule (general) Section.
	Brand Name + Dosage Form + Strength	Mevin Capsule 200mg
	Composition	Each Capsule contains: Mebeverine HCl…….200mg
	Diary No. Date of R & I & fee	Dy. No. 16416 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901938 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	A03AA04 Synthetic anticholinergics, esters with tertiary amino group
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Provided reference is of modified release formulation.
	Me-too status	Provided reference is of modified release formulation.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	Revision of label claim as per RRAs along with fee of Rs. 30000/- is required.
	Decision: Approved with following label claim; Each Capsule contains; Mebeverine hydrochloride (SR pellets)…….200mg Registration letter shall be issued after submission of fee of Rs. 30000/- as per SRO 496(I)/2023 dated 17.04.2023 along with source of pellets by the firm.	
480.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Capsule (general) Section.
	Brand Name + Dosage Form + Strength	Cycloprine Capsule 15mg
	Composition	Each Extended Release Capsule contains: Cyclobenzaprine HCl as Extended Relelase Pellets 15.79% (USP) …….15mg
	Diary No. Date of R & I & fee	Dy. No. 15446 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844504 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	M03BX08 Other centrally acting agents
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	AMRIX® 15mg USFDA Approved
	Me-too status	Zapsy Capsule 15mg Reg. No. 103486 M/s Biomark Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	Source of Pellets is required.
	Decision: Approved. Registration letter shall be issued after submission of source of pellets along with requisite fee.	
481.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Capsule (general) Section.
	Brand Name + Dosage Form + Strength	Cycloprine Capsule 30mg
	Composition	Each Extended Release Capsule contains:

		Cyclobenzaprine HCl as Extended Relelase Pellets 15.79% (USP) …….30mg
	Diary No. Date of R & I & fee	Dy. No. 15446 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844505 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	M03BX08 Other centrally acting agents
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	AMRIX® 30mg USFDA Approved
	Me-too status	Zapsy Capsule 30mg Reg. No. 103485 M/s Biomark Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	Source of Pellets is required.
	Decision: Approved. Registration letter shall be issued after submission of source of pellets along with requisite fee.	
482.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Capsule (general) Section.
	Brand Name + Dosage Form + Strength	Vyfat Capsule 120mg
	Composition	Each Capsule contains: Orlistat (USP) …….120mg
	Diary No. Date of R & I & fee	Dy. No. 15458 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844516 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	M03BX08 Other centrally acting agents
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Xenical Capsule 120mg USFDA Approved
	Me-too status	Orlinig Capsule 120mg Reg. No. 091737 M/s Honig Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Revision of label claim as per RRAs along with fee of Rs. 30000/- is required. • Source of pellets is required.
	Decision: Approved with following label claim; **Each Capsule contains;** **Orlistat (as immediate release pellets) (USP) …….120mg** • **Registration letter shall be issued after submission of fee of Rs. 30000/- as per SRO 496(I)/2023 dated 17.04.2023 along with source of pellets by the firm.** • **Firm shall also submit the source of pellets in which stability studies of the pellets have been conducted at real time conditions i.e., 30°C ± 2°C/65% RH ± 5% RH alongwith quantification of degradation products throughout the stability studies / assigned shelf life along with COA, accelerated stability study data, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets) before issuance of registration letter.**	
483.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Dry Powder Suspension Section.
	Brand Name + Dosage Form + Strength	Flunor Dry Suspension 50mg/5mL
	Composition	Each 5mL contains: Fluconazole (USP) …….50mg
	Diary No. Date of R & I & fee	Dy. No. 16414 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901936 dated 06-03-2019, endorsed on 07.03.2019.

	Pharmacological Group	J02AC01 Triazole and tetrazole derivatives
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Fluconazole 50mg/5ml Powder for Oral Suspension MHRA Approved
	Me-too status	Semfloc Powder for Suspension 50mg/5ml Reg. No. 110279 M/s Semos Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
484.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Dry Powder Suspension Section.
	Brand Name + Dosage Form + Strength	Liso Dry Suspension 100mg/5mL
	Composition	Each 5mL suspension contains: Linezolid (In-house) …….100mg
	Diary No. Date of R & I & fee	Dy. No. 15398 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844309 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	J01XX08 Other antibacterials
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Linezolid 100 mg/5 ml granules for oral suspension MHRA Approved
	Me-too status	Zolidan for Suspension 100mg/5ml Reg. No. 112008 M/s Himark Laboratories.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications. Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
485.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Dry Powder Suspension Section.
	Brand Name + Dosage Form + Strength	Rifal-I Suspension 150mg
	Composition	Each 5mL contains: Isoniazid……..50mg Rifampin …….100mg
	Diary No. Date of R & I & fee	Dy. No. 16415 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901937 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	J04AM02 Combinations of drugs for treatment of tuberculosis
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be found
	Me-too status	Riso Reg. No. 040579 M/s Pharmawise.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• RRA reference of applied formulation is required.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. The	

	Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
486.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Cream/ Ointment/ Gel (Non-Steroidal) Section.
	Brand Name + Dosage Form + Strength	Lomela Cream 0.1/40/0.5
	Composition	Each gram cream contains: Fluocinolone Acetonide…….0.1mg Hydroquinone……..40mg Tretinoin …….0.5mg
	Diary No. Date of R & I & fee	Dy. No. 15475 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0849666 dated 05-03-2019, endorsed on 06.03.2019.
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TRI-LUMA™ Cream USFDA Approved
	Me-too status	Epidermon Cream Reg. No. 105962 M/s Moon Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Evidence of separate dispensing booth for Fluocinolone is required.
	Decision: Approved. Registration letter shall be issued after submission of evidence of availability of separate dispensing booth for steroidal formulations.	
487.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Cream/ Ointment/ Gel (Non-Steroidal) Section.
	Brand Name + Dosage Form + Strength	C-Sol Cream 0.05% w/w
	Composition	Each gram cream contains: Clobetasol propionate …….0.05%
	Diary No. Date of R & I & fee	Dy. No. 16431 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901955 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	D07AD01 Corticosteroids, very potent (group IV)
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	CLOBADERM 0.05% W/W CREAM MHRA Approved
	Me-too status	Clobetanate Cream Reg. No. 107159 M/s Axis Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Evidence of separate dispensing booth for Clobetasol is required.
	Decision: Approved. Registration letter shall be issued after submission of evidence of availability of separate dispensing booth for steroidal formulations.	
488.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Cream/ Ointment/ Gel (Non-Steroidal) Section.
	Brand Name + Dosage Form + Strength	Fusinor-H Cream 2%/ 1%
	Composition	Each gram contains: Fusidic Acid (BP)……20mg (2%w/w) Hydrocortisone Acetate (USP) …….10mg (1%w/w)

	Diary No. Date of R & I & fee	Dy. No. 15395 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844314 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	D07CA01 Corticosteroids, weak, combinations with antibiotics
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Fucidin H cream MHRA Approved
	Me-too status	Bacusid-H Cream Reg. No. 090781 M/s Sami Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Evidence of separate dispensing booth for Hydrocortisone is required.
	Decision: Approved with Innovator's Specifications. Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter along with evidence of availability of separate dispensing booth for steroidal formulations.	
489.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Cream/ Ointment/ Gel (Non-Steroidal) Section.
	Brand Name + Dosage Form + Strength	Fusinor-B Cream 2%/ 0.1%
	Composition	Each gram contains: Fusidic Acid (BP)…….20mg (2%w/w) Betamethasone as Valerate (USP) …….1mg (0.1%w/w)
	Diary No. Date of R & I & fee	Dy. No. 15396 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844315 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	D07CA01 Corticosteroids, weak, combinations with antibiotics
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	FUSIDIC ACID/BETAMETHASONE 20 MG/G + 1 MG/G CREAM MHRA Approved
	Me-too status	Bacusid-B Cream Reg. No. 090780 M/s Sami Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Evidence of separate dispensing booth for Betamethasone is required.
	Decision: Approved with Innovator's Specifications. Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter along with evidence of availability of separate dispensing booth for steroidal formulations.	
490.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Cream/ Ointment/ Gel (Non-Steroidal) Section.
	Brand Name + Dosage Form + Strength	Sebifin Cream 1%
	Composition	Each gram contains: Terbinafine Hydrochloride (USP) …….0.01gm (1%w/w)
	Diary No. Date of R & I & fee	Dy. No. 15407 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844330 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	D01AE15 Other antifungals for topical use
	Type of Form	Form-5
	Finished product Specification	**In-house Specs (Available in JP)**
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	TERBINAFINE HYDROCHLORIDE 1% CREAM MHRA Approved
	Me-too status	Ternifer 1% Cream Reg. No. 109369 M/s Shaigan Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with JP Specifications. Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
491.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Cream/ Ointment/ Gel (Non-Steroidal) Section.
	Brand Name + Dosage Form + Strength	Tacrovera Ointment 0.1%
	Composition	Each gram contains: Tacrolimus (as monohydrate)…….1mg (0.1%w/w)
	Diary No. Date of R & I & fee	Dy. No. 16418 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901941 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	D11AH01 Agents for dermatitis, excluding corticosteroids
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TACROLIMUS ACCORD 0.1 % OINTMENT MHRA Approved
	Me-too status	Enigma 0.1% Ointment Reg. No. 112031 M/s Rotex Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications. Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
492.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Cream/ Ointment/ Gel (Non-Steroidal) Section.
	Brand Name + Dosage Form + Strength	Isotretinor-E Gel 2%/ 0.05%
	Composition	Each gram contains: Erythromycin (USP)…….20mg (2%w/w) Isotretinoin (USP)…….0.5mg (0.05%w/w)
	Diary No. Date of R & I & fee	Dy. No. 16393 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844312 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	D10AD54 Retinoids for topical use in acne
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Provided evidence is not traceable.
	Me-too status	Tratin-E Gel Reg. No. 108254 M/s Fynk Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Evidence of availability of formulation in RRAs is required.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	

	The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
493.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Cream/ Ointment/ Gel (Non-Steroidal) Section.
	Brand Name + Dosage Form + Strength	Clindanor-B Gel 1%/ 5%
	Composition	Each gram contains: Clindamycin as Phosphate (USP)…….10mg (1%w/w) Benzoyl Peroxide (USP)…….50mg (5%w/w)
	Diary No. Date of R & I & fee	Dy. No. 15422 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844381 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	D10AF51 Anti-infectives for treatment of acne
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Clindamycin 10 mg/g + Benzoyl Peroxide 50 mg/g Gel MHRA Approved
	Me-too status	Duke-B Gel Reg. No. 113196 M/s Rotex Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications. Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
494.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Ampoule/ Vial (General Liquid SVPc) Section.
	Brand Name + Dosage Form + Strength	Amacin Injection 500mg
	Composition	Each 2ml injection contains: Amikacin Sulfate…….500mg
	Diary No. Date of R & I & fee	Dy. No. 15444 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844502 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	J01GB06 Other aminoglycosides
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	AMIKACIN 250MG/ML INJECTION MHRA Approved
	Me-too status	AMC 500mg Injection Reg. No. 099160 M/s Rotex Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Revised label claim as per RRAs along with fee of Rs. 30000/- is required.
	Decision: Approved a sper following revised label claim: **Each 2ml injection contains:** **Amikacin Sulfate eq. to Amikacin…….500mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
495.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Ampoule/ Vial (General Liquid SVPc) Section.

	Brand Name + Dosage Form + Strength	Amacin Injection 100mg
	Composition	Each 2ml Ampoule contains: Amikacin as Sulfate…….100mg
	Diary No. Date of R & I & fee	Dy. No. 16427 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901951 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	J01GB06 Other aminoglycosides
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	AMIKIN INJECTION 100MG/2ML MHRA Approved
	Me-too status	AMC 100mg Injection Reg. No. 100802 M/s Rotex Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
496.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Ampoule/ Vial (General Liquid SVPc) Section.
	Brand Name + Dosage Form + Strength	Ligonor Injection 1%
	Composition	Each Ampoule (2mL) contains: Lignocaine (USP)…….20mg (1%)
	Diary No. Date of R & I & fee	Dy. No. 15392 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844311 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	N01BB02 Amides
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	LIDOCAINE 1% W/V SOLUTION FOR INJECTION MHRA Approved
	Me-too status	Rotacaine 1% Injection Reg. No. 112030 M/s Rotex Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
497.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Ampoule/ Vial (General Liquid SVPc) Section.
	Brand Name + Dosage Form + Strength	Ligonor Injection 2%
	Composition	Each Ampoule (2mL) contains: Lignocaine (USP)…….40mg (2%)
	Diary No. Date of R & I & fee	Dy. No. 15397 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844310 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	N01BB02 Amides
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	2% w/v Lidocaine Injection BP MHRA Approved
	Me-too status	Avecaine 2% Injection Reg. No. 097106 M/s Avensis Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.

	Remarks of the Evaluator	
	Decision: Approved.	
498.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Ampoule/ Vial (General Liquid SVPc) Section.
	Brand Name + Dosage Form + Strength	Diclonor Injection 75mg/3mL
	Composition	Each 3mL Ampoule contains: Diclofenac Sodium…….75mg
	Diary No. Date of R & I & fee	Dy. No. 15424 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844386 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	M01AB05 Acetic acid derivatives and related substances
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Not Provided
	Me-too status	Linofenac Injection Reg. No. 106983 M/s Linear Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Evidence of approval of formulation in RRAs is required.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
499.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Ampoule/ Vial (General Liquid SVPc) Section.
	Brand Name + Dosage Form + Strength	Diclonor-P Injection 75mg/20mg
	Composition	Each 2mL Ampoule contains: Diclofenac Sodium…….75mg Lidocaine as HCl……....20mg
	Diary No. Date of R & I & fee	Dy. No. 15476 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0849667 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	N01BB52 Lidocaine, combinations
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Not Provided
	Me-too status	Lisodim Injection Reg. No. 113174 M/s Surge Laboratories.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Evidence of approval of formulation in RRAs is required.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
500.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792)

		Cream/ Ointment/ Gel (Non-Steroidal) Section.
	Brand Name + Dosage Form + Strength	Dipmeth-G Cream 0.05%/ 0.1%
	Composition	Each gram cream contains: Betamethasone (as Dipropionate)…….0.5mg Gentamycin (as Sulfate)…….1mg
	Diary No. Date of R & I & fee	Dy. No. 16409 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901931 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	D07CC01 Corticosteroids, potent, combinations with antibiotics
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Provided evidence is not traceable
	Me-too status	Cutibet-G Cream Reg. No. 092953 M/s Tabros Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Evidence of approval of formulation in RRAs is required. • Evidence of separate dispensing booth for Betamethasone is required.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
501.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Ampoule/ Vial (General Liquid SVPc) Section.
	Brand Name + Dosage Form + Strength	Trinor Injection 40mg/mL
	Composition	Each Ampoule (1mL) contains: Lignocaine (USP)…….....40mg
	Diary No. Date of R & I & fee	Dy. No. 15409 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844328 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	H02AB08 Glucocorticoids
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Kenalog Intra-articular / Intramuscular Injection 40mg/ml MHRA Approved
	Me-too status	Kenatex Injection Reg. No. 097783 M/s Rotex Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Revise Form-5 with composition indicating Triamcinolone Acetonide along with fee of Rs. 30000/- is required.
	Decision: Approved.	
502.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Ampoule/ Vial (General Liquid SVPc) Section.
	Brand Name + Dosage Form + Strength	Norket Injection 500mg
	Composition	Each vial (10ml) contains: Ketamine HCl eq. to Ketamine…….....500mg

	Diary No. Date of R & I & fee	Dy. No. 16420 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901943 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	N01AX03 Other general anesthetics
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ketamine 50 mg/ml Injection MHRA Approved
	Me-too status	Fasket Injection Reg. No. 101578 M/s Pharmasol.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Liquid Injection ampoule (Psychotropic) section" from CLB. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
503.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Ampoule/ Vial (General Liquid SVPc) Section.
	Brand Name + Dosage Form + Strength	Calrol Injection 1mcg/ml
	Composition	Each 1ml Ampoule contains: Calcitriol……....1mcg
	Diary No. Date of R & I & fee	Dy. No. 15445 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844503 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	A11CC04 Vitamin D and analogues
	Type of Form	Form-5
	Finished product Specification	**In-house Specs (Available in USP)**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	CALCIJEX® (calcitriol injection) 1 mcg/mL USFDA Approved
	Me-too status	Rotacal Injection Reg. No. 107285 M/s Rotex Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
504.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Ampoule/ Vial (General Liquid SVPc) Section.
	Brand Name + Dosage Form + Strength	Suxmeth Injection 100mg/2ml
	Composition	Each 2ml Ampoule contains: Suxamethonium Chloride (BP)……....100mg
	Diary No. Date of R & I & fee	Dy. No. 16417 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901940 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	M03AB01 Choline derivatives
	Type of Form	Form-5
	Finished product Specification	**BP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Suxamethonium Chloride 100mg/2ml Solution for Injection MHRA Approved

	Me-too status	Ritho Injection Reg. No. 100951 M/s Aulton Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
505.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Methynor Injection 40mg/2ml
	Composition	Each ml contains: Methylprednisolone Acetate……....40mg
	Diary No. Date of R & I & fee	Dy. No. 16413 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901935 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	H02AB04 Glucocorticoids
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	DEPO-MEDROL® (methylprednisolone acetate injectable suspension, USP) USFDA Approved
	Me-too status	Depo-Pred Injection Reg. No. 097782 M/s Rotex Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Evidence of availability of requisite manufacturing facility is required.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Liquid Injection (Steroid) section" from CLB. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
506.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Ampoule/ Vial (General Liquid SVPc) Section.
	Brand Name + Dosage Form + Strength	Pentazoc Injection 30mg
	Composition	Each 1ml Ampoule contains: Pentazocin (as Lactate)……....30mg
	Diary No. Date of R & I & fee	Dy. No. 16421 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901944 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	N02AD01 Benzomorphan derivatives
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TALWIN (pentazocine), injection, for intramuscular, subcutaneous, or intravenous use USFDA Approved
	Me-too status	Pentazocin Injection Reg. No. 100782 M/s Iqra Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Liquid Injection ampoule (Psychotropic) section" from CLB.	

	The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
507.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Ampoule/ Vial (General Liquid SVPc) Section.
	Brand Name + Dosage Form + Strength	Pherine Injection 50mg/2mL
	Composition	Each 2ml Ampoule contains: Tramadol HCl……....50mg
	Diary No. Date of R & I & fee	Dy. No. 16424 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901947 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	N02AX02 Other opioids
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Provided evidence is for 100mg/2ml ampoule.
	Me-too status	Provided evidence is not traceable. Generic formulation is either as 50mg/ml or 100mg/2ml.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Evidence of availability of formulation in RRAs is required. • Evidence of Me-too status of formulation is required.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor registered previously by DRAP. **Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.**	
508.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Ampoule/ Vial (General Liquid SVPc) Section.
	Brand Name + Dosage Form + Strength	Nuset Injection 8mg/4mL
	Composition	Each Ampoule (4mL) contains: Ondansetron as Hydrochloride (USP)…….....8mg
	Diary No. Date of R & I & fee	Dy. No. 15404 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844303 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	A04AA01 Serotonin (5HT3) antagonists
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ondansetron 2 mg/ml Solution for Injection USFDA Approved
	Me-too status	Onseget Injection 8mg Reg. No. 112600 M/s Getz Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Revised label claim as per RRAs along with fee of Rs. 30000/- is required.
	Decision: Approved with following label; **Each Ampoule (4ml) contains;** **Ondansetron as Hydrochloride Dihydrate…….8mg** **Registration letter shall be issued after submission of fee of Rs. 30000/- as per SRO 496(I)/2023 dated 17.04.2023. by the firm.**	

509.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Ampoule/ Vial (General Liquid SVPc) Section.
	Brand Name + Dosage Form + Strength	Buprenor Injection 0.3mg
	Composition	Each 1ml Ampoule contains: Buprenorphine (As Hydrochloride)……....0.3mg
	Diary No. Date of R & I & fee	Dy. No. 16430 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901954 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	N02AE01 Oripavine derivatives
	Type of Form	Form-5
	Finished product Specification	**In-house Specs (Available in BP)**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	BUPRENEX ® (buprenorphine hydrochloride) injection USFDA Approved
	Me-too status	Biogesic Injection Reg. No. 097760 M/s Iqra Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved. Registration letter shall be issued after confirmation of Section approval and submission of NOC from Ministry of narcotics Control by the firm.	
510.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Ampoule/ Vial (General Liquid SVPc) Section.
	Brand Name + Dosage Form + Strength	Atabes Injection 50mg
	Composition	Each 5ml Ampoule contains: Atracurium besylate……....50mg
	Diary No. Date of R & I & fee	Dy. No. 16432 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1902576 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	M03AC04 Other quaternary ammonium compounds
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Atracurium Besilate 10 mg/ml Solution for Injection MHRA Approved
	Me-too status	ATR Injection 50mg Reg. No. 100807 M/s Rotex Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
511.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Ampoule/ Vial (General Liquid SVPc) Section.
	Brand Name + Dosage Form + Strength	Lornoxinor Injection 8mg/2ml
	Composition	Each Vial (2ml) contains: Lornoxicam……....8mg
	Diary No. Date of R & I & fee	Dy. No. 16432 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1902576 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	M01AC05 Oxicams
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Provided evidence is not traceable
	Me-too status	Orno Injection Reg. No. 083160 M/s Sami Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Evidence of availability of formulation in RRAs is required. • Evidence of availability of lyophilization facility is required. • Clarification is required either solvent is in combi pack or not.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Lyophilized injectable (general) section" from CLB. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
512.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Ampoule/ Vial (General Liquid SVPc) Section.
	Brand Name + Dosage Form + Strength	Idrofos Injection 3mg/3ml
	Composition	Each 3ml Ampoule contains: Ibandronate sodium monohydrate eq. to Ibandronic acid……....3mg
	Diary No. Date of R & I & fee	Dy. No. 15474 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0849664 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	M05BA06 Bisphosphonates
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Not Provided
	Me-too status	Zoltranz Injection Reg. No. 104979 M/s Rotex Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Evidence of availability of formulation in ampoule packaging in RRAs is required.
	Decision: Deferred for evidence of approval of applied formulation in glass ampoule by reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
513.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Sertin Tablet 50mg
	Composition	Each Film-coated Tablet contains: Sertraline as Hydrochloride (USP)…….50mg
	Diary No. Date of R & I & fee	Dy. No. 15479 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901902 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	N06AB06 Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	**USP Specs**

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	SERTRALINE 50MG TABLETS MHRA Approved.
	Me-too status	Sertagon 50mg Tablet Reg. No. 110884 M/s Trigon Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
514.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Telmisa-A Tablet 40mg/10mg
	Composition	Each Tablet contains: Amlodipine as Besylate (USP)…….10mg Telmisartan (USP)……40mg
	Diary No. Date of R & I & fee	Dy. No. 15456 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844514 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	C09DB04 Angiotensin II receptor blockers (ARBs) and calcium channel blockers
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Twynsta TABLET 10/40 (As Bilayered Tablet) USFDA Approved.
	Me-too status	Telnip-A 10/40 Tablet Reg. No. 112773 M/s The Searle Company Limited..
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Revised label claim as per RRA along with fee of Rs. 30000/- is required.
	Decision: Approved as per following label claim; **Each Bilayered tablet contains;** **Amlodipine as Besylate …….10mg** **Telmisartan ……40mg** **Registration letter shall be issued after confirmation of availability of bilayered tablet manufacturing facility and submission of fee of Rs. 30000/- for correction/pre-approval change of product description as per SRO 496(I)/2023 dated 17.04.2023 by the firm.**	
515.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Telmisa-A Tablet 80mg/5mg
	Composition	Each Tablet contains: Amlodipine as Besylate …….5mg Telmisartan ……80mg
	Diary No. Date of R & I & fee	Dy. No. 15455 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844513 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	C09DB04 Angiotensin II receptor blockers (ARBs) and calcium channel blockers
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Twynsta TABLET 5/80 (As Bilayered Tablet) USFDA Approved.
	Me-too status	Telnip-A 5/80 Tablet Reg. No. 112774 M/s The Searle Company Limited..

	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Revised label claim as per RRA along with fee of Rs. 30000/- is required.
	Decision: Approved as per following label claim; **Each Bilayered tablet contains;** **Amlodipine as Besylate …….5mg** **Telmisartan ……80mg** **Registration letter shall be issued after confirmation of availability of bilayered tablet manufacturing facility and submission of fee of Rs. 30000/- for correction/pre-approval change of product description as per SRO 496(I)/2023 dated 17.04.2023 by the firm.**	
516.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Telmisa-H Tablet 40mg/12.5mg
	Composition	Each Tablet contains: Hydrochlorothiazide (USP)…….12.5mg Telmisartan (USP)……80mg
	Diary No. Date of R & I & fee	Dy. No. 15457 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844515 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	C09DA07 Angiotensin II receptor blockers (ARBs) and diuretics
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Micardis HCT TABLET 12.5/80 (As Bilayered Tablet) USFDA Approved.
	Me-too status	Elsart-H 12.5/80 Tablet Reg. No. 112705 M/s Hi-Q Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Revised label claim as per RRA along with fee of Rs. 30000/- is required.
	Decision: Approved with following label; **Each Bilayered tablet contains;** **Hydrochlorothiazide …….12.5mg** **Telmisartan ……80mg** **Registration letter shall be issued after confirmation of availability of bilayered tablet manufacturing facility and submission of fee of Rs. 30000/- for correction/pre-approval change of product description as per SRO 496(I)/2023 dated 17.04.2023 by the firm.**	
517.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Lamosyn Tablet 25mg
	Composition	Each Uncoated tablet contains: Lamotrigine (USP)…….25mg
	Diary No. Date of R & I & fee	Dy. No. 15429 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0801850 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	N03AX09 Other antiepileptics
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lamictal 50 mg Tablets USFDA Approved.
	Me-too status	Trignin Tablet 25mg Reg. No. 105401 M/s Hi-Q.

	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
518.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Zevert Tablet 16mg
	Composition	Each Uncoated tablet contains: Betahistine as Dihydrochloride (BP)…….16mg
	Diary No. Date of R & I & fee	Dy. No. 15471 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0825948 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	N07CA01 Antivertigo preparations
	Type of Form	Form-5
	Finished product Specification	**BP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Betahistine Dihydrochloride 16 mg Tablets MHRA Approved.
	Me-too status	Dowbet Tablet 16mg Reg. No. 107870 M/s Martin Dow.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	Revised Label Claim as per RRA along with fee of Rs. 30000/- is required.
	Decision: Approved with following label; **Each Uncoated tablet contains;** **Betahistine Dihydrochloride……16mg** **Registration letter shall be issued after submission of fee of Rs. 30000/- for correction/pre-approval change in label claim as per SRO 496(I)/2023 dated 17.04.2023 by the firm.**	
519.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Siomet Tablet 50mg/500mg
	Composition	Each Film-Coated Tablet contains: Metformin HCl…….500mg Sitagliptin Phosphate Monohydrate……50mg
	Diary No. Date of R & I & fee	Dy. No. 15415 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844322 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	A10BD07 Combinations of oral blood glucose lowering drugs
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Janumet TABLET 50/500 USFDA Approved.
	Me-too status	Obformin 50/500 Tablet Reg. No. 113053 M/s Obsons Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Revised label claim as per RRA along with fee of Rs. 30000/- is required.
	Decision: Approved with following label; **Each Bilayered tablet contains;** **Metformin HCl…….500mg** **Sitagliptin Phosphate Monohydrate eq. to Sitagliptin..…50mg** **Registration letter shall be issued after submission of fee of Rs. 30000/- for correction/pre-approval change in label claim as per SRO 496(I)/2023 dated 17.04.2023 by the firm.**	

520.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Astelin Tablet 10mg
	Composition	Each Film coated tablet contains: Atorvastatin as Calcium Trihydrate…….10mg
	Diary No. Date of R & I & fee	Dy. No. 16428 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901952 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	C10AA05 HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ATORVASTATIN 10 MG TABLETS MHRA Approved.
	Me-too status	Axolt 10mg Tablet of M/s Evolution Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
521.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Mirnite Tablet 15mg
	Composition	Each Film coated tablet contains: Mirtazapine (USP)…….15mg
	Diary No. Date of R & I & fee	Dy. No. 15462 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844520 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	N06AX11 Other antidepressants
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Remeron 15 MG TABLETS USFDA Approved.
	Me-too status	Mirtazep 15mg Tablet Reg. No. 110105 M/s Zafa Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
522.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Acnac Tablet 100mg
	Composition	Each Film coated tablet contains: Aceclofenac (USP)…….100mg
	Diary No. Date of R & I & fee	Dy. No. 15427 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0801848 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	M01AB16 Acetic acid derivatives and related substances
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Aceclofenac 100 mg Film-coated Tablets, MHRA approved.

	Me-too status	Acenac 100Mg Tablets, S.J & G. Fazul Ellahie, Reg. No. 039336.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications. Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
523.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Paroxid Tablet 20mg
	Composition	Each Enteric Film coated Controlled Release tablet contains: Paroxetine as Hydrochloride Hemihydrate (USP)…….20mg
	Diary No. Date of R & I & fee	Dy. No. 15491 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901927 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	N06AB05 Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Submitted evidence is of film coated tablet not control release tablet
	Me-too status	Submitted evidence is not traceable
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Evidence of availability of formulation in RRAs is required. • Evidence of availability of Me-Too is required.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor registered previously by DRAP.	
524.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Idronic Tablet 150mg
	Composition	Each Film coated tablet contains: Ibandronic acid as Ibandronate Monosodium monohydrate…….150mg
	Diary No. Date of R & I & fee	Dy. No. 15435 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0811893 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	M05BA06 Bisphosphonates
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Boniva 150 MG TABLETS USFDA Approved.
	Me-too status	Banjib 150Mg Tablets, Reg. No. 112614 M/s Ray Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications. Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
525.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792)

		Tablet (general) Section.
	Brand Name + Dosage Form + Strength	Nebinor Tablet 5mg
	Composition	Each Uncoated tablet contains: Nebivolol as Hydrochloride (USP)…….5mg
	Diary No. Date of R & I & fee	Dy. No. 15459 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844517 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	C07AB12 Beta blocking agents, selective
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Bystolic 5mg TABLETS USFDA Approved.
	Me-too status	Ebilol 5Mg Tablets, Reg. No. 110701 M/s CCL Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications. Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
526.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Capsule (general) Section.
	Brand Name + Dosage Form + Strength	Thioact Capsule 4mg
	Composition	Each Capsule contains: Thiocolchicoside (In-house)…….4mg
	Diary No. Date of R & I & fee	Dy. No. 15486 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901909 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	M03BX05 Other centrally acting agents
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MIOREL 4 mg, capsule ANSM France Approved
	Me-too status	Thiolaksent Capsule 4mg Reg. No. 112968 M/s Bio-Labs (Pvt.) Ltd.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications. Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
527.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Capsule (general) Section.
	Brand Name + Dosage Form + Strength	Tamsurid Capsule 0.4mg
	Composition	Each Capsule contains: Tamsulosin Hydrochloride as extended release pellets 0.2% (USP)…….0.4mg
	Diary No. Date of R & I & fee	Dy. No. 15454 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0844512 dated 05-03-2019, endorsed on 06.03.2019.
	Pharmacological Group	G04CA02 Alpha-adrenoreceptor antagonists
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Flomax Capsule USFDA Approved
	Me-too status	Temey Capsule 0.4mg Reg. No. 108145 M/s Siam Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with USP Specifications. Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter along with documents for source of pellets.	
528.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Purpal Tablet 20mg
	Composition	Each gastro-resistant tablet contains: Esomeprazole (as magnesium dihydrate)…….20mg
	Diary No. Date of R & I & fee	Dy. No. 14304 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0749397 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	A02BC05 Proton pump inhibitors
	Type of Form	Form-5
	Finished product Specification	**Innovator's Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ESOMEPRAZOLE 20 MG GASTRO-RESISTANT TABLETS MHRA Approved.
	Me-too status	Eprazole 20mg Tablet of M/s Fynk Pharma.
	GMP status	Not Provided.
	Remarks of the Evaluator	• • Latest GMP inspection report/ certificate is required.
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three years, before issuance of registration letter.	
529.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Tritop Tablet 25mg
	Composition	Each film-coated tablet contains: Topiramate…….25mg
	Diary No. Date of R & I & fee	Dy. No. 14308 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739951 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	N03AX11 Other antiepileptics
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TOPIRAMATE MILPHARM 25 MG FILM-COATED TABLETS MHRA Approved
	Me-too status	Hach 25mg tablet by Zafa Pharma
	GMP status	Not Provided.
	Remarks of the Evaluator	• • Latest GMP inspection report/ certificate is required.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within last three years, before issuance of registration letter.	

530.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Mastal Tablet 200mg
	Composition	Each film-coated tablet contains: Ofloxacin…….200mg
	Diary No. Date of R & I & fee	Dy. No. 14318 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739962 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	J01MA01 Fluoroquinolones
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ofloxacin 200mg Tablets MHRA Approved
	Me-too status	Ofloper Tablet Reg. No. 111758 M/s Quaper Pvt. Ltd.,
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within last three years, before issuance of registration letter.	
531.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Arvin Vaginal Tablet 500mg
	Composition	Each vaginal tablet contains: Clotrimazole…….500mg
	Diary No. Date of R & I & fee	Dy. No. 14324 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739971 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	G01AF02 Imidazole derivatives
	Type of Form	Form-5
	Finished product Specification	**USP Specs (Available in BP)**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Clotrimazole 500mg Vaginal Tablet MHRA Approved
	Me-too status	Gylot Vaginal Tablet Reg. No. 111685 M/s Dyson Research Lab,
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved with BP specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three years, before issuance of registration letter.	
532.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Teen Tablet 200mg
	Composition	Each film coated tablet contains: Clopidogrel as bisulfate…….75mg
	Diary No. Date of R & I & fee	Dy. No. 14334 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739982 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	B01AC04 Platelet aggregation inhibitors excl. heparin

	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Clopidogrel 75 mg film-coated tablets MHRA Approved
	Me-too status	Dragrel Tablet Reg. No. 112038 M/s MTI Medical,
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within last three years, before issuance of registration letter.	
533.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Hamic Capsule 6/25mg
	Composition	Each capsule contains: Olanzapine…….6mg Fluoxetine…….25mg
	Diary No. Date of R & I & fee	Dy. No. 14332 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739980 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	N06CA03 Antidepressants in combination with psycholeptics
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	SYMBYAX (olanzapine and fluoxetine HCl capsules) USFDA Approved
	Me-too status	Magiplus Capsule Reg. No. 113007 M/s Dyson Research Lab,
	GMP status	Not Provided.
	Remarks of the Evaluator	• Revised label claim as per RRAs along with fee of Rs. 30000/- is required. • Section Approval is required. • Latest GMP inspection report/ certificate is required.
	Decision: Approved as per following label claim: **Each capsule contains:** **Olanzapine…….6mg** **Fluoxetine as HCl…….25mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, along with latest GMP inspection report conducted within last three years, before issuance of registration letter**	
534.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Biox Capsule 200mg
	Composition	Each capsule contains: Celecoxib…….200mg
	Diary No. Date of R & I & fee	Dy. No. 14310 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739953 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	M01AH01 Coxibs
	Type of Form	Form-5
	Finished product Specification	**BP Specs**
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Celecoxib 200 mg capsules MHRA Approved
	Me-too status	Colixib Capsule Reg. No. 100505 M/s Hi-Q Pharma,
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved.	
535.	Name and address of manufacturer/ Applicant	M/s De-Mont Research Laboratories (Pvt.) Ltd., 20-Km, Lahore-Sheikhupura Road, Sheikhupura (DML No.000844) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Vorif Suspension 40mg
	Composition	Each ml after reconstitution contains: Voriconazole…….40mg
	Diary No. Date of R & I & fee	Dy. No. 14343 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 0739991 dated 07-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	J02AC03 Triazole and tetrazole derivatives
	Type of Form	Form-5
	Finished product Specification	**Innovator's Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	VFEND® (voriconazole) for Oral Suspension USFDA Approved.
	Me-too status	Vorimed Dry Suspension Reg. No. 093710 M/s Hi-med Pharma.
	GMP status	Not Provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate is required.
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three years, before issuance of registration letter.	
536.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Cream/ Ointment/ Gel (Non-Steroidal) Section.
	Brand Name + Dosage Form + Strength	Dipmeth-S Ointment 15g
	Composition	Each gram contains: Betamethasone Dipropionate 0.064%w/w eq. to Betamethasone…….0.05% (w/w) Salicylic Acid……..3.0%(w/w)
	Diary No. Date of R & I & fee	Dy. No. 16410 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901932 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	D07BC01 Corticosteroids, potent, combinations with antiseptics
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Diprosalic Health Canada Approved
	Me-too status	Betacline-S Ointment Reg. No. 096920 M/s Caliph Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Evidence of separate dispensing booth for Fluocinolone is required.

	Decision: Approved with Innovator's Specifications. Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter along with evidence of availability of separate dispensing booth for steroidal formulations.	
537.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Cream/ Ointment/ Gel (Non-Steroidal) Section.
	Brand Name + Dosage Form + Strength	Adlene Cream 1mg
	Composition	Each gram contains: Adapalene……..0.1%(w/w)
	Diary No. Date of R & I & fee	Dy. No. 16433 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901939 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	D10AD03 Retinoids for topical use in acne
	Type of Form	Form-5
	Finished product Specification	**BP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	DIFFERIN® Cream USFDA Approved
	Me-too status	Zonalene Cream Reg. No. 111814 M/s Horizon Healthcare.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved.	
538.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Ampoule/ Vial (General Liquid SVPc) Section.
	Brand Name + Dosage Form + Strength	Thioact Injection 4mg/ml
	Composition	Each 2ml Ampoule contains: Thiocolchicoside…….....4mg
	Diary No. Date of R & I & fee	Dy. No. 16419 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901942 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	M03BX05 Other centrally acting agents
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Not Provided
	Me-too status	Chicowel Injection Reg. No. 107680 M/s Welmark Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Evidence of availability of formulation in RRAs is required.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
539.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Ampoule/ Vial (General Liquid SVPc) Section.
	Brand Name + Dosage Form + Strength	Trimcinol Injection 40mg/0.04mg
	Composition	Each 4ml Ampoule contains: Phloroglucinol Dihydrate…….....40mg

		Trimethyl Phloroglucinol…….0.04mg
	Diary No. Date of R & I & fee	Dy. No. 16422 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901945 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	A03AX12 Other drugs for functional gastrointestinal disorders
	Type of Form	Form-5
	Finished product Specification	**In-house Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	PHLOROGLUCINOL/TRIMETHYLPHLOROGLUCINOL ACINO 40 mg/0.04 mg, solution for injection in ampoule ANSM France Approved.
	Me-too status	P-Glo Injection Reg. No. 111065 M/s CCL Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications. Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
540.	Name and address of manufacturer/ Applicant	M/s. Nortech Pharmaceuticals (Pvt.) Ltd. 203 Industrial Triangle Kahuta Road, Islamabad. - (DML No. 000792) Section Approval not provided.
	Brand Name + Dosage Form + Strength	Dexa-P Injection 4mg
	Composition	Each ml Ampoule contains: Dexamethasone (as sodium phosphate)…….4mg
	Diary No. Date of R & I & fee	Dy. No. 16423 dated 07.03.2019. Fee paid Rs. 20,000/- vide Slip No. 1901946 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	H02AB02 Glucocorticoids
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Decadron Injection USFDA Approved
	Me-too status	DMX Injection Reg. No. 103653 M/s Rotex Pharma.
	GMP status	Last inspection conducted on 29.04.2021. GMP status is good.
	Remarks of the Evaluator	• Evidence of availability of requisite manufacturing facility is required. • Revised label claim as per RRAs along with fee of Rs. 30000/- is required.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Liquid InjectionAmpoule (Steroid) section" from CLB. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	

CONTRACT MANUFACTURING CASES OF FORM-5

541.	Name and address of manufacturer/ Applicant	M/s. Arsons Pharmaceuticl Industries (Pvt.) Ltd., 22-KM, Multan Road Off 2.5KM, Defense Road, Lahore (contract giver) (DML No.000514) Contract with M/s. MedPharm Research Lab, 28-KM, Ferozepur Road, Lahore (Contract Acceptor) (DML No.000878) Dry Powder Suspension (Cephalosporin) Section.

	Brand Name + Dosage Form + Strength	Arcef DS 100mg/5ml
	Composition	Each 5ml contains: Cefixime as trihydrate…….100mg
	Diary No. Date of R & I & fee	Dy. No. 16598 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0730987 dated 25-02-2019, endorsed on 06.03.2019.
	Pharmacological Group	J01DD08 Third-generation cephalosporins
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Suprax 100mg/5ml Oral Suspension USFDA Approved.
	Me-too status	Brilcef 100mg Dry Suspension Reg. No. 113205 M/s Briell Pharma.
	GMP status	Renewal of DML inspection report of 12-01-2018 is provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate of MedPharm Research Lab is required.

	Decision: Approved. The registration letter shall be issued after confirmation of availability of Latest GMP inspection report/ certificate of MedPharm Research Lab. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s. MedPharm Research Lab, 28-KM, Ferozepur Road, Lahore.	
542.	Name and address of manufacturer/ Applicant	M/s. Arsons Pharmaceuticl Industries (Pvt.) Ltd., 22-KM, Multan Road Off 2.5KM, Defense Road, Lahore (contract giver) (DML No.000514) Contract with M/s. MedPharm Research Lab, 28-KM, Ferozepur Road, Lahore (Contract Acceptor) (DML No.000878) Dry Powder Suspension (Cephalosporin) Section.
	Brand Name + Dosage Form + Strength	Arcef DS 200mg/5ml
	Composition	Each 5ml contains: Cefixime as trihydrate…….200mg
	Diary No. Date of R & I & fee	Dy. No. 16599 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0730988 dated 25-02-2019, endorsed on 06.03.2019.
	Pharmacological Group	J01DD08 Third-generation cephalosporins
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Suprax 200mg/5ml Oral Suspension USFDA Approved.
	Me-too status	Brilcef 200mg Dry Suspension Reg. No. 113206 M/s Briell Pharma.
	GMP status	Renewal of DML inspection report of 12-01-2018 is provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate of MedPharm Research Lab is required.
	Decision: Approved. The registration letter shall be issued after confirmation of availability of Latest GMP inspection report/ certificate of MedPharm Research Lab. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s. MedPharm Research Lab, 28-KM, Ferozepur Road, Lahore.	

543.	Name and address of manufacturer/ Applicant	M/s. Arsons Pharmaceuticl Industries (Pvt.) Ltd., 22-KM, Multan Road Off 2.5KM, Defense Road, Lahore (contract giver) (DML No.000514) Contract with M/s. MedPharm Research Lab, 28-KM, Ferozepur Road, Lahore (Contract Acceptor) (DML No.000878) Capsule (Cephalosporin) Section.
	Brand Name + Dosage Form + Strength	Arcef Capsule 400mg
	Composition	Each Capsule contains: Cefixime as trihydrate…….400mg
	Diary No. Date of R & I & fee	Dy. No. 16600 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0730989 dated 25-02-2019, endorsed on 06.03.2019.
	Pharmacological Group	J01DD08 Third-generation cephalosporins
	Type of Form	Form-5
	Finished product Specification	**In-house Specs (Manufacturer's Specs as per 313th RB Meeting)**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Suprax 400mg Capsule USFDA Approved.
	Me-too status	Mixef Capsule Reg. No. 113088 M/s Biogen Pharma.
	GMP status	Renewal of DML inspection report of 12-01-2018 is provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate of MedPharm Research Lab is required.
	Decision: Approved. The registration letter shall be issued after confirmation of availability of Latest GMP inspection report/ certificate of MedPharm Research Lab. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s. MedPharm Research Lab, 28-KM, Ferozepur Road, Lahore.	
544.	Name and address of manufacturer/ Applicant	M/s. Arsons Pharmaceuticl Industries (Pvt.) Ltd., 22-KM, Multan Road Off 2.5KM, Defense Road, Lahore (contract giver) (DML No.000514) Contract with M/s. MedPharm Research Lab, 28-KM, Ferozepur Road, Lahore (Contract Acceptor) (DML No.000878) Dry Powder Injection (Cephalosporin) Section.
	Brand Name + Dosage Form + Strength	Arzone IM Injection 250mg
	Composition	Each vial contains: Ceftriaxone as sodium…….250mg
	Diary No. Date of R & I & fee	Dy. No. 16600 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0730989 dated 25-02-2019, endorsed on 06.03.2019.
	Pharmacological Group	J01DD04 Third-generation cephalosporins
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ceftriaxone 250mg powder for solution for injection MHRA Approved.
	Me-too status	Arixkan 250mg Injection Reg. No. 113143 M/s Jaskan Pharma.
	GMP status	Renewal of DML inspection report of 12-01-2018 is provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate of MedPharm Research Lab is required.
	Decision: Approved. The registration letter shall be issued after confirmation of availability of Latest GMP inspection report/ certificate of MedPharm Research Lab.	

	Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s. MedPharm Research Lab, 28-KM, Ferozepur Road, Lahore.	
545.	Name and address of manufacturer/ Applicant	M/s. Arsons Pharmaceuticl Industries (Pvt.) Ltd., 22-KM, Multan Road Off 2.5KM, Defense Road, Lahore (contract giver) (DML No.000514) Contract with M/s. MedPharm Research Lab, 28-KM, Ferozepur Road, Lahore (Contract Acceptor) (DML No.000878) Dry Powder Injection (Cephalosporin) Section.
	Brand Name + Dosage Form + Strength	Arzone IM Injection 500mg
	Composition	Each vial contains: Ceftriaxone as sodium…….500mg
	Diary No. Date of R & I & fee	Dy. No. 16596 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0730985 dated 25-02-2019, endorsed on 06.03.2019.
	Pharmacological Group	J01DD04 Third-generation cephalosporins
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Rocephin for Injection 500mg USFDA Approved.
	Me-too status	Arixkan 500mg Injection Reg. No. 113144 M/s Jaskan Pharma.
	GMP status	Renewal of DML inspection report of 12-01-2018 is provided.
	Remarks of the Evaluator	• Latest GMP inspection report/ certificate of MedPharm Research Lab is required.
	Decision: Approved. The registration letter shall be issued after confirmation of availability of Latest GMP inspection report/ certificate of MedPharm Research Lab. Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s. MedPharm Research Lab, 28-KM, Ferozepur Road, Lahore.	
546.	Name and address of manufacturer/ Applicant	M/s. Delux Chemical Industries, L-T 26, A/1, Landhi Industrial Area, Karachi. (contract giver) DML Not provided. Contract with M/s. Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad. (Contract Acceptor) (DML No.000296) Lyophilized Vial (General) Section.
	Brand Name + Dosage Form + Strength	Levilax Injection 500mg/5ml
	Composition	Each vial contains: Levetiracetam…….500mg (as lyophilized powder)
	Diary No. Date of R & I & fee	Dy. No. 16809 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0815831 dated 27-02-2019, endorsed on 06.03.2019.
	Pharmacological Group	N03AX14 Other antiepileptics
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Levetiracetam Hospira 100 mg/ml concentrate for solution for infusion MHRA Approved.
	Me-too status	Lumark Injection Reg. No. 075873 M/s The Searle Company.

	GMP status	GMP inspection report of 05 & 06 December 2017 is provided.
	Remarks of the Evaluator	• Revised Form-5 from M/s Delux Chemical Industries along with fee of Rs. 50000/- is required. • DML of M/s Delux Chemical Industries is required. • Latest GMP inspection report/ certificate of M/s Bio-Labs (Pvt.) Ltd. is required.
	Decision: Deferred for following: • **Revised Form-5 from M/s Delux Chemical Industries along with fee of Rs. 75,000/-.** • **Latest GMP inspection report/ certificate of M/s Bio-Labs (Pvt.) Ltd.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	

DEFERRED CASES

547.	Name and address of manufacturer / Applicant	M/s Wahabsons Pharmaceuticals, 4km Buner Road, Barikot, Swat
	Brand Name +Dosage Form + Strength	Zinkowab Syrup 20mg/5ml
	Composition	Each 5ml contains: Zinc Gluconate eq. to 2.8mg Elemental Zinc…..20mg
	Diary No. Date of R& I & fee	Dy. No. 3873, 24-05-2017; Rs.20,000/- (24-05-2017)
	Pharmacological Group	Zinc supplement
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications.
	Pack size & Demanded Price	60ml & Rs.62/-
	Approval status of product in Reference Regulatory Authorities.	Orazinc of M/s Mericon Industries (USFDA Approved)
	Me-too status	E-Zinc syrup of M/s Woodwards Pharmaceuticals
	GMP status	Last GMP inspection was conducted on 23-01-2017, and the report does not conclude GMP compliance.
	Remarks of the Evaluator.	The date of last inspection doesn't fall within one year. Letter has been issued on **26th April, 2018** and reminder has been issued on **10th July, 2018.**
	Decision of 284th RB Meeting	Registration Board deferred the case for further deliberation**. (M-284)**
	Remarks of the Evaluator.	Firm has submitted copy of GMP inspection report dated 25-10-2018, and the report does not have any conclusion and the recommendations include "Apart from aforementioned recommendations, the firm is further advised to □ Develop an independent quality assurance department and appoint an experienced assurance manager □ To improve water treatment system
	Decision of 286th RB Meeting	*Registration Board referred the case to QA&LT Division for updated GMP status of the firm.*
	Remarks of Evaluator	i. The evidence of approval in RRA could not be verified. ii. As per Dietary Reference Value (DRF) given by European Food Safety Authority the amount of zinc taken by an adult through normal diet is 8 to 14mg/day. The upper tolerable limit of zinc is 25mg/day. **iii.** The Tolerable upper Intake level of Zinc for adults as per health Canada is 40mg/day. iv. Based on above facts, it can be concluded that applied product may fall in category of Dietary Supplement.
	Decision of RB in 323rd meeting:	

	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
	Remarks of evaluator: The firm has now requested to consider their product a dietary supplement.	
Decision: Registration Board decided to reject the application since dietary supplements are not considered as Drug as per DRAP Act, 2012.		
548.	Name and address of manufacturer/ Applicant	M/s Nabi Qasim Industries (Pvt) Limited, 17/24, Korangi Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Co-Redupres 10/160/25 Tablet
	Composition	Each film coated tablet contains: Amlodipine Besylate eq. to Amlodipine ……. 10mg Valsartan ……..……..…160mg Hydrochlorothiazide ……...…….. 25mg
	Diary No. Date of R & I & fee	Dy. No.3783; 26-12-2016; Rs.20,000/- (26-12-2016)
	Pharmacological Group	B01AC04 Platelet aggregation inhibitors excl. heparin
	Type of Form	Form-5
	Finished product Specification	**USP Specs**
	Pack size & Demanded Price	14's & 28's: As per PRC
	Approval status of product in Reference Regulatory Authorities	Exforge HCT Tablet 10/160/25 (Novartis USA)
	Me-too status	Exforge HCT 10/160/25 (Novartis Pharma-Karachi)
	GMP status	QA Division vide letter No.F.4-4/89-QA dated 18-01-2018 clarified that as per panel Inspection Reports Dated 03-08- 2017 and 02-11-2017, the firm Nabiqasim Industries (Pvt) Ltd., Plot No. 17, Sector 24, Korangi Industrial Area, Karachi was considered to be operating at acceptable level of compliance of GMP requirements.
	Decision of 278th RB	*Deferred for submission of evidence of fee challan for applied formulation.*
	Remarks of Evaluator	Now the firm has submitted new fee of Rs. 30000/- vide slip no. 87406915914 dated 04-04-2023.
	Decision: Approved.	
549.	Name and address of manufacturer / Applicant	M/s. Dyson Research Laboratories (Pvt.) Ltd. 28-Km Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Dylone Tablets 2.5mg
	Diary No. Date of R& I & fee	(Duplicate Dossier) Dy. No. 212 dated 25/05/2011 Rs.8,000/- (Photocopy) Differential fee (photocopy) of Rs.12,000/- submitted on. dated 21/06/2016 Dy. No Receipt of application was verified from R&I
	Composition	Each tablet contains: Tibolone….2.5mg
	Pharmacological Group	Gonadomimetic
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	As per S.R. O
	Approval Status of Product in Reference Regulatory Authorities	Tibolone 2.5 mg tablets: each tablet contains 2.5 mg tibolone., **MHRA approved**.
	Me-too Status	Tibopause Tablet 2.5mg of M/s. Zafa Pharmaceuticals (Reg.no.024213)
	GMP Status	Panel inspection report dated 13-07-2020 concluded with the following remarks: "The panel of inspectors recommend the renewal of Drug Manufacturing License of M/s. Dyson Research Laboratories (Pvt.)

		Ltd. Located at 28-km Ferozepur Road, Lahore (bearing no. 000559 by way of formulation) of following approved sections: 1. Tablet (General) 2. Tablet (Hormonal) 3. Liquid Syrup (General) 4. Oral Dry Powder Suspension (General) 5. Capsule (General)
	Remarks of the Evaluator.	Firm has asked to provide the section approval letter of steroidal and non-steroidal hormone tablet section issued by the Licensing Division. In their reply, firm submitted the copy of letter which they submitted to the Licensing Division for change of title of section from tablet hormone to steroidal tablet (hormone) section.
	Decision of RB in 312th Meeting: *Deferred for submission of section approval letter of steroidal tablet (hormone) section issued by Licensing Division.*	
Remarks: The firm has now submitted copy of approval letter No. F. 1-7/2003-Lic (Vol-IV) dated 22-02-2023 for Tablet (Steroidal Hormone) Section issued by Secretary Licensing Board.		
Decision: Approved.		
550.	Name and address of manufacturer / Applicant	M/s Epharm Laboratories.A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Ketomine 30mg/ml Injection
	Composition	Each ml Contains: Ketorolac Tromethamine…30mg
	Diary No. Date of R& I & fee	Dy.No 31972 dated 25-09-2018 Rs.20,000/- dated 25-09-2018
	Pharmacological Group	Anti-Inflammatory
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, As per PRC
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Toralac Injection 30mg/ml bt M/s Vision Pharma
	GMP status	27-4-2017, Overall GMP was satisfactory
	Remarks of Evaluator VI	Firm was asked why they did not perform terminal sterilization. Firm has revised the procedure and submitted that now they have performed terminal sterilization via autoclaving. But they did not submit fee for correction.
	Decision of RB in 316th Meeting: *Deferred for scientific rationale of performing terminal sterilization with reference to innovator product.*	
Remarks: The Firm has submitted that Terminal sterilization process is superior to filtration process as filtration is not a substitute for terminal sterilization. Product is heat stable this is the basis of performing terminal sterilization. Moreover, the firm has submitted fee challan of Rs. 7500/- for change in manufacturing method. In this context, it is submitted that the **Innovator does not perform terminal sterilization of its formulation**.		
Decision: Deferred for scientific justification of using Terminal sterilization with reference to Innovator product being heat labile.		
551.	Name and address of manufacturer / Applicant	M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R-2, Industrial Estate Gadoon, Swabi
	Brand Name +Dosage Form + Strength	Onised 8mg Tablet
	Composition	Each Film Coated Tablet Contains: Ondansetron as HCl dihydrate…8mg

	Diary No. Date of R& I & fee	Dy. No.12357 dated 06.03.2019 Rs. 20,000/- dated 04.03.2019
	Pharmacological Group	Serotonin (5HT3) antagonists
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ondansetron 8 mg Film-coated Tablets. **MHRA** approved
	Me-too status	Ondan Tablet film-coated 8mg. Reg No. 82657
	GMP status	Firm has submitted copy of inspection report dated 17-09-2020 which confirms fair level of compliance with GMP guidelines. The firm should rectify all observations mentioned in the report.
	Remarks of the Evaluator.	• The drug product specifications have not been evaluated.
		• Revised the pharmacological group from selective Serotonin (5HT3) receptor antagonists to Serotonin (5HT3) antagonists. • Already adjusted the weight of the API in master formulation. But did not revise Ondansetron as HCl dihydrate to Ondansetron HCl dihydrate in master formulation. • Submitted Rs. 7500/- fee, challan- 15513550
	Decision of 317th RB: *Deferred for:* • *Revision of Ondansetron as HCl dihydrate to Ondansetron HCl dihydrate in master formulation.* • *Updated satisfactory GMP inspection status from QA&LT Division.*	
Remarks of Evaluator: The firm has submitted revised master formulation indicating Ondansetron HCl dihydrate. The firm has also submitted copy of GMP inspection report dated 29-06-2022.		
Decision: Approved.		
552.	Name and address of manufacturer / Applicant	M/s Wahabsons Pharmaceuticals, 4km Buner Road, Barikot, Swat (DML No. 000533) Dry Powder Suspension (General) Section.
	Brand Name +Dosage Form + Strength	Wamotid oral suspension
	Composition	Each 5ml contains: Famotidine……..10mg
	Diary No. Date of R& I & fee	Dy No. 237: 30-6-2016 PKR 20,000/-: 30-6-2016
	Pharmacological Group	Histamine H2 receptor antagonist
	Type of Form	Form 5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	60ml amber coloured bottle: Rs 52/-
	Approval status of product in Reference Regulatory Authorities.	Internationally available as dry powder for suspension in the strength of 40 mg/ 5 ml.
	Me-too status	Peptiban suspension by Werrick
	GMP status	Could not be confirmed
	Remarks of the Evaluator.	The product approved by USFDA is FAMOTIDINE 40mg/5ml for suspension, Oral. Dry Powder Suspension (General) section approval letter vide No. F.3-5/99-Lic(Vol-I) dated 19.05.2022 is submitted. GMP inspection report dated 04.03.2022 is submitted
	Decision of RB in 323rd meeting: *Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.*	
Remarks of Evaluator: The firm has submitted revised Form-5 indicating following formulation along with fee challan of Rs. 30000/: **Each 5ml contains:**		

Famotidine……40mg		
Decision: Approved with following composition: **Each 5ml contains:** **Famotidine…….40mg**		
553.	Name and address of manufacturer/ Applicant	M/s Relizon Pharmaceuticals, Plot No. 118, Sundar Industrial Estate. Raiwind Road, Lahore. (contract giver) (DML No. 000875) Contract with M/s. GT Pharma (Pvt.) Ltd. Plot No. 713, Sundar Industrial Estate Raiwind Road, Lahore. (Contract Acceptor) (DML No.000829) Liquid Injectable (General) for ampoules and vials SVP
	Brand Name + Dosage Form + Strength	Rolac 30mg/1ml Injection
	Composition	Each 1mL ampoule contains; Ketorolac as Tromethamine….30mg
	Diary No. Date of R & I & fee	Dy. No. 16187 dated 07.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0841697 dated 06-03-2019, endorsed on 07.03.2019.
	Pharmacological Group	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, Acetic acid derivatives and related substances. ATC Code: M01AB15
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Ketorolac trometamol 30mg/ml Solution for Injection MHRA Approved.
	Me-too status	Ketometa 30mg Injection Reg. No. 108436 M/s Lahore Chemical & Pharmaceutical Works Lahore.
	GMP status	GMP certificate dated 14.12.2021 valid till 12.10.2023 is submitted.
	Remarks of the Evaluator	i. The label claim applied is Ketorolac as tromethamine, the label claim of RRA approved product is Ketorolac tromethamine 30mg. justification or correction along with full fee as per Notification No. 7-11/2012-B&A/DRAP dated 07.05.2021. The firm has submitted revised label vide letter No. RZ-DRAP-R-001 dated 09.01.2023 as under; Each 1ml Ampoule Contains; Ketorolac Tromethamine…30mg • Fee of Rs. 75000/- is paid vide slip No. 7693122747 dated 10.01.2023 for changes.
	Decision of RB in 324th Meeting: *Deferred for the details of sterilization method for applied formulation.*	
Remarks of Evaluator: The firm has submitted that they will perform terminal sterilization at 121^0C for 30 minutes for the applied product. In this context, it is submitted that the **Innovator does not perform terminal sterilization of its formulation**.		
Decision: Deferred for scientific justification of using Terminal sterilization with reference to Innovator product being heat labile.		
554.	Name and address of manufacturer/ Applicant	M/s CSH Pharmaceuticals (Pvt.) Ltd. 32-KM Ferozpur Road Lahore. (Contract Giver) (DML No. 000737). Contract with M/s Medisave Pharmaceuticals, Plot No. 578-579, Sundar Industrial Estate, Sundar Raiwind Road Lahore. (Contract acceptor) (DML No. 000681)
	Brand Name + Dosage Form + Strength	Hb-Plus 100mg/5ml Injection (IV)
	Composition	Each 5ml Ampoule Contains; Iron Sucrose equivalent to Elemental Iron……100mg

	Diary No. Date of R & I & fee	Dy.No.16976 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0740089 dated 6.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Iron, parenteral preparations ATC Code: B03AC
	Type of Form	Form- 5 (Contract Application)
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	5 ampoules of 5ml each. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Sucrofer 20 mg iron/ml, Solution for injection /infusion (iron sucrose) - UK/H/6369/001/DC; PL 20568/0083 MHRA Approved.
	Me-too status	Venofer IV Injection Reg. No. 085031 M/s OBS Pakistan Karachi.
	GMP status	Last inspection conducted on 10.01.2018
	Remarks of the Evaluator	i. Latest GMP inspection report/certificate of M/s Medisave Pharma is required. ii. Firm has referred to the Capacity assessment inspection report of M/s. Medisave pharmaceuticals, Lahore presented in 317th meeting of Registration Board, wherein Board decided to allow contract manufacturing from M/s Medisave Pharmaceuticals, Plot 578-579, Sundar Industrial Estate, Lahore for following sections: • General Tablet Section (General), • Capsule Section (Cephalosporin) • Dry Powder Suspension Section (Cephalosporin) • Dry Powder Injection Section (Cephalosporin) • Liquid Injection • Infusion (LVP) Section • Liquid Syrup Section.
	Decision of RB in 323rd meeting: *Deferred for evidence of availability of atomic absorption spectrophotometer as required by the USP monograph.*	
Remarks of Evaluator: The firm has submitted that they had changed their specifications from USP to BP where there is no requirement of Atomic absorption spectrophotometer. The firm has also submitted fee challan of Rs. 7500/- vide no. 16001451481 dated 13-03-2023.		
Decision: Approved with BP specifications.		
555.	Name and address of manufacturer/ Applicant	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad, Peshawar. (DML 000565). Tablet Section (Hormone)
	Brand Name + Dosage Form + Strength	NOPROST Vaginal tablet 3mg
	Composition	Each Tablet Contains; Dinoprostone USP …….. 3.0mg
	Diary No. Date of R & I & fee	Dy. No. 14408; dated 07-03-2019; Fee paid Rs. 20000/- vide Slip No. 0832350 dated 06.03.2019 endorsed on 07.03.2019.
	Pharmacological Group	UTEROTONICS, Prostaglandins. ATC code: G02AD02
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be verified.
	Me-too status	Ditone E2 Vaginal Tablet Reg. No. 084376 M/s Shaigan Pharmaceutical Rawalpindi.
	GMP status	Last panel inspection conducted on 03.12.2021. GMP status is good.

	Remarks of the Evaluator	The RRA reference could not be verified. Evidence of applied product in RRA is required.
	Decision of RB in 323rd meeting: *Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.*	
Remarks of Evaluator: The firm has submitted evidence of availability of formulation in RRAs as Prostin E2 Vaginal Tablet 3mg registered in MHRA which can be accessed @: https://mhraproducts4853.blob.core.windows.net/docs/2c8657a1bc46e111868a98c7db229ef5773234a5		
Decision: Approved.		
556.	Name and address of manufacturer/ Applicant	M/s. Trigon Pharmaceuticals (Pvt.) Ltd. 8-KM, Thoker Raiwind Road, Lahore. (contract giver) (DML No.000342). Contract with M/s. McOlson Research Laboratories (Pvt.) Ltd. Plot No. 2, M2-Pharma zone, 26 KM, Lahore Sharikpur Road, Sheikhupura. (Contract acceptor) (DML No. 000844) Capsule (General) Section
	Brand Name + Dosage Form + Strength	Esomepragon 20mg Capsules
	Composition	Each capsule contains; Esompragon….20mg
	Diary No. Date of R & I & fee	Dy.No.16116 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0844239 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Proton Pump inhibitors. ATC Code: A02BC05
	Type of Form	Form-5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Esomeprazole 20mg Gastro-resistant Capsules (esomeprazole magnesium dihydrate) - PL 16028/0166. MHRA Approved.
	Me-too status	Nexum 20mg Capsule Reg. No. 033890 M/s Getz Pharma (Pvt.) Ltd. Karachi.
	GMP status	Inspection report dated 2018 is submitted.
	Remarks of the Evaluator	i. Latest GMP inspection report/Certificate of M/s McOlson Research Lab is required. ii. Label claim is unclear. It is required to be submitted along with full fee i.e. Rs. 75000/- iii. Source of pellets is required to be defined along with submission of requisite fee.
	Decision of RB in 324th meeting: *Deferred for clarification of label claim for applied formulation along with fee of Rs. 75,000/- as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.*	
	Remarks of Evaluator: The firm has now submitted revised Form-5 along with fee of Rs. 75000/- vide slip no. 5783212286 dated 27-01-2023 indicating following composition: Each capsule contains: Esomeprzole magnesium trihydrate enteric coated pellets eq. to Esomeprazole…….20mg	
Decision: Approved. **Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s. McOlson Research Laboratories (Pvt.) Ltd. Plot No. 2, M2-Pharma zone, 26 KM, Lahore Sharikpur Road, Sheikhupura.**		
557.	Name and address of manufacturer/ Applicant	M/s. Trigon Pharmaceuticals (Pvt.) Ltd. 8-KM, Thoker Raiwind Road, Lahore. (contract giver) (DML No.000342). Contract with

		M/s. McOlson Research Laboratories (Pvt.) Ltd. Plot No. 2, M2-Pharma zone, 26 KM, Lahore Sharikpur Road, Sheikhupura. (Contract acceptor) (DML No. 000844) Capsule (General) Section
	Brand Name + Dosage Form + Strength	Esomepragon 40mg Capsules
	Composition	Each capsule contains; Esomperaon….40mg
	Diary No. Date of R & I & fee	Dy.No.16117 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0844240 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Proton Pump inhibitors. ATC Code: A02BC05
	Type of Form	Form-5
	Finished product Specification	USP Specifications.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	ESOMEPRAZOLE 40 MG GASTRO-RESISTANT CAPSULES HARD. MHRA Approved.
	Me-too status	Nexum 40mg Capsule Reg. No. 033891 M/s Getz Pharma (Pvt.) Ltd. Karachi.
	GMP status	Inspection report dated 2018 is submitted.
	Remarks of the Evaluator	166. Latest GMP inspection report/Certificate of M/s McOlson Research Lab is required. 167. Label claim is unclear. It is required to be submitted along with full fee i.e. Rs. 75000/- 168. Source of pellets is required to be defined along with submission of requisite fee.
	Decision of RB in 324th meeting: *Deferred for clarification of label claim for applied formulation along with fee of Rs. 75,000/- as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.*	
	Remarks of Evaluator: The firm has now submitted revised Form-5 along with fee of Rs. 75000/- vide slip no. 76223412823 dated 27-01-2023 indicating following composition: Each capsule contains: Esomeprzole magnesium trihydrate enteric coated pellets eq. to Esomeprazole…….40mg	
Decision: Approved. **Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s. McOlson Research Laboratories (Pvt.) Ltd. Plot No. 2, M2-Pharma zone, 26 KM, Lahore Sharikpur Road, Sheikhupura.**		
558.	Name and address of manufacturer/ Applicant	M/s. Trigon Pharmaceuticals (Pvt.) Ltd. 8-KM, Thoker Raiwind Road, Lahore. (contract giver) (DML No.000342). Contract with M/s. McOlson Research Laboratories (Pvt.) Ltd. Plot No. 2, M2-Pharma zone, 26 KM, Lahore Sharikpur Road, Sheikhupura. (Contract acceptor) (DML No. 000844) Capsule (General) Section
	Brand Name + Dosage Form + Strength	Omepragon 20mg Capsule
	Composition	Each Capsule Contains; Omepragon…20mg
	Diary No. Date of R & I & fee	Dy.No.16113 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0844236 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Proton Pump inhibitors. ATC Code: A02BC05
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	14's. As per SRO.

	Approval status of product in Reference Regulatory Authorities	Esomeprazole 20mg Gastro-resistant Capsules (esomeprazole magnesium dihydrate) - PL 16028/0166. MHRA Approved.
	Me-too status	Nexum 20mg Capsule Reg. No. 033890 M/s Getz Pharma (Pvt.) Ltd. Karachi.
	GMP status	Inspection report dated 2018 is submitted.
	Remarks of the Evaluator	i. Latest GMP inspection report/Certificate of M/s McOlson Research Lab is required. ii. Label claim needs to be corrected as per innovator product along with submission of full fee i.e. Rs. 75000/-. iii. Source of pellets is required to be defined along with submission of required fee.
	Decision of RB in 324th meeting: *Deferred for clarification of label claim for applied formulation along with fee of Rs. 75,000/- as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.*	
	Remarks of Evaluator: The firm has now submitted revised Form-5 along with fee of Rs. 75000/- vide slip no. 50514502 dated 27-01-2023 indicating following composition: Each capsule contains: Omeprzole enteric coated pellets eq. to Omeprazole…….20mg	
Decision: Approved. **Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s. McOlson Research Laboratories (Pvt.) Ltd. Plot No. 2, M2-Pharma zone, 26 KM, Lahore Sharikpur Road, Sheikhupura.**		
559.	Name and address of manufacturer/ Applicant	M/s. Trigon Pharmaceuticals (Pvt.) Ltd. 8-KM, Thoker Raiwind Road, Lahore. (contract giver) (DML No.000342). Contract with M/s. McOlson Research Laboratories (Pvt.) Ltd. Plot No. 2, M2-Pharma zone, 26 KM, Lahore Sharikpur Road, Sheikhupura. (Contract acceptor) (DML No. 000844) Capsule (General) Section
	Brand Name + Dosage Form + Strength	Omepragon 40mg Capsule
	Composition	Each Capsule Contains; Omepragon…40mg
	Diary No. Date of R & I & fee	Dy.No.16112 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0844235 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Proton Pump inhibitors. ATC Code: A02BC05
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	14's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	ESOMEPRAZOLE 40 MG GASTRO-RESISTANT CAPSULES HARD. MHRA Approved.
	Me-too status	Nexum 40mg Capsule Reg. No. 033891 M/s Getz Pharma (Pvt.) Ltd. Karachi.
	GMP status	Inspection report dated 2018 is submitted.
	Remarks of the Evaluator	i. Latest GMP inspection report/Certificate of M/s McOlson Research Lab is required. ii. Label claim needs to be corrected as per innovator product, along with submission of full fee i.e. Rs. 75000/-. iii. Source of pellets is required to be defined along with submission of required fee.
	Decision of RB in 324th meeting: *Deferred for clarification of label claim for applied formulation along with fee of Rs. 75,000/- as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.*	

	Remarks of Evaluator: The firm has now submitted revised Form-5 along with fee of Rs. 75000/- vide slip no. 90018900 dated 27-01-2023 indicating following composition: Each capsule contains: Omeprzole enteric coated pellets eq. to Omeprazole…….40mg	
Decision: Approved. **Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s. McOlson Research Laboratories (Pvt.) Ltd. Plot No. 2, M2-Pharma zone, 26 KM, Lahore Sharikpur Road, Sheikhupura.**		
560.	Name and address of manufacturer/ Applicant	M/s. Trigon Pharmaceuticals (Pvt.) Ltd. 8-KM, Thoker Raiwind Road, Lahore. (contract giver) (DML No.000342). Contract with M/s. McOlson Research Laboratories (Pvt.) Ltd. Plot No. 2, M2-Pharma zone, 26 KM, Lahore Sharikpur Road, Sheikhupura. (Contract acceptor) (DML No. 000844) Capsule (General) Section
	Brand Name + Dosage Form + Strength	Dexlagon 30mg Capsule
	Composition	Each Capsule Contains; Dexlansoprazole as Dual Delayed Release pellets…30mg
	Diary No. Date of R & I & fee	Dy.No.16114 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0844237 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Proton pump inhibitors. ATC Code: A02BC06
	Type of Form	Form-5
	Finished product Specification	**Manufacturers Specifications**
	Pack size & Demanded Price	14's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	DEXILANT (dexlansoprazole) delayed-release capsules, for oral use Delayed-release capsules: 30 mg and 60 mg MHRA Approved.
	Me-too status	Daplazole DDR Capsule 30 mg Reg. No. 104251 M/s AGP Ltd. Karachi.
	GMP status	Inspection report dated 2018 is submitted.
	Remarks of the Evaluator	i. Latest GMP inspection report/Certificate of M/s McOlson Research Lab is required. ii. Source of pellets is required to be defined along with submission of required fee. iii. Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.
	Decision of RB in 324th meeting: *Deferred for submission of stability studies data of three batches as per the guidelines and checklist approved by Registration Board in its 312th meeting.*	
	Remarks of Evaluator: The firm has submitted that the same formulation of their contract manufacturer i.e. M/s McOlson Research Laboratories, Sheikhupura has already been approved by Registration Board in its 312th meeting on the basis of stability data and onsite inspection. The registration letter has also been issued vide No. F. 5-5/2021-Reg-II (M-312).	
Decision: Disposed off for non submission of stability data till 31st Dec 2022. The firm may apply on CTD		
561.	Name and address of manufacturer/ Applicant	M/s. Trigon Pharmaceuticals (Pvt.) Ltd. 8-KM, Thoker Raiwind Road, Lahore. (contract giver) (DML No.000342). Contract with M/s. McOlson Research Laboratories (Pvt.) Ltd. Plot No. 2, M2-Pharma zone, 26 KM, Lahore Sharikpur Road, Sheikhupura. (Contract acceptor) (DML No. 000844) Capsule (General) Section

	Brand Name + Dosage Form + Strength	Dexlagon 60mg Capsule
	Composition	Each Capsule Contains; Dexlansoprazole as Dual Delayed Release pellets…60mg
	Diary No. Date of R & I & fee	Dy.No.16115 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 0844238 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Proton pump inhibitors. ATC Code: A02BC06
	Type of Form	Form-5
	Finished product Specification	**Manufacturers Specifications**
	Pack size & Demanded Price	14's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	DEXILANT (dexlansoprazole) delayed-release capsules, for oral use Delayed-release capsules: 30 mg and 60 mg MHRA Approved.
	Me-too status	Remit DR Capsules 60 mg Reg. No. 090301 M/s Scotmann Pharmaceuticals Plot No. 5-D, Sector I-10/3 Islamabad.
	GMP status	Inspection report dated 2018 is submitted.
	Remarks of the Evaluator	i. Latest GMP inspection report/Certificate of M/s McOlson Research Lab is required. ii. Source of pellets is required to be defined along with submission of required fee. iii. Stability study data as per guidelines provided in 293rd meeting of Registration Board is required.
	Decision of RB in 324th meeting: *Deferred for submission of stability studies data of three batches as per the guidelines and checklist approved by Registration Board in its 312th meeting.*	
	Remarks of Evaluator: The firm has submitted that the same formulation of their contract manufacturer i.e. M/s McOlson Research Laboratories, Sheikhupura has already been approved by Registration Board in its 312th meeting on the basis of stability data and onsite inspection. The registration letter has also been issued vide No. F. 5-5/2021-Reg-II (M-312).	
Decision: Approved.		
562.	Name and address of manufacturer/ Applicant	M/s. McOlson Research Laboratories (Pvt.) Ltd. Plot No. 2, M2-Pharma zone, 26 KM, Lahore Sharikpur Road, Sheikhupura. (Contract Giver) (DML No. 000664). Contract with M/s.DeMont Research Laboratories (Pvt.) Ltd. 20-KM, Lahore-Sharikpur Road, Sheikhupura. (Contract acceptor) (DML No. 000844) Sachet (General) Section.
	Brand Name + Dosage Form + Strength	Ringet 20mg/1680mg Sachet
	Composition	Each Sachet Contains; Omeprazole……...20mg Sodium Bicarbonate …1680mg
	Diary No. Date of R & I & fee	Dy.No. 16149 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 1900476 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Proton pump inhibitors ATC Code: A02BC01
	Type of Form	Form-5
	Finished product Specification	**USP Specifications**
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	ZEGERID (20mg/packet ; 1.68gm/packet, 40mg/packet ; 1.68gm/packet) for Oral Suspension USFDA Approved

	Me-too status	Risek Insta Sachet 20mg + 1680mg by M/s Getz Pharma (Reg# 58547)
	GMP status	Not submitted
	Decision of 324th Meeting	*Deferred for following:* *i. Form-5 is filled and signed by M/s DeMont, Form-5 filled and signed by M/s Dyson Research Laboratories (Applicant for registration) is required along with full fee i.e. Rs.75000/-.* *ii. Latest GMP inspection report of DeMont Research Lab conducted within last three years.*
	Response of the firm	i. Form-5 filled & signed by M/s McOlson Laboratories submitted along with fee of Rs. 75000/- vide slip no. 8340945715 dated 27-01-2023. ii. Copy of GMP inspection report dated 05-03-2019 along with copy of receiving of application for conduction of GMP inspection dated 19-04-2022 is submitted.
	Decision: Approved. **Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s.DeMont Research Laboratories (Pvt.) Ltd. 20-KM, Lahore-Sharikpur Road, Sheikhupura.**	
563.	Name and address of manufacturer/ Applicant	M/s. McOlson Research Laboratories (Pvt.) Ltd. Plot No. 2, M2-Pharma zone, 26 KM, Lahore Sharikpur Road, Sheikhupura. (Contract Giver) (DML No. 000664). Contract with M/s.DeMont Research Laboratories (Pvt.) Ltd. 20-KM, Lahore-Sharikpur Road, Sheikhupura. (Contract acceptor) (DML No. 000844) Sachet (General) Section.
	Brand Name + Dosage Form + Strength	NOWEEZ 4mg Sachet
	Composition	Each Sachet Contains; Montelukast (as sodium)……4mg
	Diary No. Date of R & I & fee	Dy.No.16148 dated 07-03-2019; Fee Rs.50,000 paid vide slip No. 1900475 dated 05.03.2019, endorsed on 06.03.2019
	Pharmacological Group	Proton pump inhibitors ATC Code: A02BC01
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	SINGULAIR PAEDIATRIC 4MG GRANULES. MHRA Approved.
	Me-too status	Singulair 4mg granules, Reg. No. 031377 M/s OBS Healthcare Karachi
	GMP status	Not submitted
	Decision of 324th Meeting	*Deferred for following:* *i. Form-5 is filled and signed by M/s DeMont, Form-5 filled and signed by M/s Dyson Research Laboratories (Applicant for registration) is required along with full fee i.e. Rs.75000/-.* *ii. Latest GMP inspection report of DeMont Research Lab conducted within last three years.*
	Response of the firm	i. Form-5 filled & signed by M/s McOlson Laboratories submitted along with fee of Rs. 75000/- vide slip no. 8340945715 dated 27-01-2023. ii. Copy of GMP inspection report dated 05-03-2019 along with copy of receiving of application for conduction of GMP inspection dated 19-04-2022 is submitted.

	Decision: Approved. **Registration Board further authorized its Chairman for issuance of registration letter upon consideration of satisfactory capacity assessment of manufacturing and testing facility of M/s.DeMont Research Laboratories (Pvt.) Ltd. 20-KM, Lahore-Sharikpur Road, Sheikhupura.**	
564.	Name and address of manufacturer/ Applicant	M/s. Bio-Mark Pharmaceuticals Plot 527, Sunder Industrial Estate, Lahore (Contract Giver) (DML No. 000863) Contract with M/s. Dyson Research Laboratories, 28-KM, Ferozpur Road, Lahore (Contract Acceptor) (DML No. 000559).. (Contract Acceptor) Tablet (hormone) Section.
	Brand Name + Dosage Form + Strength	BIO-PROGYNOVA 2mgTablets
	Composition	Each sugar coated tablet contains; Estradiol valerate…..2mg Norgestrel…….0.5mg
	Diary No. Date of R & I & fee	Dy. No. 10886 dated 05.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0849873 dated 01-03-2019, endorsed on 04.03.2019. <u>Duplicate dossier:</u> Dy. No. 596 dated 06.01.2023
	Pharmacological Group	Progestogens and estrogens, sequential preparations ATC Code: G03FB01
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	21's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Cyclo-Progynova® 2mg (Sugar coated) White Tablets 2mg oestradiol valerate Pale Brown Tablets 500 micrograms norgestrel 2mg oestradiol valerate MHRA Approved.
	Me-too status	Progyluton tab Reg No. 012367 M/s Medipharm Lahore (bayer)
	GMP status	Not proivded
	Decision of 326th Meeting	*Deferred for submission of manufacturing and testing details and revised label claim as per innovator product along with fee of Rs. 75000/- as per No.F.7-11/2012-B&A/DRAP dated 07-05-2021 notification.*
	Response of the firm	i. The firm has submitted that they will exactly follow the Innovator product. However, the did not submit manufacturing & testing details and fee of Rs. 75000/-
	Decision: Deferred for submission of manufacturing and testing details and revised label claim as per innovator product along with fee of Rs. 75000/- as per No.F.7-11/2012-B&A/DRAP dated 07-05-2021 notification.	
565.	Name and address of manufacturer/ Applicant	M/s. Bio-Mark Pharmaceuticals Plot 527, Sunder Industrial Estate, Lahore (Contract Giver) (DML No. 000863) Contract with M/s. Dyson Research Laboratories, 28-KM, Ferozpur Road, Lahore (Contract Acceptor) (DML No. 000559).. (Contract Acceptor) Tablet (hormone) Section.
	Brand Name + Dosage Form + Strength	Markgest 100mg Vaginal Tablet
	Composition	Each tablet contains; Progesterone…..100mg
	Diary No. Date of R & I & fee	Dy. No. 10885 dated 05.03.2019. Fee paid Rs. 50,000/- vide Slip No. 0849872 dated 01-03-2019, endorsed on 04.03.2019. <u>Duplicate dossier:</u> Dy. No. 598 dated 06.01.2023
	Pharmacological Group	Pregnen (4) derivatives

		ATC Code: G03DA04
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	21's, 90's. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Endometrin Progesterone 100mg Insert; vaginal USFDA Approved.
	Me-too status	Could not be verified.
	GMP status	Not provided
	Decision of 326th Meeting	*Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee and stability study data as per the guidelines provided in 293rd meeting of Registration Board.*
	Response of the firm	i. The firm has submitted that Me-Too is not available, hence the application was submitted on Form-5D. The firm has not submitted the stability data.
	Decision: Registration Board decided to reject the application since the firm has not submitted stability study data of 3 batches of the drug product before the lapse of deadline decided by DRAP Authority i.e. till 31st December 2022.	

APPLICATIONS OF M/S ADVANCED PHARMACEUTICALS CONSIDERED BY RB IN ITS 295TH MEETING IN LIGHT OF PRIORITY APPROVAL / REGISTRATION POLICY FOR DRUGS DURING THE COVID-19 PANDEMIC

Sr. No.	Name of Manufacturer	Brand Name & Composition	Dy. No. Date & Fee Status	Pack Size/ Demanded Price	GMP Status	Decision of RB in 295th meeting
566.	M/s Advanced Pharmaceuticals Plot No.38, Street No S-4, National Industrial Zone Rawat	Advanced-C Tablet 500mg Each tablet contains: Ascorbic Acid…500mg	Dy. No. 9579 dated 30/04/2020 Rs. 20,000/- 30-04-2020 Form 5	As per SRO	GMP status not confirmed. Reference formulation is chewable tablet while applied formulation is plain tablet.	*Registration Board referred the case to QA & LT Division for updated status of GMP.*
567.		Advanced-C Chewable Tablet 500mg Each tablet contains: Ascorbic Acid…500mg	Dy. No. 9578 dated 30/04/2020 Rs. 20,000/- 30-04-2020 Form 5	As per SRO	GMP status not confirmed. Reference formulation is chewable tablet while applied formulation is plain tablet.	*Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with*

						submission of requisite fee. The Board also referred the case to QA & LT Division for updated status of GMP.

Remarks of Evaluator:

Now, the firm has submitted copy of DML renewal inspection dated 16-11-2022. The firm has not submitted evidence of availability of plain Vitamin C tablet in RRAs for product at sr. no. 566. Moreover, the firm has already indicated chewable word in brand name for product at sr. no. 567 but same is not indicated in composition and the firm has submitted that their composition is for chewable tablet.

Decision: Registration Board decided as follows:

- **Rejected product at sr. no. 566 as the formulation is not available in RRAs.**
- **Approved the product at sr. no. 567 with following label:**
  Each chewable tablet contains:

Ascorbic Acid…500mg

Registration letter shall be issued after submission of fee of Rs. 7500/- as per SRO 496(I)/2023 dated 17.04.2023. by the firm.

Agenda of Evaluator PEC-X

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

a. New cases

568.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form + Strength	Veti-M Vet Injection 50ml
	Composition	Each ml Contains: Meloxicam…7.5mg
	Diary No. Date of R& I & fee	Dy.No 859 dated 06-01-2021 Rs.20,000/- dated 06-01-2021
	Pharmacological Group	Anti-inflammatory/ Anti-rheumatic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Melo Grand 7.5 Injection of M/s Grand Pharma (Pvt) Ltd., Islamabad (Reg. No. 111554)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	• **Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
569.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form + Strength	Tylo-Vetz 20% Injection 50ml

	Composition	Each ml contains: Tylosin Tartrate Eq. To Tylosin Base…200mg
	Diary No. Date of R& I & fee	Dy.No 853 dated 06-01-2021 Rs.20,000/- dated 06-01-2021
	Pharmacological Group	Anti-bacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Tysin Injection (50ml) of M/s S.J&G. Fazul Ellahie (Pvt) Ltd Karachi (Reg. No. 026510)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	• **Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
570.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form + Strength	Tri Vetrim-S Injection 50ml
	Composition	Each ml Contains: Sulphamethoxypyridazine…150mg Trimethoprim…30mg Tylosin Tartrate…50mg
	Diary No. Date of R& I & fee	Dy.No 857 dated 06-01-2021 Rs.20,000/- dated 06-01-2021
	Pharmacological Group	Anti-bacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Tylotrim Injection (50ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 046515)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	• **Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML. **Shortcomings:** • The firm has applied for Sulphamethoxypyridazine…150mg, Trimethoprim…30mg and **Tylosin Tartrate…50mg/ml** while the reference formulation is **Each ml Contains:** **Sulphamethoxypyridazine…150mg** **Trimethoprim…30mg** **Tylosin as Tartrate…50mg** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved with following label claim: **Each ml Contains:** **Sulphamethoxypyridazine…150mg** **Trimethoprim…30mg** **Tylosin as Tartrate…50mg**	

	The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
571.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form + Strength	V-Mec Injection 10ml
	Composition	Each ml Contains: Doramectin…10mg
	Diary No. Date of R& I & fee	Dy.No 860 dated 06-01-2021 Rs.20,000/- dated 06-01-2021
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Doramax Injection (10ml) of M/s Mylab (Pvt) Ltd, Khankah Sharif, Bahawalpur. (Reg. No. 088125)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	• **Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
572.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form + Strength	Pen-S Vet Powder Injection
	Composition	Each vial contains: Penicillin G Procaine…30,00,000 IU Penicillin G Sodium…10,00,000 IU Dihydro Streptomycin Sulphate…5gm
	Diary No. Date of R& I & fee	Dy.No 858 dated 06-01-2021 Rs.20,000/- dated 06-01-2021
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml vial (5gm); Decontrolled
	Me-too status	PG-Vet Injection (50ml) of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No.080957)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of Penicillin Injection (Veterinary) Section. • Provide conversion of Penicillin G Procaine and Penicillin G Sodium from IU to grams
	Decision: Deferred for following: • **Confirmation of Penicillin Injection (Veterinary) Section from Licensing Division.** • **conversion of Penicillin G Procaine and Penicillin G Sodium from IU to grams** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
573.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh

	Brand Name +Dosage Form + Strength	Vetz-Vita Oral Powder
	Composition	Each gram contains: Vitamin A...800gm Vitamin D3... 160gm Vitamin E... 380gm Vitamin B1...1000gm Vitamin B2...1250gm Vitamin B12...1gm Vitamin B3...6250gm Vitamin B6...4000gm Copper Sulphate...250gm Magnesium Sulphate...25000gm Calcium Chloride...23gm Zinc Sulphate...2170gm Manganese Sulphate...10000gm Potassium Iodide...500gm Sodium Selenite...10gm D.C.P (Phosphorous)...150000gm Sodium Chloride...120000gm
	Diary No. Date of R& I & fee	Dy.No 863 dated 06-01-2021 Rs.20,000/- dated 06-01-2021
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 20gm, 30gm, 50gm, 100gm, 150gm, 250gm, 500gm, 1Kg, 5Kg, 25Kg; Decontrolled
	Me-too status	White Gold Powder of M/s Leads Pharma (Pvt) Ltd Islamabad (Reg. No. 058842)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	• **Oral Powder (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Deferred for confirmation of testing facility.	
574.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Enro-P Injection
	Composition	Each ml contains: Enrofloxacin…….200mg
	Diary No. Date of R& I & fee	Dy.No 2826 dated 25-01-2021 Rs.20,000/- dated 22-01-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml; Decontrolled
	Me-too status	Ceriflox 20% Injection (10ml, 50ml, 100ml) of M/s Star Laboratories (Pvt) Ltd, Lahore (Reg. No. 058940)
	GMP status	Panel unanimously recommends the grant of additional sections based on inspection dated 17-02-2022
	Remarks of the Evaluator [X]	Approval of **Liquid Injection Section (General-Veterinary)** confirmed vide panel inspection report dated 29-11-18 and 01-01-2019, for issuance of GMP certificate. **Shortcomings:**

		• Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, both 50ml and 100ml pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier. • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit following before issuance of registration letter. • **Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021** • **Latest GMP inspection report conducted within the period of last three years** • **Choice of only one pack size**	
575.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form + Strength	Mepyrvetz Injection 50ml
	Composition	Each ml contains: Mepyramine Maleate…50mg
	Diary No. Date of R& I & fee	Dy.No 856 dated 06-01-2021 Rs.20,000/- dated 06-01-2021
	Pharmacological Group	Anti-allergic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Meprax Injection (50ml) of M/s Mylab (Pvt) Ltd, Khankah Sharif, Bahawalpur. (Reg. No. 112258)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	• **Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters including its food safety concerns in regional and global regulatory authorities.	
576.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form + Strength	L-S Vetz Injection 100ml
	Composition	Each ml contains: Lincomycin HCl…75mg Spiramycin adipate…125mg
	Diary No. Date of R& I & fee	Dy.No 855 dated 06-01-2021 Rs.20,000/- dated 06-01-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Lincospira Injection (100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 046570)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	• **Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for salt form correction as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	

577.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form + Strength	Tylo-Vetz 20% Injection 10ml
	Composition	Each ml Contains: Tylosin Tartrate eq. to Tylosin Base…200mg
	Diary No. Date of R& I & fee	Dy.No 854 dated 06-01-2021 Rs.20,000/- dated 06-01-2021
	Pharmacological Group	Anti-bacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Tylo-Pro 20 Injection (10ml) of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113549)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	• **Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
578.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form + Strength	Pentavetz Injection 50ml
	Composition	Each ml contains: Cyanocobalamine…0.5mg Sodium Selenite…1mg Adenosine Triphosphate Tetrasodium Dihydrate Salt…1mg Potassium Aspartate…10mg Magnesium Aspartate…15mg
	Diary No. Date of R& I & fee	Dy.No 861 dated 06-01-2021 Rs.20,000/- dated 06-01-2021
	Pharmacological Group	Anti-stress
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Biosal Injection (50ml) of M/s Zakfas Pharmaceuticals (Pvt) Ltd. Multan (Reg. No. 052320)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	• **Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Deferred for confirmation of testing facility.	
579.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form + Strength	Vetmectin-E Injection for 50ml
	Composition	Each ml contains: Ivermectin…10mg Vitamin E…5mg
	Diary No. Date of R& I & fee	Dy.No 862 dated 06-01-2021 Rs.20,000/- dated 06-01-2021
	Pharmacological Group	Dewormer

	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	I Vet E Injection (50ml) of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 069601)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [x]	• **Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
580.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name +Dosage Form + Strength	Tetrasul Injection 100ml
	Composition	Each ml contains: **Sulphamerazine**…100mg **Sulphadiazine**…60mg **Sulphathiazole**…40mg **Trimethoprim**…40mg
	Diary No. Date of R& I & fee	Dy.No 852 dated 06-01-2021 Rs.20,000/- dated 06-01-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Trisulpha Injection (100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd Lahore (Reg. No. 057003)
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [x]	• **Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML.
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
581.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Oxy KP Injection
	Composition	Each ml contains: Oxytetracycline HCl…200mg **Ketoprofen**…30mg
	Diary No. Date of R& I & fee	Dy.No 2828 dated 25-01-2021 Rs.20,000/- dated 22-01-2021
	Pharmacological Group	Antibacterial/NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml, 20ml, 30ml, 50ml, 100ml; Decontrolled
	Me-too status	Oxyfen LA Injection **(10ml, 20ml, 30ml, 50ml, 100ml)** of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore. (Reg. No. 071091)
	GMP status	Panel unanimously recommends the grant of additional sections based on inspection dated 17-02-2022

	Remarks of the Evaluator [X]	Approval of **Liquid Injection Section (General-Veterinary)** confirmed vide panel inspection report dated 29-11-18 and 01-01-2019, for issuance of GMP certificate. **Shortcomings:** • The firm has applied for Oxytetracycline HCl…200mg and Ketoprofen…30mg, while the referred generic product contains **Each ml contains:-** **Oxytetracycline (as HCl) ….200mg** **Ketoprofen …….……..……..30mg** Submit evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board; or revise formulation in line with reference product. • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier. • Latest GMP inspection report conducted within the period of last three years.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
582.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Linco-TP Powder
	Composition	Each gm contains: Lincomycin HCl…44mg
	Diary No. Date of R& I & fee	Dy.No 2827 dated 25-01-2021 Rs.20,000/- dated 22-01-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg; Decontrolled
	Me-too status	Malinco 44 Oral Powder of M/s Mallard Pharmaceuticals (Pvt) Ltd., Multan (Reg. No. 112112)
	GMP status	Panel unanimously recommends the grant of additional sections based on inspection dated 17-02-2022
	Remarks of the Evaluator [X]	**Oral Powder (General-Vet) section** confirmed vide panel inspection report for grant of additional section based on inspection conducted on 17-02-2022. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 30,000/- for salt form correction as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
583.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Oxkit Injection
	Composition	Each ml contains: Oxytetracycline as HCl…200mg **Ketoprofen**…30mg
	Diary No. Date of R& I & fee	Dy.No 194 dated 01-01-2021 Rs.20,000/- dated 19-11-2020
	Pharmacological Group	Antibiotic

	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml; Decontrolled
	Me-too status	Oxyfen LA Injection **(10ml, 20ml, 30ml, 50ml, 100ml)** of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore. (Reg. No. 071091)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Shortcomings:** • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
584.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Amcol Water Soluble Powder
	Composition	Each gram contains: Amoxicillin Trihydrate…200mg Colistin Sulphate…6,000,000 IU
	Diary No. Date of R& I & fee	Dy.No 2650 dated 22-01-2021 Rs.20,000/- dated 22-01-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg, 5Kg, 25Kg; Decontrolled
	Me-too status	Almoxin-C Water Soluble Powder of M/s Breeze Pharma (Pvt.) Ltd., Islamabad (Reg. No. 075662)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Oral Dry Powder (Penicillin) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML.
	Decision: Approved with following label claim: **Each gram contains:** **Amoxicillin as Trihydrate…200mg** **Colistin Sulphate…6,000,000 IU** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
585.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Spectinamox Water Soluble Powder
	Composition	Each gram contains: Amoxicillin Trihydrate…200mg

		Lincomycin HCl eq. to Lincomycin…88mg Spectinomycin Dihydrochloride Pentahydrate eq. to Spectinomycin…88mg
	Diary No. Date of R& I & fee	Dy.No 2651 dated 22-01-2021 Rs.20,000/- dated 22-01-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 2.5Kg, 25Kg; Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Oral Dry Powder (Penicillin) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
586.	Name and address of manufacturer / Applicant	M/s Elko Organization Pvt Ltd., Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Bupex Injection 50mg/ml 50ml
	Composition	Each ml contains: Buparvaquone…50mg
	Diary No. Date of R& I & fee	Dy.No 628 dated 05-01-2021 Rs.20,000/- dated 04-01-2021
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Eter Bupra Injection (50ml) of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 109843)
	GMP status	Inspection conducted on 03-03-2021 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid injectable (General) Veterinary section** confirmed vide panel inspection dated 22-08-2022 report for grant of DML renewal
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
587.	Name and address of manufacturer / Applicant	M/s Elko Organization Pvt Ltd., Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Bupex Injection 50mg/ml 20ml
	Composition	Each ml contains: Buparvaquone…50mg
	Diary No. Date of R& I & fee	Dy.No 1061 dated 07-01-2021 Rs.20,000/- dated 07-01-2021
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	20ml; Decontrolled

	Me-too status	Empilex Injection (20ml) of M/s Manhattan Pharma, Karachi. (Reg. No.109090)
	GMP status	Inspection conducted on 03-03-2021 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid injectable (General) Veterinary section** confirmed vide panel inspection dated 22-08-2022 report for grant of DML renewal
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
588.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Cynofos Injection 100ml
	Composition	Each ml contains: Toldimphos Sodium…200mg Cyanocobalamin…0.05mg
	Diary No. Date of R& I & fee	Dy.No 1400 dated 11-01-2021 Rs.20,000/- dated 11-01-2021
	Pharmacological Group	Phosphorus/ Vitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Tonovit Injetion (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 033253)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator [X]	• **Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
589.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Cynofos Injection 50ml
	Composition	Each ml contains: Toldimphos Sodium…200mg Cyanocobalamin…0.05mg
	Diary No. Date of R& I & fee	Dy.No 1399 dated 11-01-2021 Rs.20,000/- dated 11-01-2021
	Pharmacological Group	Phosphorus/ Vitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Tonovit Injetion (10ml, 20ml, 50ml, 100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 033253)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator [X]	• **Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
590.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories (Pvt) Ltd., 136 sector 15 Korangi Industrial Area Karachi.

	Brand Name +Dosage Form + Strength	Diarrostop Oral Powder
	Composition	Each gram contains: Neomycin Sulphate…33.33mg Streptomycin Sulphate…33.33mg Sulfaguanidine…333.33mg Kaolin…333.33mg Pectin…33.33mg Bismuth Subnitrate…166.67mg Vitamin A Acetate…6666.67 IU
	Diary No. Date of R& I & fee	Dy.No 2090 dated 18-01-2021 Rs.20,000/- dated 18-01-2021
	Pharmacological Group	Antibiotics/ Antidiarrheal/ Vitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	6 x 12gm, 15 x 100gm, 1000gm: Decontrolled
	Me-too status	Diarroban Powder of M/s Star Laboratories (Pvt) Ltd Lahore (Reg. No. 026438)
	GMP status	Last GMP inspection is conducted on 25-01-2022 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator [X]	• **Dry Powder Sachet Vet Section** confirmed from panel inspection report conducted on 31-03-2022 for renewal of DML.
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
591.	Name and address of manufacturer / Applicant	M/s Hawk Bio Pharma Pvt Ltd. Plot # 10, Street # s-6, National Industrial Estate, RCCI, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Amprohawk-90 Oral Powder
	Composition	Each gram contains: Amprolium HCl…900mg
	Diary No. Date of R& I & fee	Dy.No 2089 dated 18-01-2021 Rs.20,000/- dated 18-01-2021
	Pharmacological Group	Coccidiostat
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm, 2500gm: Decontrolled
	Me-too status	Pentaprol 90 Powder of M/s Neotech Pharmaceuticals (Pvt) Ltd. Kamoke (Reg. No. 111416)
	GMP status	Last GMP inspection is conducted on 25-01-2022 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator [X]	• **Veterinary Oral Powder (General) Section** confirmed vide letter No. F.1-31/2011-Lic (M-235) dated 03-07-2013.
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
592.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries, Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Paractin-T Injection 50ml
	Composition	Each ml contains: Ivermectin…20mg
	Diary No. Date of R& I & fee	Dy.No 1398 dated 11-01-2021 Rs.20,000/- dated 11-01-2021
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5

	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Ivermec 2% Injection (50ml) of M/s Grand Pharma (Pvt) Ltd., Islamabad. (Reg. No.111547)
	GMP status	cGMP certificate dated 30-04-2021 based on inspection conducted on 15-04-2021.
	Remarks of the Evaluator [X]	• **Liquid Injection (General) Section (Veterinary)** confirmed vide panel inspection report based on inspection conducted on 12-04-2021 & 15-04-2021 for renewal of DML
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
593.	Name and address of manufacturer / Applicant	M/s S.J & G Fazul Ellahie Pvt Ltd., E-46, S.I.T.E. Karachi.
	Brand Name +Dosage Form + Strength	Biowin Injection 50ml
	Composition	Each ml contains: Cyanocobalamin…0.5mg Sodium Selenite…1mg Adenosine Triphosphate Tetrasodium Dihydrate…1mg Potassium Aspartate Semihydrate…15mg Magnesium Aspartate Tetrahydrate…15mg
	Diary No. Date of R& I & fee	Dy.No 2235 dated 19-01-2021 Rs.20,000/- dated 19-01-2021
	Pharmacological Group	Multivitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Biosal injection (50ml) of M/s Zakfas Pharmaceuticals (Pvt) Ltd. Multan. (Reg. No. 052320)
	GMP status	Last GMP inspection is conducted on 24-02-2023 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator [X]	• **Liquid Injectable (Veterinary) Section** confirmed vide panel inspection report based on inspection conducted on 15-01-2020 for grant of GMP certificate. • The firm has submitted list of equipments for confirmation of testing facility (atomic absorption spectrophotometer) • Initially, Potassium Aspartate Semihydrate…15mg/ml is mentioned on label claim in Form-5 while Potassium Aspartate Semihydrate…10mg/ml is mentioned in master formulation; The firm has now revised the formulation as mentioned below: **Each ml contains:** **Cyanocobalamin…0.5mg** **Sodium Selenite…1mg** **Adenosine Triphosphate Tetrasodium Dihydrate…1mg** **Potassium Aspartate Semihydrate…10mg** **Magnesium Aspartate Tetrahydrate…15mg** The firm has submitted fee Rs. 30,000/- vide deposit slip No. 1808174501 for revision of master formula (for correction/pre-approval change in strength of API and finished product specifications).
	Decision: Approved with as per innovator's specifications.	
594.	Name and address of manufacturer / Applicant	M/s Elegance Pharmaceuticals, Chak Belli Pandori Road, Distt. Rawalpindi

	Brand Name +Dosage Form + Strength	Hexitol 85 Powder
	Composition	Each gm contains: Methenamine…850mg Vitamin B1…7mg Vitamin C…1mg Sorbitol…50mg
	Diary No. Date of R& I & fee	Dy.No 5385 dated 18-02-2021 Rs.20,000/- dated 18-02-2021
	Pharmacological Group	Amino acid, Multivitamin, **Expectorant**
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg; Decontrolled
	Me-too status	Uritox Powder of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 075722)
	GMP status	
	Remarks of the Evaluator [X]	• **Oral dry Powder (Veterinary) Section** confirmed vide letter No. F. 1-18/2010-Lic dated 27-08-2012 **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in pharmacological group and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
595.	Name and address of manufacturer / Applicant	M/s Elegance Pharmaceuticals, Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name +Dosage Form + Strength	Gumbogence Powder
	Composition	Each gm Powder Contains: Ammonium Chloride…300mg DL-Methionine…100mg Sorbitol…50mg Vitamin A…150,0 IU **Vitamin C**…100mg **Aspirin**…100mg
	Diary No. Date of R& I & fee	Dy.No 5384 dated 18-02-2021 Rs.20,000/- dated 18-02-2021
	Pharmacological Group	Amino acid, Multivitamin, Expectorant
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg; Decontrolled
	Me-too status	Gumbosol Powder of M/s Westmont Pharmaceutical Industry, Gujar Khan, Distt. Rawalpindi (Reg. No. 063752)
	GMP status	
	Remarks of the Evaluator [X]	• **Oral dry Powder (Veterinary) Section** confirmed vide letter No. F. 1-18/2010-Lic dated 27-08-2012 **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
596.	Name and address of manufacturer / Applicant	M/s Elegance Pharmaceuticals, Chak Belli Pandori Road, Distt. Rawalpindi

	Brand Name +Dosage Form + Strength	Tylorim-B Liquid
	Composition	Each ml contains: Tylosin Tartrate…5% Sulphamethoxypyridazine…5% Trimethoprim…4% Bromhexine HCl…0.5%
	Diary No. Date of R& I & fee	Dy.No 5382 dated 18-02-2021 Rs.20,000/- dated 18-02-2021
	Pharmacological Group	Antibacterial, Anti-viral
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1Liter; Decontrolled
	Me-too status	Tetra Star Liquid of M/s Biogen Pharma. Rawat (Reg. No. 075621)
	GMP status	
	Remarks of the Evaluator [X]	**Oral Liquid Syrup (Veterinary) Section** confirmed vide letter No. F. 1-18/2010-Lic dated 27-08-2012 **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • The reference formulation is **Each ml contains:** **Tylosin as Tartrate…5%** **Sulphamethoxypyridazine…5%** **Trimethoprim…4%** **Bromhexine HCl…0.5%** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved with following label claim: **Each ml contains:** **Tylosin as Tartrate…50mg** **Sulphamethoxypyridazine…50mg** **Trimethoprim…40mg** **Bromhexine HCl…5mg** **The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 30,000/- for correction/pre-approval change in formulation and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
597.	Name and address of manufacturer / Applicant	M/s Elegance Pharmaceuticals, Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name +Dosage Form + Strength	Cintin-B Liquid
	Composition	Each ml contains: Enrofloxacin…100mg Colistin Sulphate…0.55 MIU Bromhexine HCl…5mg
	Diary No. Date of R& I & fee	Dy.No 5381 dated 18-02-2021 Rs.20,000/- dated 18-02-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1Liter; Decontrolled
	Me-too status	Enro CB Liquid of M/s D-Maarson Pharmaceuticals, Rawat, Islamabad (Reg. No. 074083)
	GMP status	

	Remarks of the Evaluator [X]	• **Oral Liquid Syrup (Veterinary) Section** confirmed vide letter No. F. 1-18/2010-Lic dated 27-08-2012 **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
598.	Name and address of manufacturer / Applicant	M/s Elegance Pharmaceuticals, Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name +Dosage Form + Strength	Enrogence Oral Liquid
	Composition	Each ml contains: Enrofloxacin…200mg
	Diary No. Date of R& I & fee	Dy.No 5383 dated 18-02-2021 Rs.20,000/- dated 18-02-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 200ml, 400ml, 450ml, 500ml, 1Liter; Decontrolled
	Me-too status	Enroexcel 20 Oral Solution of M/s Mediexcel Pharmaceuticals, Islamabad (Reg. No. 031405)
	GMP status	
	Remarks of the Evaluator [X]	• **Oral Liquid Syrup (Veterinary) Section** confirmed vide letter No. F. 1-18/2010-Lic dated 27-08-2012 **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
599.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Bioimido Injection 10ml
	Composition	Each ml contains: Imidocarb Dipropionate…120mg
	Diary No. Date of R& I & fee	Dy.No 4917 dated 15-02-2021 Rs.20,000/- dated 11-02-2021
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Imivetz Injection (10ml) of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 106669)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for salt form correction as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
600.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad

	Brand Name +Dosage Form + Strength	Procel Injection 30ml
	Composition	Each vial contains: Procaine Penicillin…4,000,000 IU
	Diary No. Date of R& I & fee	Dy.No 4918 dated 15-02-2021 Rs.20,000/- dated 11-02-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	30ml: Decontrolled
	Me-too status	Provet 40 Lac Dry Injection (30ml) of M/s Breeze Pharma Islamabad (Reg. No. 059162)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Dry Powder Injection (Penicillin) Veterinary section** confirmed vide letter No. F.1-12/89-Lic (Vol-III) dated 19-12-2017
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
601.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Benzosol Dry Powder Injection
	Composition	Each ml contains: Benzyl Penicillin…0.5 MIU Procaine Penicillin…1.5 MIU Streptomycin Sulphate…5gm
	Diary No. Date of R& I & fee	Dy.No 4919 dated 15-02-2021 Rs.20,000/- dated 11-02-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	**5gm**: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Dry Powder Injection (Penicillin) Veterinary section** confirmed vide letter No. F.1-12/89-Lic (Vol-III) dated 19-12-2017 **Shortcomings:** • Clarification regarding applied strength is required since same quantities of APIs are mentioned **per millilitre** on cover letter and **per vial (5gm)** in Form-5; provide accordingly evidence of applied formulation/drug already approved by DRAP **with same pack size as applied** (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Clarification regarding applied strength since same quantities of APIs are mentioned per millilitre on cover letter and per vial (5gm) in Form-5** • **evidence of applied formulation/drug already approved by DRAP with same pack size as applied (generic / me-too status) alongwith registration number, brand name and name of firm.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
602.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad

	Brand Name +Dosage Form + Strength	Bioroxin Solution
	Composition	Each ml contains: Pefloxacin…100mg (as Pefloxacin Methanesulfonate …139.6mg)
	Diary No. Date of R& I & fee	Dy.No 4915 dated 15-02-2021 Rs.20,000/- dated 15-02-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, 2.5L, 5L: As recommended by the PRC
	Me-too status	Peperoxin Solution of M/s Hassan Brothers, Faisalabad. (Reg. No. 082807)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Oral Liquid section (General) Veterinary** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML.
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
603.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Fostyphate Water Soluble Powder
	Composition	Each gm contains: Fosfomycin Calcium …200mg Tylosin Tartrate…50mg Fructose 1,6 Diphosphate…180mg Sodium Phosphate…150mg Magnesium Phosphate…100mg Sodium Chloride q.s…1000mg
	Diary No. Date of R& I & fee	Dy.No 4916 dated 15-02-2021 Rs.20,000/- dated 15-02-2021
	Pharmacological Group	Broad spectrum antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg, 5Kg, 25Kg: As recommended by the PRC
	Me-too status	Fofact Powder of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 075626)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Oral Dry Powder section (Veterinary)** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. • The reference formulation is **Each gm contains:** **Fosfomycin Calcium …200mg** **Tylosin as Tartrate…50mg** **Fructose 1,6 Diphosphate…180mg** **Sodium Phosphate…150mg** **Magnesium Phosphate…100mg** **Sodium Chloride q.s…1000mg**

		Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved with following label claim. **Each gm contains:** **Fosfomycin Calcium …200mg** **Tylosin as Tartrate…50mg** **Fructose 1,6 Diphosphate…180mg** **Sodium Phosphate…150mg** **Magnesium Phosphate…100mg** **Sodium Chloride q.s…1000mg** **The firm shall submit fee of Rs.30000/- for correction in formulation (salt form) and pre-approval change of finished product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 the following before issuance of registration letter.**	
604.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Monium-C Powder
	Composition	Each gm contains: Ammonium Chloride…300gm **Aspirin**…100mg **Vitamin C**…100mg DL-Methionine…100mg Vitamin A…1500 IU Sorbitol…50mg
	Diary No. Date of R& I & fee	Dy.No 4203 dated 08-02-2021 Rs.20,000/- dated 21-12-2020
	Pharmacological Group	Electrolyte supplement, Expectorant, NSAID, **Diuretic**
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 15000gm, 20000gm, 25000gm: Decontrolled
	Me-too status	Scada Water Soluble Powder of M/s Decent Pharma, Rawat, Islamabad. (Reg. No. 079819)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022. **Shortcomings:** • Firm shall submit fee of Rs.7,500/- for correction in pharmacological group, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
605.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	F-Pfloxacin Oral Liquid
	Composition	Each ml contains: Pefloxacin Methanesulfonate…139.6mg (Pefloxacine Base)…100mg
	Diary No. Date of R& I & fee	Dy.No 6025 dated 24-02-2021 Rs.20,000/- dated 15-02-2021
	Pharmacological Group	Antibacterial, Anti-infective
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 200ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 10000ml, 15000ml, 20000ml, 25000ml; Decontrolled

	Me-too status	Peperoxin Solution of M/s Hassan Brothers, Faisalabad. (Reg. No. 082807)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Liquid General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Decision: Approved upto 20000ml pack size.	
606.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Seltone Solution
	Composition	Each ml contains: Sodium Selenite as Selenium…2.3mg Sorbitol…50mg Choline Chloride…50mg Vitamin-E…200mg Zinc Chloride as Zinc…4mg
	Diary No. Date of R& I & fee	Dy.No 6024 dated 24-02-2021 Rs.20,000/- dated 15-02-2021
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 200ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 10000ml, 15000ml, 20000ml, 25000ml; Decontrolled
	Me-too status	Supertone Solution of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 049629)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Liquid General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022. **Shortcomings:** • Solubility of formulation
	Decision: Deferred for Solubility of formulation. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
607.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Leepack Powder
	Composition	Each gm contains: Lincomycin HCl…222mg Spectinomycin Sulphate…444.7mg
	Diary No. Date of R& I & fee	Dy.No 4202 dated 08-02-2021 Rs.20,000/- dated 21-12-2020
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 15000gm, 20000gm, 25000gm; Decontrolled
	Me-too status	Nobi-Spectin Powder of M/s Noble Pharma Mirpur Azad Kashmir (Reg. No. 058729)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.

	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Decision: Approved upto pack size of 20000gm. The firm shall submit fee of Rs. 30,000/- for salt form correction as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
608.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	S-Mix Powder
	Composition	Each gm contains: Lincomycin HCl…50mg Spectinomycin HCl…75mg Spiramycin Adipate…25mg Bromhexine HCl…5mg
	Diary No. Date of R& I & fee	Dy.No 4205 dated 08-02-2021 Rs.20,000/- dated 21-12-2020
	Pharmacological Group	Antibacterial, mucolytic agent
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 15000gm, 20000gm, 25000gm; Decontrolled
	Me-too status	Spiralinc-B Powder of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 079716)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Decision: Approved upto pack size of 20000gm. The firm shall submit fee of Rs. 30,000/- for salt form correction as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
609.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Vetfos Powder
	Composition	Each gm contains: Calcium Fosfomycin…20% Tylosin Tartrate…5%
	Diary No. Date of R& I & fee	Dy.No 4204 dated 08-02-2021 Rs.20,000/- dated 21-12-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 15000gm, 20000gm, 25000gm; Decontrolled
	Me-too status	Fosvet Plus-T Powder of M/s Epla Labs Karachi (Reg. No. 025721)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022. **Shortcomings:** • The reference formulation is **Each gm contains:** **Fosfomycin Calcium …20%** **Tylosin as Tartrate…5%**

		Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved upto pack size of 20000gm with following label claim: **Each gm contains:** **Fosfomycin Calcium …200mg** **Tylosin as Tartrate…50mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
610.	Name and address of manufacturer / Applicant	M/s Hawk Bio Pharma Pvt Ltd. Plot # 10, Street # s-6, National Industrial Estate, RCCI, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Hawk Enrocol Oral Powder
	Composition	Each gm contains: Enrofloxacin HCl…200mg Colistin Sulphate…45,000 IU
	Diary No. Date of R& I & fee	Dy.No 5120 dated 16-02-2021 Rs.20,000/- dated 15-02-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm, 2500gm: Decontrolled
	Me-too status	Enrofas-C Oral Powder of M/s Intervac (Pvt) Ltd., Lahore (Reg. No.048246)
	GMP status	Last GMP inspection is conducted on 25-01-2022 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator [X]	• **Veterinary Oral Powder (General) Section** confirmed vide letter No. F.1-31/2011-Lic (M-235) dated 03-07-2013.
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
611.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Prosel Spray
	Composition	Each ml contains: Fipronil…2.5mg
	Diary No. Date of R& I & fee	Dy.No 6328 dated 25-02-2021 Rs.20,000/- dated 24-02-2021
	Pharmacological Group	Antiparasitic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml and 250ml; Decontrolled
	Me-too status	Forontline Spray of M/s Rhone Poulenc, Lahore (Reg. No. 022176)
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator [X]	• **Aerosol General (Vet) section** confirmed vide cGMP certificate based upon evaluation conducted on 24-01-2023 and 25-01-2023
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
612.	Name and address of manufacturer / Applicant	M/s Elko Organization Pvt Ltd., Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi

	Brand Name +Dosage Form + Strength	Penasep Dry Powder Injection 50ml
	Composition	Each vial contains: Penicillin G Procaine…3,000,000 IU Penicillin G Sodium…1,000,000 IU Dihydro Streptomycin Sulphate…5gm
	Diary No. Date of R& I & fee	Dy.No 5781 dated 22-02-2021 Rs.20,000/- dated 22-02-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	PG-VET Injection (50ml) of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 080957)
	GMP status	Inspection conducted on 03-03-2021 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of **Liquid injectable (Penicillin) Veterinary** section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Liquid injectable (Penicillin) Veterinary section" from CLB. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
613.	Name and address of manufacturer / Applicant	M/s Elko Organization Pvt Ltd., Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	EL-Floxacin Injection 500ml
	Composition	Each ml contains: Enrofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 3960 dated 03-02-2021 Rs.20,000/- dated 03-02-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	500ml; Decontrolled
	Me-too status	Envet 10% Injection (500ml) of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 102013)
	GMP status	Inspection conducted on 03-03-2021 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Infusion LVP (General) Veterinary section** confirmed vide panel inspection dated 22-08-2022 report for grant of renewal of DML
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
614.	Name and address of manufacturer / Applicant	M/s Venus Pharma, 23 Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Enrocin 10% Injection 50ml
	Composition	Each ml contains: Enrofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 4074 dated 04-02-2021 Rs.20,000/- dated 04-02-2021

	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Envet 10% Injection (50ml) of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 102012)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Liquid Injectable (General) section" from CLB. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
615.	Name and address of manufacturer / Applicant	M/s Venus Pharma, 23 Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Enrocin 20% Injection 50ml
	Composition	Each ml contains: Enrofloxacin…200mg
	Diary No. Date of R& I & fee	Dy.No 4073 dated 04-02-2021 Rs.20,000/- dated 04-02-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Enflox-20% Injection (50ml) of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 112216)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Liquid Injectable (General) section" from CLB. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
616.	Name and address of manufacturer / Applicant	M/s Venus Pharma, 23 Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Valron Injection 50ml
	Composition	Each ml contains: **Diclofenac Sodium**…100mg
	Diary No. Date of R& I & fee	Dy.No 4071 dated 04-02-2021 Rs.20,000/- dated 04-02-2021

	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Liquid Injectable (General) section" from CLB. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
617.	Name and address of manufacturer / Applicant	M/s Venus Pharma, 23 Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Annvil Injection 50ml
	Composition	Each ml contains: Pheniramine Maleate…11.35mg
	Diary No. Date of R& I & fee	Dy.No 4072 dated 04-02-2021 Rs.20,000/- dated 04-02-2021
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Antil Injection (50ml) of M/s Izfaar Pharmaceutical Industries, Lahore. (Reg. No. 074750)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for following: • **Opinion of EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters** • **Submission of evidence of approval of required manufacturing facility of "Liquid Injectable (General) section" from CLB.**	
618.	Name and address of manufacturer / Applicant	M/s Venus Pharma, 23 Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Mectin-V Injection 50ml
	Composition	Each ml contains: Ivermectin…10mg
	Diary No. Date of R& I & fee	Dy.No 4075 dated 04-02-2021 Rs.20,000/- dated 04-02-2021

	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Ivoron Injection (50ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi (Reg. No.112248)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Liquid Injectable (General) section" from CLB. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
619.	Name and address of manufacturer / Applicant	M/s Venus Pharma, 23 Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Chloroquine Phosphate Injection 50ml
	Composition	Each ml contains: Chloroquine as Phosphate…40mg
	Diary No. Date of R& I & fee	Dy.No 4076 dated 04-02-2021 Rs.20,000/- dated 04-02-2021
	Pharmacological Group	Antimalarial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Chloroquine Injection (50ml) of M/s Kakasian Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 058950)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for following: • **Opinion of EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters** • **Submission of evidence of approval of required manufacturing facility of "Liquid Injectable (General) section" from CLB.**	
620.	Name and address of manufacturer / Applicant	M/s Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Sahianwala Faisalabad
	Brand Name +Dosage Form + Strength	Me Sel Oral Liquid
	Composition	Each ml contains: Vitamin E (Alpha Tocopherol acetate) …100mg Sodium Selenite…2mg
	Diary No. Date of R& I & fee	Dy.No 9883 dated 30-03-2021 Rs.20,000/- dated 30-03-2021
	Pharmacological Group	Vitamin
	Type of Form	Form-5

	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, 2500ml and 5000ml; Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	Last GMP inspection conducted on 07-03-2023 concludes that firm was considered to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Oral liquid (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017 **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm along with testing facility. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
621.	Name and address of manufacturer / Applicant	M/s Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Sahianwala, Faisalabad
	Brand Name +Dosage Form + Strength	Maji Gambo Powder
	Composition	Each gm contains: Potassium Citrate…180mg Sodium Citrate…120mg Vitamin B1…0.3mg Vitamin B2…0.15mg Nicotinamide…3.2mg Menadione Bisulfate…1.15mg Vitamin C…11mg
	Diary No. Date of R& I & fee	Dy.No 9882 dated 30-03-2021 Rs.20,000/- dated 30-03-2021
	Pharmacological Group	Vitamin preparation
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm and 10000gm; Decontrolled
	Me-too status	Bimbo-H Water Soluble Powder of M/s D-Haans Pharmaceuticals, Bhimber, Azad Kashmir. (Reg. No. 102231)
	GMP status	Last GMP inspection conducted on 07-03-2023 concludes that firm was considered to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Oral powder (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
622.	Name and address of manufacturer / Applicant	M/s Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Sahianwala, Faisalabad
	Brand Name +Dosage Form + Strength	DS-Majidox Powder
	Composition	Each gm contains: Tylosin Tartrate…100mg Doxycycline HCl…200mg Dihydrostreptomycin…40mg Bromhexine HCl…5mg
	Diary No. Date of R& I & fee	Dy.No 9885 dated 30-03-2021 Rs.20,000/- dated 30-03-2021

	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm,10000gm and 25000gm; Decontrolled
	Me-too status	Tylobrom-S Powder of M/s Attabak Pharmaceuticals, Islamabad (Reg. No. 075698)
	GMP status	Last GMP inspection conducted on 07-03-2023 concludes that firm was considered to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Oral powder (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017 **Shortcomings:** • The reference formulation is **Each gm contains:** **Tylosin as Tartrate…100mg** **Doxycycline HCl…200mg** **Dihydrostreptomycin…40mg** **Bromhexine HCl…5mg**
	Decision: Approved upto 10000gm pack size and with following label claim: **Each gm contains:** **Tylosin as Tartrate…100mg** **Doxycycline HCl…200mg** **Dihydrostreptomycin…40mg** **Bromhexine HCl…5mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
623.	Name and address of manufacturer / Applicant	M/s Vantage Laboratories Pvt Ltd., 54-RB, Sarhali, 6-Km, Sangla Hill, Shahkot Road, Faisalabad
	Brand Name +Dosage Form + Strength	Oxcel + Drench
	Composition	Each ml Contains: Oxfendazole…22.65mg Selenium…00.35mg Cobalt Sulphate…3.82mg
	Diary No. Date of R& I & fee	Dy.No 9450 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, and 5000ml; Decontrolled
	Me-too status	Ovizole SC Drench of M/s Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur. (Reg. No. 074008)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for following: • **confirmation of relevant manufacturing facility from Licensing Division.** • **latest GMP inspection report conducted within the period of last three years.**	

	The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
624.	Name and address of manufacturer / Applicant	M/s Vantage Laboratories Pvt Ltd., 54-RB, Sarhali, 6-Km, Sangla Hill, Shahkot Road, Faisalabad
	Brand Name +Dosage Form + Strength	Alzole 10 Drench
	Composition	Each ml contains: Albendazole…100mg
	Diary No. Date of R& I & fee	Dy.No 9453 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, and 5000ml; Decontrolled
	Me-too status	Albamax 100 Drench of M/s Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur. (Reg. No. 074007)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for following: • **confirmation of relevant manufacturing facility from Licensing Division.** • **latest GMP inspection report conducted within the period of last three years.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
625.	Name and address of manufacturer / Applicant	M/s Vantage Laboratories Pvt Ltd., 54-RB, Sarhali, 6-Km, Sangla Hill, Shahkot Road, Faisalabad
	Brand Name +Dosage Form + Strength	Effinol Oral Liquid
	Composition	Each ml contains: Enrofloxacin…100mg Aminophylline…40mg Guaiphenesin…100mg
	Diary No. Date of R& I & fee	Dy.No 9452 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Antibacterial, expectorant
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, and 5000ml; Decontrolled
	Me-too status	EG Enro Plus Liquid of M/s Elegance Pharmaceutical, Rawalpindi (Reg. No.074099)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for following:	

	• **confirmation of relevant manufacturing facility from Licensing Division.** • **latest GMP inspection report conducted within the period of last three years.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
626.	Name and address of manufacturer / Applicant	M/s Vantage Laboratories Pvt Ltd., 54-RB, Sarhali, 6-Km, Sangla Hill, Shahkot Road, Faisalabad
	Brand Name +Dosage Form + Strength	Nicilan 72 Oral Powder
	Composition	Each Gm contains: Neomycin Sulphate…720mg
	Diary No. Date of R& I & fee	Dy.No 9456 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	New-Mycin 72% Oral Powder of M/s Bio-Oxime Pharmaceuticals, Faisalabad. (Reg. No. 080133)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for following: • **confirmation of relevant manufacturing facility from Licensing Division.** • **latest GMP inspection report conducted within the period of last three years.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
627.	Name and address of manufacturer / Applicant	M/s Vantage Laboratories Pvt Ltd., 54-RB, Sarhali, 6-Km, Sangla Hill, Shahkot Road, Faisalabad
	Brand Name +Dosage Form + Strength	Doxiro 500 W/S Powder
	Composition	Each gram contains: Doxycycline Hyclate…500mg
	Diary No. Date of R& I & fee	Dy.No 9460 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Soludox 50% W/S Powder of M/s Prix Pharmaceutica, Lahore (Reg. No. 032212)
	GMP status	

	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for following: • **confirmation of relevant manufacturing facility from Licensing Division.** • **latest GMP inspection report conducted within the period of last three years.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
628.	Name and address of manufacturer / Applicant	M/s Vantage Laboratories Pvt Ltd., 54-RB, Sarhali, 6-Km, Sangla Hill, Shahkot Road, Faisalabad
	Brand Name +Dosage Form + Strength	Broment Oral Liquid
	Composition	Each ml contains: Bromhexine HCl…20mg Menthol…40mg
	Diary No. Date of R& I & fee	Dy.No 9459 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Mucolytic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, and 5000ml; Decontrolled
	Me-too status	Bromo-Plus Liquid of M/s Elegance Pharmaceutical, Rawalpindi (Reg. No. 073917)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for following: • **confirmation of relevant manufacturing facility from Licensing Division.** • **latest GMP inspection report conducted within the period of last three years.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
629.	Name and address of manufacturer / Applicant	M/s Vantage Laboratories Pvt Ltd., 54-RB, Sarhali, 6-Km, Sangla Hill, Shahkot Road, Faisalabad
	Brand Name +Dosage Form + Strength	Deltage Topical Liquid
	Composition	Each ml contains: Deltamethrin…2.5%
	Diary No. Date of R& I & fee	Dy.No 9457 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Insecticide
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, and **5000ml**; Decontrolled
	Me-too status	I-Dmeth Solution of M/s International Pharma Lab's Lahore (Reg. No. 052388)

	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for following: • **confirmation of relevant manufacturing facility from Licensing Division.** • **latest GMP inspection report conducted within the period of last three years.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
630.	Name and address of manufacturer / Applicant	M/s Vantage Laboratories Pvt Ltd., 54-RB, Sarhali, 6-Km, Sangla Hill, Shahkot Road, Faisalabad
	Brand Name +Dosage Form + Strength	Linco 4.4 Oral Powder
	Composition	Each gram contains: Lincomycin HCl…44mg
	Diary No. Date of R& I & fee	Dy.No 9455 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Lincopri 44 Oral Powder of M/s Prix Pharmaceutica, Lahore (Reg. No. 063897)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for following: • **confirmation of relevant manufacturing facility from Licensing Division.** • **latest GMP inspection report conducted within the period of last three years.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
631.	Name and address of manufacturer / Applicant	M/s Vantage Laboratories Pvt Ltd., 54-RB, Sarhali, 6-Km, Sangla Hill, Shahkot Road, Faisalabad
	Brand Name +Dosage Form + Strength	Menditage Oral Liquid
	Composition	Each ml contains: **Enrofloxacin**…75mg **Sulphamethoxypyridazine**…75mg **Sulphamethazine**…50mg **Trimethoprim**…25mg
	Diary No. Date of R& I & fee	Dy.No 9458 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form-5

	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, and 5000ml; Decontrolled
	Me-too status	Pro Chick Oral Liquid of M/s Majestic Pharma, Faisalabad. (Reg. No. 089834)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
632.	Name and address of manufacturer / Applicant	M/s Vantage Laboratories Pvt Ltd., 54-RB, Sarhali, 6-Km, Sangla Hill, Shahkot Road, Faisalabad
	Brand Name +Dosage Form + Strength	Hepatage Oral Liquid
	Composition	Each ml contains: Vitamin E…200mg Choline Chloride…50mg Zinc…4mg Sorbitol…50mg Selenium…2.3mg
	Diary No. Date of R& I & fee	Dy.No 9451 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Immune booster
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, and 5000ml; Decontrolled
	Me-too status	Supertone Solution of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 049629)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Solubility of formulation
	Decision: Deferred for following: • **confirmation of relevant manufacturing facility from Licensing Division.** • **latest GMP inspection report conducted within the period of last three years.** • **Solubility of formulation** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
633.	Name and address of manufacturer / Applicant	M/s Vantage Laboratories Pvt Ltd., 54-RB, Sarhali, 6-Km, Sangla Hill, Shahkot Road, Faisalabad
	Brand Name +Dosage Form + Strength	Oxyflon Powder
	Composition	Each gram contains: Neomycin Sulphate…150mg Florfenicol…100mg Oxytetracycline HCl…300mg

	Diary No. Date of R& I & fee	Dy.No 9454 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Stenop Powder of M/s Majestic Pharma, Faisalabad. (Reg. No. 089846)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for following: • **confirmation of relevant manufacturing facility from Licensing Division.** • **latest GMP inspection report conducted within the period of last three years.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
634.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals, 14-km, Adyala Road, Post Office Dahgal, Rawalpindi.
	Brand Name +Dosage Form + Strength	Lostin-60 Injection 10ml
	Composition	Each ml contains: Colistin Sulphate…0.60 MIU
	Diary No. Date of R& I & fee	Dy.No 7658 dated 09-03-2021 Rs.20,000/- dated 09-03-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	Panel inspection conducted on 01-12-2020 for renewal of DML
	Remarks of the Evaluator [X]	**Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) with same pack size alongwith registration number, brand name and name of firm. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for following: • **confirmation of relevant manufacturing facility from Licensing Division.** • **evidence of applied formulation/drug already approved by DRAP (generic / me-too status) with same pack size alongwith registration number, brand name and name of firm.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
635.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals, 14-km, Adyala Road, Post Office Dahgal, Rawalpindi.

	Brand Name +Dosage Form + Strength	Lostin-60 Injection 100ml
	Composition	Each ml contains: Colistin Sulphate…0.60 MIU
	Diary No. Date of R& I & fee	Dy.No 7657 dated 09-03-2021 Rs.20,000/- dated 09-03-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	Panel inspection conducted on 01-12-2020 for renewal of DML
	Remarks of the Evaluator [X]	**Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) with same pack size alongwith registration number, brand name and name of firm. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for following: • **confirmation of relevant manufacturing facility from Licensing Division.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) with same pack size alongwith registration number, brand name and name of firm.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
636.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals, 14-km, Adyala Road, Post Office Dahgal, Rawalpindi.
	Brand Name +Dosage Form + Strength	Lostin-60 Injection 50ml
	Composition	Each ml contains: Colistin Sulphate…0.60 MIU
	Diary No. Date of R& I & fee	Dy.No 7659 dated 09-03-2021 Rs.20,000/- dated 09-03-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Intercoli-60 Injection (50ml) of M/s Intervac (Pvt) Ltd., Sheikhupura. (Reg. No. 112385)
	GMP status	Panel inspection conducted on 01-12-2020 for renewal of DML
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for confirmation of relevant manufacturing facility from Licensing Division. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
637.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals, 14-km, Adyala Road, Post Office Dahgal, Rawalpindi.
	Brand Name +Dosage Form + Strength	Lostin-20 Injection 50ml

	Composition	Each ml contains: Colistin Sulphate…0.20 MIU
	Diary No. Date of R& I & fee	Dy.No 7627 dated 09-03-2021 Rs.20,000/- dated 09-03-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	Panel inspection conducted on 01-12-2020 for renewal of DML
	Remarks of the Evaluator [X]	**Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) with same pack size alongwith registration number, brand name and name of firm. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for following: • **confirmation of relevant manufacturing facility from Licensing Division.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) with same pack size alongwith registration number, brand name and name of firm.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
638.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals, 14-km, Adyala Road, Post Office Dahgal, Rawalpindi.
	Brand Name +Dosage Form + Strength	Lostin-20 Injection 100ml
	Composition	Each ml contains: Colistin Sulphate…0.20 MIU
	Diary No. Date of R& I & fee	Dy.No 7629 dated 09-03-2021 Rs.20,000/- dated 09-03-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Coliexcel Injection (100ml) of M/s Mediexcel Pharmaceuticals, Islamabad. (Reg. No. 102166)
	GMP status	Panel inspection conducted on 01-12-2020 for renewal of DML
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for confirmation of relevant manufacturing facility from Licensing Division. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
639.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals, 14-km, Adyala Road, Post Office Dahgal, Rawalpindi.
	Brand Name +Dosage Form + Strength	Kerofen-10% Injection 10ml

	Composition	Each ml contains: **Ketoprofen**…100mg
	Diary No. Date of R& I & fee	Dy.No 7660 dated 09-03-2021 Rs.20,000/- dated 09-03-2021
	Pharmacological Group	NSAID/Analgesic
	Type of Form	Form-5
	Finished product Specification	BP (Vet) specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Ketoject Injection (10ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	Panel inspection conducted on 01-12-2020 for renewal of DML
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
640.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals, 14-km, Adyala Road, Post Office Dahgal, Rawalpindi.
	Brand Name +Dosage Form + Strength	Kerofen-10% Injection 20ml
	Composition	Each ml contains: **Ketoprofen**…100mg
	Diary No. Date of R& I & fee	Dy.No 7656 dated 09-03-2021 Rs.20,000/- dated 09-03-2021
	Pharmacological Group	NSAID/Analgesic
	Type of Form	Form-5
	Finished product Specification	BP (Vet) specifications
	Pack size & Demanded Price	20ml; Decontrolled
	Me-too status	Ketoject Injection (20ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	Panel inspection conducted on 01-12-2020 for renewal of DML
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
641.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals, 14-km, Adyala Road, Post Office Dahgal, Rawalpindi.
	Brand Name +Dosage Form + Strength	Kerofen-10% Injection 50ml
	Composition	Each ml contains: **Ketoprofen**…100mg
	Diary No. Date of R& I & fee	Dy.No 7618 dated 09-03-2021 Rs.20,000/- dated 09-03-2021
	Pharmacological Group	NSAID/Analgesic
	Type of Form	Form-5
	Finished product Specification	BP (Vet) specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Ketoject Injection (50ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	Panel inspection conducted on 01-12-2020 for renewal of DML

	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
642.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals, 14-km, Adyala Road, Post Office Dahgal, Rawalpindi.
	Brand Name +Dosage Form + Strength	Kerofen-10% Injection 100ml
	Composition	Each ml contains: **Ketoprofen**…100mg
	Diary No. Date of R& I & fee	Dy.No 7649 dated 09-03-2021 Rs.20,000/- dated 09-03-2021
	Pharmacological Group	NSAID/Analgesic
	Type of Form	Form-5
	Finished product Specification	BP (Vet) specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Ketoject Injection (100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 043141)
	GMP status	Panel inspection conducted on 01-12-2020 for renewal of DML
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
643.	Name and address of manufacturer / Applicant	M/s Univet Pharmaceuticals, 14-km, Adyala Road, Post Office Dahgal, Rawalpindi.
	Brand Name +Dosage Form + Strength	Zix-Sel Liquid
	Composition	Each ml Contains: Vitamin E…200mg Selenium…2mg Zinc…9mg
	Diary No. Date of R& I & fee	Dy.No 8311 dated 15-03-2021 Rs.20,000/- dated 15-03-2021
	Pharmacological Group	Nutritional Supplement
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml; Decontrolled
	Me-too status	Sel-E Solution of M/s Noble Pharma, Mirpur Azad Kashmir. (Reg. No.063641)
	GMP status	Panel inspection conducted on 01-12-2020 for renewal of DML
	Remarks of the Evaluator [X]	**Oral Liquid (General) Veterinary section** confirmed vide letter No. F.1-41/2006-Lic dated 09-12-2014 **Shortcomings:** • Solubility of formulation
	Decision: Deferred for Solubility of formulation. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	

644.	Name and address of manufacturer / Applicant	M/s Elegance Pharmaceuticals, Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name +Dosage Form + Strength	Bio Tiamulin 12.5 Powder
	Composition	Each gm contains: Tiamulin Hydrogen Fumarate Eq. to Tiamulin Base…125mg
	Diary No. Date of R& I & fee	Dy.No 9477 dated 26-03-2021 Rs.20,000/- dated 24-03-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	27.8gm, 100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 15000gm, and 25000gm; Decontrolled
	Me-too status	SB Tiamulin Oral Powder of M/s SB Pharma Kahuta Road Islamabad (Reg. No. 048219)
	GMP status	
	Remarks of the Evaluator [X]	• **Oral dry Powder (Veterinary) Section** confirmed vide letter No. F. 1-18/2010-Lic dated 27-08-2012 **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
645.	Name and address of manufacturer / Applicant	M/s Elegance Pharmaceuticals, Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name +Dosage Form + Strength	Pyrigence 30 Powder
	Composition	Each gram contains: Sulphachlorpyridazine…30%
	Diary No. Date of R& I & fee	Dy.No 9476 dated 26-03-2021 Rs.20,000/- dated 24-03-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, and 2000gm; Decontrolled
	Me-too status	Nobi ESB3 Powder of M/s Noble Pharma Mirpur Azad Kashmir (Reg. No. 058734)
	GMP status	
	Remarks of the Evaluator [X]	• **Oral dry Powder (Veterinary) Section** confirmed vide letter No. F. 1-18/2010-Lic dated 27-08-2012 **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
646.	Name and address of manufacturer / Applicant	M/s Elegance Pharmaceuticals, Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name +Dosage Form + Strength	Hexitol 90 Powder
	Composition	Each gm contains: Methenamine Mandelate…900mg Vitamin B1…7mg Vitamin C…1mg Sorbitol…50mg

	Diary No. Date of R& I & fee	Dy.No 9478 dated 26-03-2021 Rs.20,000/- dated 18-02-2021
	Pharmacological Group	Amino acid, Multivitamin, Expectorant
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, and 25000gm; Decontrolled
	Me-too status	Vety-Flush Powder of M/s Vety-Care Islamabad (Reg. No. 019938)
	GMP status	
	Remarks of the Evaluator [X]	• **Oral dry Powder (Veterinary) Section** confirmed vide letter No. F. 1-18/2010-Lic dated 27-08-2012 **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications and pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
647.	Name and address of manufacturer / Applicant	M/s Elegance Pharmaceuticals, Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name +Dosage Form + Strength	Elecol Powder
	Composition	Each gram contains: Colistin Sulphate…6 MIU
	Diary No. Date of R& I & fee	Dy.No 9472 dated 26-03-2021 Rs.20,000/- dated 24-03-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, and 1000gm; Decontrolled
	Me-too status	Colivetz Oral Powder of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh (Reg. No. 079296)
	GMP status	
	Remarks of the Evaluator [X]	• **Oral dry Powder (Veterinary) Section** confirmed vide letter No. F. 1-18/2010-Lic dated 27-08-2012 **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
648.	Name and address of manufacturer / Applicant	M/s Elegance Pharmaceuticals, Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name +Dosage Form + Strength	Acerin-C Powder
	Composition	Each gm contains: **Aspirin**…200mg **Vitamin C**…600mg
	Diary No. Date of R& I & fee	Dy.No 9475 dated 26-03-2021 Rs.20,000/- dated 24-03-2021
	Pharmacological Group	NSAID/ Vitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications

	Pack size & Demanded Price	100gm, 500gm, and 1000gm; Decontrolled
	Me-too status	Bio-Aspervet-C Oral Powder of M/s Hawk Bio Pharma (Pvt) Ltd., Rawat, Islamabad (Reg. No.079104)
	GMP status	
	Remarks of the Evaluator [X]	• **Oral dry Powder (Veterinary) Section** confirmed vide letter No. F. 1-18/2010-Lic dated 27-08-2012 **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
649.	Name and address of manufacturer / Applicant	M/s Elegance Pharmaceuticals, Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name +Dosage Form + Strength	Adek-EP Powder
	Composition	Each gm contains: Vitamin A…25000 IU Vitamin D3…250 IU Vitamin E…5mg Vitamin K3…4mg
	Diary No. Date of R& I & fee	Dy.No 9481 dated 26-03-2021 Rs.20,000/- dated 24-03-2021
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1000gm, 5000gm, 10000gm and 25000gm; Decontrolled
	Me-too status	Power-ADEK Powder of M/s Intervac (Pvt) Ltd. Sheikhupura (Reg. No.069653)
	GMP status	
	Remarks of the Evaluator [X]	• **Oral dry Powder (Veterinary) Section** confirmed vide letter No. F. 1-18/2010-Lic dated 27-08-2012 **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
650.	Name and address of manufacturer / Applicant	M/s Elegance Pharmaceuticals, Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name +Dosage Form + Strength	Neomin 70 Powder
	Composition	Each gm contains: Neomycin Sulphate…700mg
	Diary No. Date of R& I & fee	Dy.No 9479 dated 26-03-2021 Rs.20,000/- dated 24-03-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm, 5000gm, 10000gm, 15000gm, and 25000gm; Decontrolled
	Me-too status	Neomycin 70% Powder of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 075694)
	GMP status	
	Remarks of the Evaluator [X]	• **Oral dry Powder (Veterinary) Section** confirmed vide letter No. F. 1-18/2010-Lic dated 27-08-2012 **Shortcomings:**

		• Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
651.	Name and address of manufacturer / Applicant	M/s Elegance Pharmaceuticals, Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name +Dosage Form + Strength	Ferimycin Powder
	Composition	Each gm contains: Florfenicol…150mg Neomycin Sulphate…150mg
	Diary No. Date of R& I & fee	Dy.No 9474 dated 26-03-2021 Rs.20,000/- dated 24-03-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, and 1000gm; Decontrolled
	Me-too status	Fenmycine Water Soluble Powder of M/s D-Haans Pharmaceuticals, Azad Kashmir. (Reg. No. 102223)
	GMP status	
	Remarks of the Evaluator [X]	• **Oral dry Powder (Veterinary) Section** confirmed vide letter No. F. 1-18/2010-Lic dated 27-08-2012 **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
652.	Name and address of manufacturer / Applicant	M/s Elegance Pharmaceuticals, Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name +Dosage Form + Strength	E-Colin Liquid
	Composition	Each ml contains: Enrofloxacin HCl…20gm Colistin Sulphate…4500000 IU
	Diary No. Date of R& I & fee	Dy.No 9473 dated 26-03-2021 Rs.20,000/- dated 24-03-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml; Decontrolled
	Me-too status	Encoli Oral Powder of M/s Westmont Pharmaceutical Industries Rawalpindi (Reg. No. 049765)
	GMP status	
	Remarks of the Evaluator [X]	• **Oral Liquid Syrup (Veterinary) Section** confirmed vide letter No. F. 1-18/2010-Lic dated 27-08-2012 **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
653.	Name and address of manufacturer / Applicant	M/s Elegance Pharmaceuticals, Chak Belli Pandori Road, Distt. Rawalpindi

	Brand Name +Dosage Form + Strength	Doxyfen-T Liquid
	Composition	Each ml contains: Doxycycline HCl…200mg Tylosin Tartrate…100mg Guaifenesin…200mg Aminophylline…80mg
	Diary No. Date of R& I & fee	Dy.No 9480 dated 26-03-2021 Rs.20,000/- dated 24-03-2021
	Pharmacological Group	Antibiotic, Expectorant, bronchodilator
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml; Decontrolled
	Me-too status	Tyco-G Oral Liquid of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 075704)
	GMP status	
	Remarks of the Evaluator [X]	**Oral Liquid Syrup (Veterinary) Section** confirmed vide letter No. F. 1-18/2010-Lic dated 27-08-2012 **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • The reference formulation is **Each ml contains:** **Doxycycline HCl…200mg** **Tylosin as Tartrate…100mg** **Guaifenesin…200mg** **Aminophylline…80mg** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved with following label claim: **Each ml contains:** **Doxycycline HCl…200mg** **Tylosin as Tartrate…100mg** **Guaifenesin…200mg** **Aminophylline…80mg** **The firm shall submit following before issuance of registration letter:** • **fee of Rs. 30,000/- for correction/pre-approval change in formulation and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **latest GMP inspection report conducted within the period of last three years.**	
654.	Name and address of manufacturer / Applicant	M/s Elegance Pharmaceuticals, Chak Belli Pandori Road, Distt. Rawalpindi
	Brand Name +Dosage Form + Strength	ADEK Super Liquid
	Composition	Each ml contains: Vitamin A…10,000 IU Vitamin D3…2,000 IU Vitamin E…4mg Vitamin K3…2mg
	Diary No. Date of R& I & fee	Dy.No 9482 dated 26-03-2021 Rs.20,000/- dated 24-03-2021
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 5000ml, and 10000ml; Decontrolled
	Me-too status	Adek Excel Oral Solution of M/s Nawan Laboratories (Pvt) Ltd, Karachi (Reg. No. 058985)

	GMP status	
	Remarks of the Evaluator [X]	**Oral Liquid Syrup (Veterinary) Section** confirmed vide letter No. F. 1-18/2010-Lic dated 27-08-2012 **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
655.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries, Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Emec Injection
	Composition	Each 100ml contains: Ivermectin…1g Vitamin E…0.5gm
	Diary No. Date of R& I & fee	Dy.No 9879 dated 30-03-2021 Rs.20,000/- dated 30-03-2021
	Pharmacological Group	Anthelmintic, Vitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml; Decontrolled
	Me-too status	I Vet E Injection (50ml, 100ml) of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No.069601)
	GMP status	cGMP certificate dated 30-04-2021 based on inspection conducted on 15-04-2021.
	Remarks of the Evaluator [X]	• **Liquid Injection (General) Section (Veterinary)** confirmed vide panel inspection report based on inspection conducted on 12-04-2021 & 15-04-2021 for renewal of DML • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, both 50ml and 100ml pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier.
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **Choice of only one pack size** • **fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**	
656.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries, Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Selen E Liquid
	Composition	Each ml contains: Vitamin E…120mg Selenium as Sodium Selenite…2.2mg
	Diary No. Date of R& I & fee	Dy.No 9878 dated 30-03-2021 Rs.20,000/- dated 30-03-2021
	Pharmacological Group	**Antitumor** and antioxidant
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1000ml, 25000ml; Decontrolled
	Me-too status	S. Vit E Liquid of M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi (Reg. No. 046513)
	GMP status	cGMP certificate dated 30-04-2021 based on inspection conducted on 15-04-2021.

	Remarks of the Evaluator [X]	• **Liquid Section(General) (Veterinary)** confirmed vide panel inspection report based on inspection conducted on 31-03-2021 & 08-04-2021 for renewal of DML **Shortcomings:** • The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.
	Decision: Deferred for confirmation of testing facility.	
657.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries, Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Erythroprim Powder
	Composition	Each gm contains: Erythromycin Thiocyanate …100mg Trimethoprim…20mg Sulphadiazine…100mg
	Diary No. Date of R& I & fee	Dy.No 9877 dated 30-03-2021 Rs.20,000/- dated 30-03-2021
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm,1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Erythro-TS Powder of M/s Nawan Laboratories (Pvt) Ltd, Karachi (Reg. No. 026417)
	GMP status	cGMP certificate dated 30-04-2021 based on inspection conducted on 15-04-2021.
	Remarks of the Evaluator [X]	• **Oral Powder (General) Section (Veterinary)** confirmed vide panel inspection report based on inspection conducted on 31-03-2021 & 08-04-2021 for renewal of DML
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
658.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries, Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Enteromox-C Oral Powder
	Composition	Each gram contains: Amoxicillin as Trihydrate…150mg Colistin Sulphate…250 IU
	Diary No. Date of R& I & fee	Dy.No 9876 dated 30-03-2021 Rs.20,000/- dated 30-03-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm,1000gm, 2500gm, 5000gm, 10000gm; Decontrolled
	Me-too status	Amoxicol Water Soluble Powder of M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi (Reg. No. 049690)
	GMP status	cGMP certificate dated 30-04-2021 based on inspection conducted on 15-04-2021.
	Remarks of the Evaluator [X]	**Oral Powder Penicillin** Section confirmed vide panel inspection dated 31-03-2021 & 08-04-2021 report for renewal of DML.
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	

659.	Name and address of manufacturer / Applicant	M/s Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Sahianwala Faisalabad
	Brand Name +Dosage Form + Strength	Maji Amune-Forte Oral Liquid
	Composition	Each ml contains: Vitamin E…200mg Sorbi-tol…50mg Choline Chloride…50mg Selenium…2.3mg Zinc…4mg
	Diary No. Date of R& I & fee	Dy.No 9881 dated 30-03-2021 Rs.20,000/- dated 30-03-2021
	Pharmacological Group	Antibacterial, Mucolytic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml and 10000ml; Decontrolled
	Me-too status	EG Supertonic Solution of M/s Evergreen Pharmaceuticals, Lahore. (Reg. No. 074071)
	GMP status	Last GMP inspection conducted on 07-03-2023 concludes that firm was considered to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Oral liquid (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
660.	Name and address of manufacturer / Applicant	M/s Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Sahianwala, Faisalabad
	Brand Name +Dosage Form + Strength	Maji Mant Oral Powder
	Composition	Each gram contains: **Amantadine HCl**…100mg
	Diary No. Date of R& I & fee	Dy.No 9880 dated 30-03-2021 Rs.20,000/- dated 30-03-2021
	Pharmacological Group	Antiviral
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm; Decontrolled
	Me-too status	Amantage Oral Powder of M/s Vantage Pharmaceutical, Shahkot Road, District Faisalabad. (Reg. No. 088851)
	GMP status	Last GMP inspection conducted on 07-03-2023 concludes that firm was considered to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Oral powder (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017
	Decision: : Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
661.	Name and address of manufacturer / Applicant	M/s Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Sahianwala, Faisalabad
	Brand Name +Dosage Form + Strength	Mega Flor-50 Oral Powder
	Composition	Each gram contains: Florfenicol…500mg
	Diary No. Date of R& I & fee	Dy.No 9884 dated 30-03-2021 Rs.20,000/- dated 30-03-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications

	Pack size & Demanded Price	100gm, 150gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm and 10000gm; Decontrolled
	Me-too status	Naflor Powder of M/s Nawan Laboratories (Pvt) Ltd., Karachi. (Reg. No.049513)
	GMP status	Last GMP inspection conducted on 07-03-2023 concludes that firm was considered to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Oral powder (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
662.	Name and address of manufacturer / Applicant	M/s Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Sahianwala, Faisalabad
	Brand Name +Dosage Form + Strength	Amino Dox-Gt Oral Liquid
	Composition	Each ml contains: Doxycycline HCl…200mg Tylosin Tartrate…100mg Guaifenesin…200mg Aminophylline…80mg
	Diary No. Date of R& I & fee	Dy.No 9887 dated 30-03-2021 Rs.20,000/- dated 30-03-2021
	Pharmacological Group	Antibiotic, mucolytic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1000ml, and 5000ml; Decontrolled
	Me-too status	Tyco-G Oral Liquid of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 075704)
	GMP status	Last GMP inspection conducted on 07-03-2023 concludes that firm was considered to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Oral liquid (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017 **Shortcomings:** • The reference formulation is **Each ml contains:** **Doxycycline HCl…200mg** **Tylosin as Tartrate…100mg** **Guaifenesin…200mg** **Aminophylline…80mg** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved with following label claim: **Each ml contains:** **Doxycycline HCl…200mg** **Tylosin as Tartrate…100mg** **Guaifenesin…200mg** **Aminophylline…80mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
663.	Name and address of manufacturer / Applicant	M/s Majestic Pharma, Plot No. 21, Phase No.1-A, M-3 Industrial City, Sahianwala, Faisalabad

	Brand Name +Dosage Form + Strength	Farmadox-M Powder
	Composition	Each gm Contains: **Tylosin Tartrate**…10% **Doxycycline Hyclate**…20% **Colistin Sulphate**…450000 IU Bromhexine HCl…0.5% **Streptomycin Sulphate**…3.6%
	Diary No. Date of R& I & fee	Dy.No 9886 dated 30-03-2021 Rs.20,000/- dated 30-03-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1000gm, 2500gm; Decontrolled
	Me-too status	Bacto-5 Powder of M/s Noble Pharma, Mirpur Azad Kashmir (Reg. No. 075609)
	GMP status	Last GMP inspection conducted on 07-03-2023 concludes that firm was considered to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Oral powder (General)** section confirmed vide letter No. F.1-10/2015-Lic dated 26-12-2017
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
664.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Mycocrd Oral Liquid
	Composition	Each ml contains: Tylosin Tartrate…50mg Sulphamethoxypyridazine…50mg Trimethoprim…40mg Bromhexine…5mg
	Diary No. Date of R& I & fee	Dy.No 9461 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 10000ml 25000ml; As per SRO
	Me-too status	Tilo Methox Liquid of M/s Inshal Pharmaceutical Industries, Rawat, Islamabad (Reg. No. 105042)
	GMP status	
	Remarks of the Evaluator [X]	**Vet Oral Liquid (General/ Antibiotics)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • The reference formulation is **Each ml contains:** **Tylosin as Tartrate…50mg** **Sulphamethoxypyridazine…50mg** **Trimethoprim…40mg** **Bromhexine…5mg** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Deferred for following:	

	• **justification and rationality of formulation.** • **Latest GMP inspection report conducted within the period of last three years** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
665.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Enrobect Oral Liquid
	Composition	Each 100ml Contains: Enrofloxacin…250mg Colistin Sulphate…500000 IU
	Diary No. Date of R& I & fee	Dy.No 9467 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, 2500ml, 5000ml, 10000ml 25000ml; As per SRO
	Me-too status	Vitaflox-C 25% Oral Liquid of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No.079276)
	GMP status	
	Remarks of the Evaluator [X]	**Vet Oral Liquid (General/ Antibiotics)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
666.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	4Vitz Oral Liquid
	Composition	Each ml contains: Vitamin A…10,000 IU Vitamin D3…2,000 IU Vitamin E…4mg Vitamin K3…2mg
	Diary No. Date of R& I & fee	Dy.No 9471 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 10000ml 25000ml; As per SRO
	Me-too status	Symodex Oral Liquid of M/s Biogen Pharma, Rawat (Reg. No. 080144)
	GMP status	
	Remarks of the Evaluator [X]	**Vet Oral Liquid (General/ Antibiotics)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).

	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
667.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Quinrox-20 Oral Liquid
	Composition	Each ml contains: Enrofloxacin…200mg
	Diary No. Date of R& I & fee	Dy.No 9468 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Antibiotic/ antimicrobial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, 2500ml, 5000ml, 10000ml 25000ml; As per SRO
	Me-too status	Lexi-Enroks Liquid of M/s Lexicon Pharmaceuticals (Pvt) Ltd., Karachi. (Reg. No. 046675)
	GMP status	
	Remarks of the Evaluator [X]	**Vet Oral Liquid (General/ Antibiotics)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
668.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Zeetel 5% Suspension
	Composition	Each ml contains: Closantel…50mg
	Diary No. Date of R& I & fee	Dy.No 9470 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 10000ml 25000ml; As per SRO
	Me-too status	Clant Oral Suspension of M/s Elko Organization (Private) Ltd., Karachi (Reg. No. 075649)
	GMP status	
	Remarks of the Evaluator [X]	**Vet Oral Liquid (General/ Antibiotics)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
669.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore

	Brand Name +Dosage Form + Strength	Florostin Oral Liquid
	Composition	Each ml contains: Florfenicol…250mg Colistin Sulphate…0.5 MIU
	Diary No. Date of R& I & fee	Dy.No 9465 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, 2500ml, 5000ml, 10000ml 25000ml; As per SRO
	Me-too status	Poliflor Liquid of M/s Hawk Bio Pharma (Pvt) Ltd., Rawat, Islamabad. (Reg. No. 078383)
	GMP status	
	Remarks of the Evaluator [X]	**Vet Oral Liquid (General/ Antibiotics)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
670.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Vital Plus Injection 50ml
	Composition	Each ml contains: Vitamin A…6,0000 IU Vitamin D3…6,0000 IU Vitamin E…6mg Nicotinamide…0.018mg Vitamin B6…3mg Vitamin B1…6mg
	Diary No. Date of R& I & fee	Dy.No 9469 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; As per SRO
	Me-too status	Metamide Injection (50ml) of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 075730)
	GMP status	
	Remarks of the Evaluator [X]	**Veterinary Liquid Injection (General)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
671.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore

	Brand Name +Dosage Form + Strength	Donamide WSP
	Composition	Each gm contains: Furosemide…20mg **Belladonna Extract**…2mg
	Diary No. Date of R& I & fee	Dy.No 9463 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Diuretic/ anticholinergic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: As per SRO
	Me-too status	Bella Flush Water Soluble Powder of Ms Attabak Pharmaceuticals, Islamabad (Reg. No. 075724)
	GMP status	
	Remarks of the Evaluator [X]	**Vet Oral Powder (II)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
672.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Ampro-50 WSP
	Composition	Each gm contains: Amprolium HCl…500mg
	Diary No. Date of R& I & fee	Dy.No 9462 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: As per SRO
	Me-too status	Amproexcel 50 Water Soluble Powder of Ms Mediexcel Pharmaceuticals, Islamabad. (Reg. No. 035171)
	GMP status	
	Remarks of the Evaluator [X]	**Vet Oral Powder (II)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
673.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Lincomide-40 Water Soluble Powder
	Composition	Each gm contains: Lincomycin as HCl…400mg
	Diary No. Date of R& I & fee	Dy.No 9464 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5

	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: As per SRO
	Me-too status	Lincosel-40 Oral Powder of Ms Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 089826)
	GMP status	
	Remarks of the Evaluator [X]	**Vet Oral Powder (II)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
674.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Amproquin Oral Powder
	Composition	Each gm contains: Amprolium HCl…200mg Sulphaquinoxaline base…200mg Menadione Sodium Bisulfite…2mg
	Diary No. Date of R& I & fee	Dy.No 9466 dated 26-03-2021 Rs.20,000/- dated 26-03-2021
	Pharmacological Group	Anticoccidial/Antibiotic/ coagulant
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: As per SRO
	Me-too status	Max-Coc Powder of Ms Nawan Laboratories (Pvt) Ltd., Karachi. (Reg. No. 063708)
	GMP status	
	Remarks of the Evaluator [X]	**Vet Oral Powder (II)** section confirmed vide report based on panel inspection conducted on 28-08-2018 for GMP compliance. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years).
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
675.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Thiafen Solution
	Composition	Each ml contains: Thiamphenicol…250mg
	Diary No. Date of R& I & fee	Dy.No 8313 dated 15-03-2021 Rs.20,000/- dated 15-03-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Thiafen Oral Liquid of M/s Farm Aid Group, Haripur (Reg. No. 102204)

	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator [X]	• **Oral Liquid (General) Veterinary section** confirmed vide cGMP certificate based upon evaluation conducted on 24-01-2023 and 25-01-2023
	Decision: Approved. The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
676.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Fosfosin Powder
	Composition	Each gram contains: Fosfomycin Calcium…200mg Tylosin Tartrate…100mg Fructose…180mg Sodium Phosphate…150mg Magnesium Sulphate…100mg
	Diary No. Date of R& I & fee	Dy.No 8312 dated 15-03-2021 Rs.20,000/- dated 15-03-2021
	Pharmacological Group	Antibiotic combination
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1000gm, 2500gm, 5000gm, 10000gm: Decontrolled
	Me-too status	Fosfo-20 Oral Powder of M/s Evergreen Pharmaceuticals, Lahore. (Reg. No. 088861)
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator [X]	**Oral Powder (General) Veterinary section** confirmed vide cGMP certificate based upon evaluation conducted on 24-01-2023 and 25-01-2023 **Shortcomings:** • The reference formulation is **Each gm contains:** **Fosfomycin Calcium …200mg** **Tylosin as Tartrate…100mg** **Fructose 1,6 Diphosphate…180mg** **Sodium Phosphate…150mg** **Magnesium Sulphate…100mg** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved with following label claim: **Each gm contains:** **Fosfomycin Calcium …200mg** **Tylosin as Tartrate…100mg** **Fructose 1,6 Diphosphate…180mg** **Sodium Phosphate…150mg** **Magnesium Sulphate…100mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
677.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Prochlor Injection

	Composition	Each ml Contains: Calcium Gluconate…208.30mg Magnesium Hypophosphate…53.50mg Magnesium Chloride…20mg Calcium D Sachharate…10mg Boric Acid…43.30mg Dextrose…200mg
	Diary No. Date of R& I & fee	Dy.No 7589 dated 09-03-2021 Rs.20,000/- dated 19-11-2020
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	300ml, 450ml; Decontrolled
	Me-too status	**Could not be confirmed in the applied strength and combination.**
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	**Shortcomings:** • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier. • Approval of **Liquid Injection (General) section (LVP)** by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Confirmation of Liquid Injection (General) section (LVP) from the Licensing Division.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Choice of only one pack size** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
678.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Cyclomate Injection 10ml
	Composition	Each ml contains: Cloprostenol Sodium Eq. to Cloprostenol…250mcg
	Diary No. Date of R& I & fee	Dy.No 16559 dated 15-06-2021 Rs.30,000/- dated 11-06-2021
	Pharmacological Group	Prostaglandin analogue
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	5 x 10ml; Decontrolled
	Me-too status	Fertagyl Injection (10ml) of M/s Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur (Reg. No. 074013)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator [X]	• **Liquid injectable vial (Hormones) (veterinary)** section confirmed vide cGMP certificate dated 20-07-2020
	Decision: Approved.	

679.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Invoker Liquid Injection
	Composition	Each ml contains: Amoxicillin as Trihydrate…100mg Colistin Sulphate…250,000 IU
	Diary No. Date of R& I & fee	Dy.No 11654 dated 19-04-2021 Rs.20,000/- dated 15-03-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml; Decontrolled
	Me-too status	Colimoxin Injection **(50ml, 100ml)** of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore. (Reg. No. 034576)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	• **Liquid Injection (General) section** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Shortcomings:** • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier.
	Decision: Approved. The firm shall choose only one pack size before issuance of registration letter.	
680.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd., Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Bio-Listine Oral Liquid
	Composition	Each ml contains: Enrofloxacin as HCl…100mg Colistin Sulphate…50000 IU Bromhexine…0.50%
	Diary No. Date of R& I & fee	Dy.No 11655 dated 19-04-2021 Rs.20,000/- dated 15-03-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml; Decontrolled
	Me-too status	Enrocoli Liquid of M/s Symans Pharmaceuticals (Pvt) Ltd Lahore (Reg. No. 059167)
	GMP status	cGMP certificate dated 28-02-2022 based on inspection dated 03-08-2021
	Remarks of the Evaluator [X]	**Oral Liquid section (General) Veterinary** confirmed vide panel inspection report based on inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. **Shortcomings:** • The reference formulation is **Each ml contains:** **Enrofloxacin as HCl…100mg** **Colistin Sulphate…50000 IU** **Bromhexine HCl…0.50%** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

	Decision: Approved with following label claim: **Each ml contains:** **Enrofloxacin as HCl…100mg** **Colistin Sulphate…50000 IU** **Bromhexine HCl…5mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
681.	Name and address of manufacturer / Applicant	M/s Aamster Laboratories, Plot No. 18, St# SS-2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Clavi Mox-C W/S Powder
	Composition	Each gram contains: Amoxicillin Trihydrate…200mg Colistin Sulphate…40mg Clavulanic Acid…40mg
	Diary No. Date of R& I & fee	Dy.No 12126 dated 22-04-2021 Rs.20,000/- dated 22-04-2021
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm,1000gm; Decontrolled
	Me-too status	Amcolin Powder of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No.093787)
	GMP status	Last GMP inspection conducted on 13-03-2023 concludes that firm was considered to be operating at good level of GMP compliance.
	Remarks of the Evaluator [x]	**Shortcomings:** • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • The reference formulation is **Each gram contains:** **Amoxicillin as Trihydrate…200mg** **Colistin Sulphate…40mg** **Clavulanic Acid…40mg** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Deferred for confirmation of Oral powder (Penicillin) section from the Licensing Division. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
682.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd.,25-km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Vitacom Injection
	Composition	Each ml contains: Vitamin A…80,000 IU Vitamin D3…40,000 IU Vitamin E…20mg
	Diary No. Date of R& I & fee	Dy.No 14568 dated 28-05-2021 Rs.30,000/- dated 27-05-2021
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished product Specification	As per Innovator's specifications

	Pack size & Demanded Price	10ml, 20ml, 50ml, 100ml; N/A
	Me-too status	VAD3 Injection (**10ml, 20ml, 50ml, 100ml**) of M/s Breeze Pharma Islamabad (Reg. No. 059179)
	GMP status	Last GMP inspection is conducted on **16-10-2018** and the report concludes that firm was considered to be operating at fair level of GMP compliance.
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years) • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for following: • **Confirmation of Liquid Injection (General) section from the Licensing Division.** • **Latest GMP inspection report conducted within the period of last three years** • **Choice of only one pack size** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
683.	Name and address of manufacturer / Applicant	M/s S.J & G Fazul Ellahie Pvt Ltd., E-46, S.I.T.E. Karachi.
	Brand Name +Dosage Form + Strength	Logon Injection 10ml
	Composition	Each ml contains: Flunixin Meglumine Eq. to Flunixin…50mg
	Diary No. Date of R& I & fee	Dy.No 13645 dated 20-05-2021 Rs.30,000/- dated 04-05-2021
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Floonix Injection (10ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 112246)
	GMP status	Last GMP inspection is conducted on 24-02-2023 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator [X]	• **Liquid Injectable (Veterinary) Section** confirmed vide panel inspection report based on inspection conducted on 15-01-2020 for grant of GMP certificate.
	Decision: Approved.	
684.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Feedfos Powder
	Composition	Each gram contains: Calcium Fosfomycin…25%
	Diary No. Date of R& I & fee	Dy.No 4201 dated 08-02-2021 Rs.20,000/- dated 21-12-2020
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications

	Pack size & Demanded Price	50gm, 100gm, 200gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 15000gm, 20000gm, 25000gm: Decontrolled
	Me-too status	Fosvet Premix Powder of M/s Epla Labs Karachi (Reg. No. 025722)
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed from cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022. **Shortcomings:** • The reference formulation is **Each gram contains:** **Fosfomycin Calcium …250mg** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved with following label claim: **Each gram contains:** **Fosfomycin Calcium …250mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
685.	Name and address of manufacturer / Applicant	M/s Venus Pharma, 23 km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Dexamethasone 1mg/2ml 50CC Injection
	Composition	Each ml contains: Dexamethasone Sodium Phosphate Eq. to Dexamethasone Phosphate…0.5mg
	Diary No. Date of R& I & fee	Dy.No 11383 dated 14-04-2021 Rs.20,000/- dated 14-04-2021
	Pharmacological Group	Corticosteroid
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Dexamethasone Injection (50ml) of M/s Lawrance Pharma (Pvt) Ltd, Lahore (Reg. No. 063874)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years) • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
686.	Name and address of manufacturer / Applicant	M/s Venus Pharma, 23 km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Dexsone 50cc Injection
	Composition	Each ml contains: Dexamethasone as Sodium Phosphate…2.5mg Prednisolone As Acetate…7.5mg
	Diary No. Date of R& I & fee	Dy.No 11384 dated 14-04-2021 Rs.20,000/- dated 14-04-2021
	Pharmacological Group	Corticosteroids
	Type of Form	Form 5

	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Symocortinol-S Injection (50ml) of M/s Symans Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 072672)
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years) • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
687.	Name and address of manufacturer / Applicant	M/s Biorific Pharma, Plot No.143, Industrial Triangle, Kahuta road, Islamabad.
	Brand Name +Dosage Form + Strength	Flori Forte Oral Liquid
	Composition	Each ml Contains: Florfenicol…200mg
	Diary No. Date of R& I & fee	Dy.No 12271 dated 26-04-2021 Rs.20,000/- dated 23-04-2021
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml, 200ml, 250ml, 500ml, 700ml, 1000ml, 2500ml: Decontrolled
	Me-too status	Flurotin Liquid of M/s Elegance Pharmaceuticals, Rawalpindi. (Reg. No. 075751)
	GMP status	Panel inspection report based on 12-12-2022 recommends renewal of DML
	Remarks of the Evaluator [X]	• **Liquid Syrup section (Veterinary)** confirmed vide letter No. F.1-48/2003-Lic dated 25-11-2016.
	Decision: Approved.	
688.	Name and address of manufacturer / Applicant	M/s Biorific Pharma, Plot No.143, Industrial Triangle, Kahuta road, Islamabad.
	Brand Name +Dosage Form + Strength	Tol-K Oral Liquid
	Composition	Each ml contains: Toltrazuril…25mg Vitamin K3…2mg
	Diary No. Date of R& I & fee	Dy.No 12272 dated 26-04-2021 Rs.20,000/- dated 23-04-2021
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml, 200ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Kemocox Liquid of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No.043586)
	GMP status	Panel inspection report based on 12-12-2022 recommends renewal of DML
	Remarks of the Evaluator [X]	• **Liquid Syrup section (Veterinary)** confirmed vide letter No. F.1-48/2003-Lic dated 25-11-2016.
	Decision: Approved.	
689.	Name and address of manufacturer / Applicant	M/s Biorific Pharma, Plot No.143, Industrial Triangle, Kahuta road, Islamabad.
	Brand Name +Dosage Form + Strength	Ronicol Oral Liquid

	Composition	Each ml contains: Enrofloxacin…200mg Colistin Sulphate…25mg
	Diary No. Date of R& I & fee	Dy.No 12267 dated 26-04-2021 Rs.20,000/- dated 23-04-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml, 200ml, 250ml, 500ml, 700ml,1000ml, 2500ml: Decontrolled
	Me-too status	Enrolist Liquid of M/s Wimits Pharmaceuticals, Lahore (Reg. No. 078332)
	GMP status	Panel inspection report based on 12-12-2022 recommends renewal of DML
	Remarks of the Evaluator [X]	• **Liquid Syrup section (Veterinary)** confirmed vide letter No. F.1-48/2003-Lic dated 25-11-2016.
	Decision: Approved.	
690.	Name and address of manufacturer / Applicant	M/s Biorific Pharma, Plot No.143, Industrial Triangle, Kahuta road, Islamabad.
	Brand Name +Dosage Form + Strength	Coliflo Liquid
	Composition	Each ml contains: Florfenicol…250mg Colistin Sulphate…500000IU
	Diary No. Date of R& I & fee	Dy.No 12270 dated 26-04-2021 Rs.20,000/- dated 23-04-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml, 200ml, 250ml, 500ml, 700ml,1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Flocol Liquid of M/s D-Maarson Pharmaceuticals, Rawat, Islamabad (Reg. No. 074082)
	GMP status	Panel inspection report based on 12-12-2022 recommends renewal of DML
	Remarks of the Evaluator [X]	• **Liquid Syrup section (Veterinary)** confirmed vide letter No. F.1-48/2003-Lic dated 25-11-2016.
	Decision: Approved.	
691.	Name and address of manufacturer / Applicant	M/s Biorific Pharma, Plot No.143, Industrial Triangle, Kahuta road, Islamabad.
	Brand Name +Dosage Form + Strength	Sultrop Liquid
	Composition	Each ml Contains: **Enrofloxacin**…75mg **Sulphamethoxypyridazine**…50mg **Sulphamethazine**…50mg **Trimethoprim**…25mg
	Diary No. Date of R& I & fee	Dy.No 12273 dated 26-04-2021 Rs.20,000/- dated 23-04-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml, 200ml, 250ml, 500ml, 700ml,1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Sulphacina Oral Liquid of M/s Bio-Oxime Pharmaceuticals, Faisalabad. (Reg. No. 074786)
	GMP status	Panel inspection report based on 12-12-2022 recommends renewal of DML

	Remarks of the Evaluator [X]	• **Liquid Syrup section (Veterinary)** confirmed vide letter No. F.1-48/2003-Lic dated 25-11-2016.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
692.	Name and address of manufacturer / Applicant	M/s Biorific Pharma, Plot No.143, Industrial Triangle, Kahuta road, Islamabad.
	Brand Name +Dosage Form + Strength	Toxinil Oral Powder
	Composition	Each gram Contains: Furosemide…20mg Potassium Chloride …4mg Calcium carbonate…45mg Magnesium Sulphate…1mg
	Diary No. Date of R& I & fee	Dy.No 12261 dated 26-04-2021 Rs.20,000/- dated 23-04-2021
	Pharmacological Group	Diuretic, Flusher
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm and 10000gm: Decontrolled
	Me-too status	Furosebar Water Soluble Powder of M/s Baariq Pharmaceuticals, Lahore. (Reg. No.075783)
	GMP status	Panel inspection report based on 12-12-2022 recommends renewal of DML
	Remarks of the Evaluator [X]	• **Dry Powder section (Veterinary)** confirmed vide letter No. F.1-48/2003-Lic dated 25-11-2016. • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved. The firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
693.	Name and address of manufacturer / Applicant	M/s Biorific Pharma, Plot No.143, Industrial Triangle, Kahuta road, Islamabad.
	Brand Name +Dosage Form + Strength	Flushtox Oral Powder
	Composition	Each gram Contains: Furosemide…20mg Calcium Carbonate…40mg Sodium Chloride…35mg Magnesium Sulphate…35mg
	Diary No. Date of R& I & fee	Dy.No 12260 dated 26-04-2021 Rs.20,000/- dated 23-04-2021
	Pharmacological Group	Diuretic, Flusher
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm and 10000gm: Decontrolled
	Me-too status	Dialysis Water Soluble Powder of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 075692)
	GMP status	Panel inspection report based on 12-12-2022 recommends renewal of DML
	Remarks of the Evaluator [X]	• **Dry Powder section (Veterinary)** confirmed vide letter No. F.1-48/2003-Lic dated 25-11-2016. • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

	Decision: Approved. The firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
694.	Name and address of manufacturer / Applicant	M/s Biorific Pharma, Plot No.143, Industrial Triangle, Kahuta road, Islamabad.
	Brand Name +Dosage Form + Strength	Amprofic 600gm Oral Powder
	Composition	Each gram contains: Amprolium HCl…600mg
	Diary No. Date of R& I & fee	Dy.No 12262 dated 26-04-2021 Rs.20,000/- dated 23-04-2021
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm and 25000gm: Decontrolled
	Me-too status	Amprox 60% Water Soluble Powder of M/s Alina Combine Pharmaceuticals (Pvt) Ltd. Karachi. (Reg. No. 046673)
	GMP status	Panel inspection report based on 12-12-2022 recommends renewal of DML
	Remarks of the Evaluator [X]	• **Dry Powder section (Veterinary)** confirmed vide letter No. F.1-48/2003-Lic dated 25-11-2016.
	Decision: Approved.	
695.	Name and address of manufacturer / Applicant	M/s Biorific Pharma, Plot No.143, Industrial Triangle, Kahuta road, Islamabad.
	Brand Name +Dosage Form + Strength	Neotic 70 Oral Powder
	Composition	Each 100gm contains: Neomycin Sulphate…700mg
	Diary No. Date of R& I & fee	Dy.No 12264 dated 26-04-2021 Rs.20,000/- dated 23-04-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm and 25000gm: Decontrolled
	Me-too status	Neomycin 70% Powder of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 075694)
	GMP status	Panel inspection report based on 12-12-2022 recommends renewal of DML
	Remarks of the Evaluator [X]	• **Dry Powder section (Veterinary)** confirmed vide letter No. F.1-48/2003-Lic dated 25-11-2016.
	Decision: Approved.	
696.	Name and address of manufacturer / Applicant	M/s Biorific Pharma, Plot No.143, Industrial Triangle, Kahuta road, Islamabad.
	Brand Name +Dosage Form + Strength	Neocox Powder
	Composition	Each gram contains: Oxytetracycline HCl…250mg Neomycin Sulphate…250mg Colistin Sulphate…300000 IU
	Diary No. Date of R& I & fee	Dy.No 12274 dated 26-04-2021 Rs.20,000/- dated 23-04-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 20000gm and 25000gm: Decontrolled

	Me-too status	Oxycol Forte Powder of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 071068)
	GMP status	Panel inspection report based on 12-12-2022 recommends renewal of DML
	Remarks of the Evaluator [X]	• **Dry Powder section (Veterinary)** confirmed vide letter No. F.1-48/2003-Lic dated 25-11-2016.
	Decision: Approved.	
697.	Name and address of manufacturer / Applicant	M/s Biorific Pharma, Plot No.143, Industrial Triangle, Kahuta road, Islamabad.
	Brand Name +Dosage Form + Strength	Levagin 500g Vet Oral Powder
	Composition	Each gram contains: Levamisole HCl…500mg
	Diary No. Date of R& I & fee	Dy.No 12263 dated 26-04-2021 Rs.20,000/- dated 23-04-2021
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	Wormidec Water Soluble Powder of M/s Decent Pharma, Rawat, Islamabad (Reg. No. 079827)
	GMP status	Panel inspection report based on 12-12-2022 recommends renewal of DML
	Remarks of the Evaluator [X]	• **Dry Powder section (Veterinary)** confirmed vide letter No. F.1-48/2003-Lic dated 25-11-2016.
	Decision: Approved.	
698.	Name and address of manufacturer / Applicant	M/s Biorific Pharma, Plot No.143, Industrial Triangle, Kahuta road, Islamabad.
	Brand Name +Dosage Form + Strength	Biomulin Oral Powder
	Composition	Each gram contains: Tiamulin Hydrogen Fumarate Eq. to Tiamulin Base…125mg
	Diary No. Date of R& I & fee	Dy.No 12269 dated 26-04-2021 Rs.20,000/- dated 23-04-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 200gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 20000gm, 25000gm: Decontrolled
	Me-too status	SB Tiamulin Oral Powder of M/s SB Pharma Kahuta Road Islamabad (Reg. No. 048219)
	GMP status	Panel inspection report based on 12-12-2022 recommends renewal of DML
	Remarks of the Evaluator [X]	• **Dry Powder section (Veterinary)** confirmed vide letter No. F.1-48/2003-Lic dated 25-11-2016.
	Decision: Approved.	
699.	Name and address of manufacturer / Applicant	M/s Biorific Pharma, Plot No.143, Industrial Triangle, Kahuta road, Islamabad.
	Brand Name +Dosage Form + Strength	SP-Linc Oral Powder
	Composition	Each gram contains: Lincomycin HCl…222mg Spectinomycin HCl…444.67mg
	Diary No. Date of R& I & fee	Dy.No 12268 dated 26-04-2021 Rs.20,000/- dated 23-04-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications

	Pack size & Demanded Price	100gm, 200gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm: Decontrolled
	Me-too status	Lincospect-100 Water Soluble Powder of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 080734)
	GMP status	Panel inspection report based on 12-12-2022 recommends renewal of DML
	Remarks of the Evaluator [X]	• **Dry Powder section (Veterinary)** confirmed vide letter No. F.1-48/2003-Lic dated 25-11-2016.
	Decision: Approved. The firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
700.	Name and address of manufacturer / Applicant	M/s Biorific Pharma, Plot No.143, Industrial Triangle, Kahuta road, Islamabad.
	Brand Name +Dosage Form + Strength	Fostin Powder
	Composition	Each gram contains: Fosfomycin Calcium…200mg Tylosin Tartrate…100mg Fructose…180mg Sodium Phosphate…150mg Magnesium Sulphate…100mg
	Diary No. Date of R& I & fee	Dy.No 12265 dated 26-04-2021 Rs.20,000/- dated 23-04-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1000gm, 2500gm, 5000gm: Decontrolled
	Me-too status	Fosfotyl Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 078240)
	GMP status	Panel inspection report based on 12-12-2022 recommends renewal of DML
	Remarks of the Evaluator [X]	• **Dry Powder section (Veterinary)** confirmed vide letter No. F.1-48/2003-Lic dated 25-11-2016. • The reference formulation is **Each gm contains:** **Fosfomycin Calcium …200mg** **Tylosin as Tartrate…100mg** **Fructose 1,6 Diphosphate…180mg** **Sodium Phosphate…150mg** **Magnesium Sulphate…100mg** Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved with following label claim. **Each gram contains:** **Fosfomycin Calcium …200mg** **Tylosin as Tartrate…100mg** **Fructose 1,6 Diphosphate…180mg** **Sodium Phosphate…150mg** **Magnesium Sulphate…100mg** **The firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 the following before issuance of registration letter.**	
701.	Name and address of manufacturer / Applicant	M/s Biorific Pharma, Plot No.143, Industrial Triangle, Kahuta road, Islamabad.
	Brand Name +Dosage Form + Strength	Fostif Oral Powder

	Composition	Each gram contains: Calcium Fosfomycin…200mg Tylosin Tartrate…50mg Fructose…180mg Soidum Phosphate…150mg Magnesium Phosphate…100mg Sodium Chloride…qs 1000mg
	Diary No. Date of R& I & fee	Dy.No 12266 dated 26-04-2021 Rs.20,000/- dated 23-04-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1000gm, 2500gm, 5000gm: Decontrolled
	Me-too status	Fofact Powder of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 075626)
	GMP status	Panel inspection report based on 12-12-2022 recommends renewal of DML
	Remarks of the Evaluator [x]	• **Dry Powder section (Veterinary)** confirmed vide letter No. F.1-48/2003-Lic dated 25-11-2016. • The reference formulation is **Each gm contains:** **Fosfomycin Calcium …200mg** **Tylosin as Tartrate…50mg** **Fructose 1,6 Diphosphate…180mg** **Sodium Phosphate…150mg** **Magnesium Phosphate…100mg** **Sodium Chloride…qs 1000mg** Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved with following label claim. **Each gram contains:** **Fosfomycin Calcium …200mg** **Tylosin as Tartrate…50mg** **Fructose 1,6 Diphosphate…180mg** **Sodium Phosphate…150mg** **Magnesium Phosphate…100mg** **Sodium Chloride…qs 1000mg** **The firm shall submit the following before issuance of registration letter:** • **Latest GMP inspection report conducted within the period of last three years.** • **Fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
702.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Oxytocin 10 IU Injection 100ml
	Composition	Each ml contains: Oxytocin…10IU
	Diary No. Date of R& I & fee	Dy.No 11970 dated 21-04-2021 Rs.20,000/- dated 08-04-2021
	Pharmacological Group	Hormone
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Oxytovetz Injection (100ml) of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 111469)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection

		conducted on 24-01-2020.
	Remarks of the Evaluator [X]	• **Liquid injectable vial (Hormone) (veterinary)** section confirmed vide cGMP certificate dated 20-07-2020 based upon evaluation conducted on 24-01-2020.
	Decision: Approved.	
703.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Oxytocin 10 IU Injection 250ml
	Composition	Each ml contains: Oxytocin…10IU
	Diary No. Date of R& I & fee	Dy.No 11971 dated 21-04-2021 Rs.20,000/- dated 08-04-2021
	Pharmacological Group	Hormone
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	250ml; Decontrolled
	Me-too status	Oxytovetz Injection (250ml) of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 111470)
	GMP status	cGMP certificate dated 20-07-2020 based on inspection conducted on 24-01-2020.
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of **Liquid injectable vial (Hormone) (veterinary) (LVP)** by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for confirmation of Liquid injectable vial (Hormone) (veterinary) (LVP) from the Licensing Division. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
704.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	SB Ti-Valosin FG50 Powder
	Composition	Each gram contains: Tylvalosin Tartrate…500mg
	Diary No. Date of R& I & fee	Dy.No 12813 dated 03-05-2021 Rs.20,000/- dated 03-05-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1000gm, 5000gm, 20000gm: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following:	

	• **Latest GMP inspection report conducted within the period of last three years.** • **Approval of Oral powder (General) Veeterinary section/manufacturing facility by the Central Licensing Board.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
705.	Name and address of manufacturer / Applicant	M/s SB Pharma, Plot No.5-E, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	SB Ti-Valosin Oral Powder
	Composition	Each gram contains: Tylvalosin Tartrate…625mg
	Diary No. Date of R& I & fee	Dy.No 12814 dated 03-05-2021 Rs.20,000/- dated 03-05-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	160gm, 400gm, 500gm, 1000gm, 5000gm, 20000gm: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Latest GMP inspection report conducted within the period of last three years.** • **Approval of Oral powder (General) Veeterinary section/manufacturing facility by the Central Licensing Board.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
706.	Name and address of manufacturer / Applicant	M/s Hawk Bio Pharma Pvt Ltd. Plot # 10, Street # s-6, National Industrial Estate, RCCI, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	Fullstop Oral Suspension
	Composition	Each ml contains: **Sulphadimidine**…35mg **Sulphadiazine**…36mg **Streptomycin Sulphate**…7.6mg **Neomycin Sulphate**…1.8mg Sodium Chloride…11.33mg Calcium Gluconate…2.2mg Magnesium Sulphate…0.6mg Potassium Chloride…3.6mg **Kaolin**…103.33mg **Pectin**…7.1mg

		Glycine…20.9mg
	Diary No. Date of R& I & fee	Dy.No 12812 dated 03-05-2021 Rs.20,000/- dated 03-05-2021
	Pharmacological Group	Antibiotic/mineral/ anti-diarrheal/ Amino acid
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	No-Scour Oral Suspension of M/s Nawan Laboratories (Pvt) Ltd., Karachi (Reg. No. 072673)
	GMP status	Last panel inspection was conducted on 19-11-2020 for the grant of renewal of DML.
	Remarks of the Evaluator [x]	**Veterinary oral Liquid (antibiotic) and Veterinary oral Liquid (general) sections** confirmed vide letter No. F. 1-31/2011- Lic (M-235) dated 03-07-2013.
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
707.	Name and address of manufacturer / Applicant	M/s Hawk Bio Pharma Pvt Ltd. Plot # 10, Street # s-6, National Industrial Estate, RCCI, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	Flukanide Oral Suspension
	Composition	Each ml contains: Levamisole HCl…30mg Oxyclozanide…60mg
	Diary No. Date of R& I & fee	Dy.No 12810 dated 03-05-2021 Rs.20,000/- dated 03-05-2021
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Leox D.S. Suspension of M/s Elko Organization (Pvt) Ltd., Karachi. (Reg. No. 031475)
	GMP status	Last panel inspection was conducted on 19-11-2020 for the grant of renewal of DML.
	Remarks of the Evaluator [x]	**Veterinary oral Liquid (antibiotic) and Veterinary oral Liquid (general) sections** confirmed vide letter No. F. 1-31/2011- Lic (M-235) dated 03-07-2013.
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
708.	Name and address of manufacturer / Applicant	M/s Hawk Bio Pharma Pvt Ltd. Plot # 10, Street # s-6, National Industrial Estate, RCCI, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	Endofen Drench
	Composition	Each ml contains: Triclabendazole…50mg Ivermectin…1mg Fenbendazole…50mg
	Diary No. Date of R& I & fee	Dy.No 11285 dated 13-04-2021 Rs.20,000/- dated 09-04-2021
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Triverfen Drench of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 049627)

	GMP status	Last panel inspection was conducted on 19-11-2020 for the grant of renewal of DML.
	Remarks of the Evaluator [X]	**Veterinary oral Liquid (antibiotic) and Veterinary oral Liquid (general) sections** confirmed vide letter No. F. 1-31/2011- Lic (M-235) dated 03-07-2013.
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
709.	Name and address of manufacturer / Applicant	M/s Hawk Bio Pharma Pvt Ltd. Plot # 10, Street # s-6, National Industrial Estate, RCCI, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	Albex-10 Oral Suspension
	Composition	Each ml contains: Albendazole…100mg
	Diary No. Date of R& I & fee	Dy.No 11562 dated 16-04-2021 Rs.20,000/- dated 16-04-2021
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Alvenax 10% Drench of M/s Star Laboratories (Pvt) Ltd., Lahore. (Reg. No. 043299)
	GMP status	Last panel inspection was conducted on 19-11-2020 for the grant of renewal of DML.
	Remarks of the Evaluator [X]	**Veterinary oral Liquid (antibiotic) and Veterinary oral Liquid (general) sections** confirmed vide letter No. F. 1-31/2011- Lic (M-235) dated 03-07-2013.
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
710.	Name and address of manufacturer / Applicant	M/s Hawk Bio Pharma Pvt Ltd. Plot # 10, Street # s-6, National Industrial Estate, RCCI, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	Duazole Oral Suspension
	Composition	Each ml contains: Oxyclozanide…7% Oxfendazole…3%
	Diary No. Date of R& I & fee	Dy.No 11284 dated 13-04-2021 Rs.20,000/- dated 08-04-2021
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Oxanide Oral Suspension of M/s Westmont Pharmaceutical Industries, Gujarkhan (Reg. No. 048200)
	GMP status	Last panel inspection was conducted on 19-11-2020 for the grant of renewal of DML.
	Remarks of the Evaluator [X]	**Veterinary oral Liquid (antibiotic) and Veterinary oral Liquid (general) sections** confirmed vide letter No. F. 1-31/2011- Lic (M-235) dated 03-07-2013.
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
711.	Name and address of manufacturer / Applicant	M/s Hawk Bio Pharma Pvt Ltd. Plot # 10, Street # s-6, National Industrial Estate, RCCI, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	Wormout Suspension

	Composition	Each ml Contains: Triclabendazole…85mg Oxfendazole…22.65mg
	Diary No. Date of R& I & fee	Dy.No 11563 dated 16-04-2021 Rs.20,000/- dated 16-04-2021
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Z-Triox Oral Drench of M/s Zoic International, Lahore. (Reg. No.080933)
	GMP status	Last panel inspection was conducted on 19-11-2020 for the grant of renewal of DML.
	Remarks of the Evaluator [X]	**Veterinary oral Liquid (antibiotic) and Veterinary oral Liquid (general) sections** confirmed vide letter No. F. 1-31/2011- Lic (M-235) dated 03-07-2013.
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
712.	Name and address of manufacturer / Applicant	M/s Hawk Bio Pharma Pvt Ltd. Plot # 10, Street # s-6, National Industrial Estate, RCCI, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	Endoflush Drench
	Composition	Each ml contains: Triclabendazole…120mg Ivermectin…2mg Albendazole…100mg
	Diary No. Date of R& I & fee	Dy.No 12811 dated 03-05-2021 Rs.20,000/- dated 03-05-2021
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1000ml, and 2500ml; Decontrolled
	Me-too status	Anthalex Drench of M/s Wimits Pharmaceuticals, Lahore. (Reg. No. 078335)
	GMP status	Last panel inspection was conducted on 19-11-2020 for the grant of renewal of DML.
	Remarks of the Evaluator [X]	**Veterinary oral Liquid (antibiotic) and Veterinary oral Liquid (general) sections** confirmed vide letter No. F. 1-31/2011- Lic (M-235) dated 03-07-2013.
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
713.	Name and address of manufacturer / Applicant	M/s Elko Organization Pvt Ltd., Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Diarrex Oral Suspension
	Composition	Each ml contains: Sulphadiazine…35.5mg Sulphadimidine…38.4mg Neomycin Sulphate…1.8mg Hyoscine Methyl Bromide…0.04mg Vitamin B1…0.15mg Vitamin B2…0.22mg
	Diary No. Date of R& I & fee	Dy.No 15905 dated 08-06-2021 Rs.30,000/- dated 21-05-2021 (slip No. 76845003483)
	Pharmacological Group	Antidiarrheal

	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, and 200ml; Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	Last GMP inspection is conducted on 03-03-2021 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator [X]	• **Oral Liquid (General) Veterinary section** confirmed vide panel inspection dated 22-08-2022 report for grant of renewal of DML **Shortcomings:** • **Sulphadimidine…28.4mg** is mentioned throughout the dossier while **Sulphadimidine…38.4mg** is mentioned on Form-5; clarification is required for which strength you want to apply this dossier. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Firm shall submit fee of Rs.30000/- for correction in formulation, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Deferred for following: • **evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm** • **clarification regarding the applied strength since Sulphadimidine…28.4mg is mentioned throughout the dossier while Sulphadimidine…38.4mg is mentioned on Form-5. The Firm shall submit fee of Rs.30000/- for correction in formulation, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
714.	Name and address of manufacturer / Applicant	M/s Elko Organization Pvt Ltd., Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Panasafe Spray
	Composition	Each ml contains: Oxytetracycline HCl…40mg Gentian Violet…4mg Permethrin…10mg Citronella Oil…20mg
	Diary No. Date of R& I & fee	Dy.No 11969 dated 21-04-2021 Rs.20,000/- dated 21-04-2021
	Pharmacological Group	Antibacterial/ insect repellent
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	125ml; Decontrolled
	Me-too status	Tetragen-Fly Spray of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 088095)
	GMP status	Last GMP inspection is conducted on 03-03-2021 and the report concludes that firm was considered to be operating at good level of overall GMP compliance
	Remarks of the Evaluator [X]	• Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision: Deferred for confirmation of Spray Section (Veterinary) from the Licensing Division.	

	The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
715.	Name and address of manufacturer / Applicant	M/s Mallard Pharmaceuticals Pvt Ltd. 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	Fosfo Mall Powder
	Composition	Each gram contains: Calcium Fosfomycin…200mg Tylosin Tartrate…100mg Fructose…180mg Soidum Phosphate…150mg Magnesium Sulphate…100mg
	Diary No. Date of R& I & fee	Dy.No 14277 dated 26-05-2021 Rs.30,000/- dated 26-05-2021 (slip No. 5650704030)
	Pharmacological Group	Antibacterial/ electrolytes
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	2500gm, 1000gm, 500gm, 250gm, 100gm, 10gm; Decontrolled
	Me-too status	Fosfo-20 Oral Powder of M/s Evergreen Pharmaceuticals, Lahore. (Reg. No. 088861)
	GMP status	
	Remarks of the Evaluator [X]	**Powder (General) Section confirmed vide letter No. F. 1-14/2004-Lic dated 12-09-2007** • Latest GMP inspection report conducted within the period of last three years. • The reference formulation is **Each gm contains:** **Fosfomycin Calcium …200mg** **Tylosin as Tartrate…100mg** **Fructose 1,6 Diphosphate…180mg** **Sodium Phosphate…150mg** **Magnesium Sulphate…100mg** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved with following label claim. **Each gm contains:** **Fosfomycin Calcium …200mg** **Tylosin as Tartrate…100mg** **Fructose 1,6 Diphosphate…180mg** **Sodium Phosphate…150mg** **Magnesium Sulphate…100mg** **The firm shall submit the following before issuance of registration letter:** • **Latest GMP inspection report conducted within the period of last three years.** • **Fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
716.	Name and address of manufacturer / Applicant	M/s Mallard Pharmaceuticals Pvt Ltd. 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	Minto Mall Liquid
	Composition	Each ml contains: Bromhexine HCl…20mg Menthol…40mg

	Diary No. Date of R& I & fee	Dy.No 14278 dated 26-05-2021 Rs.30,000/- dated 26-05-2021 (slip No. 7454462751)
	Pharmacological Group	Expectorant
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 1000ml; Decontrolled
	Me-too status	Bromo-Plus Liquid of M/s Elegance Pharmaceutical, Chak Belli, Rawalpindi. (Reg. No. 073917)
	GMP status	
	Remarks of the Evaluator [X]	**Liquid (General) Section confirmed vide letter No. F. 1-14/2004-Lic dated 12-09-2007** **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit the following before issuance of registration letter. • **Latest GMP inspection report conducted within the period of last three years** • **Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**	
717.	Name and address of manufacturer / Applicant	M/s Mallard Pharmaceuticals Pvt Ltd. 23km, Lahore Road, Multan, Pakistan
	Brand Name +Dosage Form + Strength	Tilco Mal Liquid
	Composition	Each ml Contains: Tilmicosin…250mg
	Diary No. Date of R& I & fee	Dy.No 14279 dated 26-05-2021 Rs.30,000/- dated 26-05-2021 (slip No. 235475219)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	60ml, 120ml, 250ml, 500ml, 1000ml; Decontrolled
	Me-too status	Kptil Oral 25% Oral Liquid of M/s Krypton Pharma (Pvt) Ltd., Faisalabad. (Reg. No. 113415)
	GMP status	
	Remarks of the Evaluator [X]	**Liquid (General) Section confirmed vide letter No. F. 1-14/2004-Lic dated 12-09-2007** **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • The reference formulation is **Each ml Contains:** **Tilmicosin as Phosphate…250mg** • The firm shall submit full fee of Rs. 30,000/- for correction/pre-approval for change in salt form of product as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.
	Decision: Approved with following label claim. **Each ml Contains:** **Tilmicosin as Phosphate…250mg** **The firm shall submit the following before issuance of registration letter:** • **Latest GMP inspection report conducted within the period of last three years.** • **Fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
718.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Pflox-D Liquid

	Composition	Each ml Contains: Pefloxacin…100mg Methanesulfonate…139.60mg
	Diary No. Date of R& I & fee	Dy.No 18249 dated 29-06-2021 Rs.30,000/- dated 28-06-2021 (slip No. 4274634872)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml; Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	
	Remarks of the Evaluator [X]	• Approval of **Liquid Section** confirmed vide letter No.F. 1-26/93-Lic (Vol-I) (M-205) dated 30-04-2007. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for following: • **Latest GMP inspection report conducted within the period of last three years.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
719.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Predniphen Injection
	Composition	Each ml Contains: Prednisolone Acetate…10mg Chlorpheniramine Maleate…4mg
	Diary No. Date of R& I & fee	Dy.No 18244 dated 29-06-2021 Rs.30,000/- dated 28-06-2021 (slip No. 942549143218)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml, 20ml, 50ml, 100ml; Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Approval of **Liquid Injection Section (Steroid-Veterinary)** by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier. • Evidence of applied formulation/drug already approved by DRAP **with same pack size as applied** (generic / me-too

		status) along with registration number, brand name and name of firm.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
720.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Retol-D Injection
	Composition	Each ml contains: Vitamin A…100,000 IU Vitamin D3…40,000 IU Vitamin E…40mg
	Diary No. Date of R& I & fee	Dy.No 13733 dated 21-05-2021 Rs.30,000/- dated 20-05-2021 (slip No. 4277028295)
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml, 50ml, 100ml; Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	
	Remarks of the Evaluator [x]	• Approval of **Liquid Injection Section (General-Veterinary)** confirmed vide panel inspection report dated 29-11-18 and 01-01-2019, for issuance of GMP certificate. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier. • Evidence of applied formulation/drug already approved by DRAP **with same pack size as applied** (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for following: • **Latest GMP inspection report conducted within the period of last three years.** • **Evidence of applied formulation/drug already approved by DRAP with same pack size as applied (generic / me-too status) along with registration number, brand name and name of firm.** • **Choice of only one pack size** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
721.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Avitialin 12.5% Powder
	Composition	Each gram contains: Tiamulin Hydrogen Fumarate…12.5mg
	Diary No. Date of R& I & fee	Dy.No 18248 dated 29-06-2021 Rs.30,000/- dated 28-06-2021 (slip No. 136561905)
	Pharmacological Group	Anti-infective, Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications

	Pack size & Demanded Price	250gm, 500gm, 1000gm, 2500gm, 5000gm, 25000gm, 50000gm: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	
	Remarks of the Evaluator [X]	• Approval of **Powder Section (General)** confirmed vide letter No.F. 1-26/93-Lic (Vol-I) (M-205) dated 30-04-2007. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for following: • **Latest GMP inspection report conducted within the period of last three years.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
722.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Tiamulin Plus Powder
	Composition	Each gram contains: Tiamulin Hydrogen Fumarate eq. to Tiamulin Base…100mg Chlortetracycline HCl Eq. to Chlortetracycline…300mg
	Diary No. Date of R& I & fee	Dy.No 18243 dated 29-06-2021 Rs.30,000/- dated 28-06-2021 (slip No. 9232363454)
	Pharmacological Group	Anti-infective, Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 25000gm: Decontrolled
	Me-too status	Sb Tiaclor Oral Powder of M/s SB Pharma Kahuta Road Islamabad. (Reg. No. 048223)
	GMP status	
	Remarks of the Evaluator [X]	• Approval of **Powder Section (General)** confirmed vide letter No.F. 1-26/93-Lic (Vol-I) (M-205) dated 30-04-2007. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
723.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Set Vet Powder
	Composition	Each gram Contains: Erythromycin Thiocyanate…100mg Trimethoprim…20mg Sulphadiazine as Sodium…100mg
	Diary No. Date of R& I & fee	Dy.No 18245 dated 29-06-2021 Rs.30,000/- dated 28-06-2021(slip No. 8894978061)

	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm, 2500gm, 5000gm: Decontrolled
	Me-too status	Erythroprim-S Water Soluble Powder of M/s ICI Pakistan Limited, Life Sciences, Lahore.(Reg. No. 081728)
	GMP status	
	Remarks of the Evaluator [X]	• Approval of **Powder Section (General)** confirmed vide letter No.F. 1-26/93-Lic (Vol-I) (M-205) dated 30-04-2007. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
724.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Avoxicillin 20% Plus Powder
	Composition	Each gram Contains: Amoxicillin Trihydrate…200mg Colistin Sulphate…800000 IU
	Diary No. Date of R& I & fee	Dy.No 18246 dated 29-06-2021 Rs.30,000/- dated 28-06-2021 (slip No. 31476368946)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	250gm, 500gm, 1000gm, 2500gm, 5000gm, 25000gm, 50000gm: Decontrolled
	Me-too status	Polimox Water Soluble Powder of M/s Biogen Pharma, Rawat Chak Beli Road, Rawat (Reg. No. 071017)
	GMP status	
	Remarks of the Evaluator [X]	• Approval of **Powder Section (Penicillin)** confirmed vide panel inspection dated 25-02-2020 for renewal of DML. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • The reference formulation is **Each gram contains:** **Amoxicillin as Trihydrate…200mg** **Colistin Sulphate…800000 IU** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved with following label claim: **Each gram contains:** **Amoxicillin as Trihydrate…200mg** **Colistin Sulphate…800000 IU** **The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 30,000/- for correction/pre-approval change in formulation and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
725.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad

	Brand Name +Dosage Form + Strength	Bromoxy Col-D Powder
	Composition	Each gram Contains: Amoxicillin Trihydrate…100mg Lincomycin HCl…50mg Colistin Sulphate…500000 IU Bromhexine HCl…5mg
	Diary No. Date of R& I & fee	Dy.No 18241 dated 29-06-2021 Rs.30,000/- dated 28-06-2021 (slip No. 20292461)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm, 2500gm, 5000gm: Decontrolled
	Me-too status	Cal-Bro Water Soluble Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 113586)
	GMP status	
	Remarks of the Evaluator [x]	• Approval of **Powder Section (Penicillin)** confirmed vide panel inspection dated 25-02-2020 for renewal of DML. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • The reference formulation is **Each gram Contains:** **Amoxicillin as Trihydrate…100mg** **Lincomycin as HCl…50mg** **Colistin Sulphate…500000 IU** **Bromhexine HCl…5mg** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved with following label claim: **Each gram Contains:** **Amoxicillin as Trihydrate…100mg** **Lincomycin as HCl…50mg** **Colistin Sulphate…500000 IU** **Bromhexine HCl…5mg** **The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
726.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Avolincicin Star Powder
	Composition	Each gram Contains: Zinc Bacitracin…100mg Lincomycin HCl…50mg
	Diary No. Date of R& I & fee	Dy.No 13737 dated 21-05-2021 Rs.30,000/- dated 20-05-2021 (slip No. 139259213)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1000gm, 2500gm, 5000gm, 25000gm, 40000gm: Decontrolled
	Me-too status	ZL-150 Feed Premix Powder of M/s Intervac (Pvt) Ltd. Sheikhupura (Reg. No. 069663)
	GMP status	

	Remarks of the Evaluator [X]	• Approval of **Powder Section (General)** confirmed vide letter No.F. 1-26/93-Lic (Vol-I) (M-205) dated 30-04-2007. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
727.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Avilosin 10 Powder
	Composition	Each gram Contains: Tylosin Phosphate…100mg
	Diary No. Date of R& I & fee	Dy.No 13734 dated 21-05-2021 Rs.30,000/- dated 20-05-2021 (slip No. 9877444354)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1000gm, 2500gm, 5000gm, 25000gm, 40000gm: Decontrolled
	Me-too status	Lincomiks 10 Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113518)
	GMP status	
	Remarks of the Evaluator [X]	• Approval of **Powder Section (General)** confirmed vide letter No.F. 1-26/93-Lic (Vol-I) (M-205) dated 30-04-2007. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter..	
728.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Avi-Zincitracin 10% Powder
	Composition	Each gram Contains: Zinc Bacitracin…100mg
	Diary No. Date of R& I & fee	Dy.No 13735 dated 21-05-2021 Rs.30,000/- dated 20-05-2021 (slip No. 8376320626)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1000gm, 2500gm, 5000gm, 25000gm, 40000gm: Decontrolled
	Me-too status	Bio ZBC 100mg Powder of M/s Bio-Labs (Pvt) Ltd., Islamabad. (Reg. No.112172)
	GMP status	
	Remarks of the Evaluator [X]	• Approval of **Powder Section (General)** confirmed vide letter No.F. 1-26/93-Lic (Vol-I) (M-205) dated 30-04-2007. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished	

	product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
729.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Avifos 25% Powder
	Composition	Each gram contains: Fosfomycin Calcium…250mg
	Diary No. Date of R& I & fee	Dy.No 13736 dated 21-05-2021 Rs.30,000/- dated 20-05-2021 (slip No. 484006029)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	250gm, 500gm, 1000gm, 2500gm, 5000gm: Decontrolled
	Me-too status	Fosvet Premix Powder of M/s Epla Labs Karachi (Reg. No. 025722)
	GMP status	
	Remarks of the Evaluator [X]	• Approval of **Powder Section (General)** confirmed vide letter No.F. 1-26/93-Lic (Vol-I) (M-205) dated 30-04-2007. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
730.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Avi-Maduracin Powder
	Composition	Each gram contains: Maduramycin…100mg
	Diary No. Date of R& I & fee	Dy.No 18250 dated 29-06-2021 Rs.30,000/- dated 28-06-2021 (slip No. 30294162)
	Pharmacological Group	Antiprotozoal, anticoccidial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1000gm, 2500gm, 5000gm, 25000gm, 40000gm: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	
	Remarks of the Evaluator [X]	• Approval of **Powder Section (General)** confirmed vide letter No.F. 1-26/93-Lic (Vol-I) (M-205) dated 30-04-2007. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Latest GMP inspection report conducted within the period of last three years.**	

	The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
731.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Avi-Nicarzin 25% Premix
	Composition	Each gram contains: Nicarbazin…250mg
	Diary No. Date of R& I & fee	Dy.No 18251 dated 29-06-2021 Rs.30,000/- dated 28-06-2021 (slip No. 6300919856)
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1000gm, 2500gm, 5000gm, 25000gm, 40000gm: Decontrolled
	Me-too status	Cocciban Powder of M/s Medi -Vet (Pvt) Ltd Lahore. (Reg. No. 026577)
	GMP status	
	Remarks of the Evaluator [X]	• Approval of **Powder Section (General)** confirmed vide letter No.F. 1-26/93-Lic (Vol-I) (M-205) dated 30-04-2007. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
732.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Avi-Clazuril Premix
	Composition	Each gram contains: Diclazuril…50mg
	Diary No. Date of R& I & fee	Dy.No 18252 dated 29-06-2021 Rs.30,000/- dated 28-06-2021 (slip No. 38488539368)
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1000gm, 2500gm, 5000gm, 25000gm, 40000gm: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	
	Remarks of the Evaluator [X]	• Approval of **Powder Section (General)** confirmed vide letter No.F. 1-26/93-Lic (Vol-I) (M-205) dated 30-04-2007. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Latest GMP inspection report conducted within the period of last three years.**	

	The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
733.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Avialinc 11 Powder
	Composition	Each gram Contains: Lincomycin HCl…110mg
	Diary No. Date of R& I & fee	Dy.No 13738 dated 21-05-2021 Rs.30,000/- dated 20-05-2021 (slip No. 455497425079)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1000gm, 2500gm, 5000gm, 25000gm, 40000gm: Decontrolled
	Me-too status	Linco-Mix 11 Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 113523)
	GMP status	
	Remarks of the Evaluator [X]	• Approval of **Powder Section (General)** confirmed vide letter No.F. 1-26/93-Lic (Vol-I) (M-205) dated 30-04-2007. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • The reference formulation is **Each gram contains:** **Lincomycin as HCl…110mg** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved with following label claim: **Each gram contains:** **Lincomycin as HCl…110mg** **The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 30,000/- for correction/pre-approval change in formulation and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
734.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Oxytocin Injection (5 IU/ml) 100ml
	Composition	Each ml contains: Oxytocin…5 IU
	Diary No. Date of R& I & fee	Form-5 Dy.No 12762 dated 30-04-2021 Rs.20,000/- dated 30-04-2021
	Pharmacological Group	Hormone
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Oxytox Injection 5 I.U. (100ml) of M/s Rex Pharmaceutical Pakistan, Karachi. (Reg. No. 035122)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	**Injectable Hormone (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. **Shortcomings:**

		• Provide conversion of Oxytocin from IU to grams
	Decision: Approved. The firm shall submit conversion of Oxytocin from IU to grams and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
735.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Oxytocin Injection (5 IU/ml) 250ml
	Composition	Each ml Contains: Oxytocin…5 IU
	Diary No. Date of R& I & fee	Dy.No 12764 dated 30-04-2021 Rs.20,000/- dated 30-04-2021
	Pharmacological Group	Hormone
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	250ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied pack size**
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of **Liquid Injectable Hormone (LVP) (Veterinary)** Section by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Provide conversion of Oxytocin from IU to grams • Evidence of applied formulation/drug already approved by DRAP **with same pack size as applied** (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Confirmation of Liquid Injectable Hormone (LVP) (Veterinary) from the Licensing Division.** • **Conversion of Oxytocin from IU to grams** • **Evidence of applied formulation/drug already approved by DRAP with same pack size as applied (generic / me-too status) alongwith registration number, brand name and name of firm.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
736.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Oxytocin Injection (5 IU/ml) 50ml
	Composition	Each ml Contains: Oxytocin…5 IU
	Diary No. Date of R& I & fee	Dy.No 12760 dated 30-04-2021 Rs.20,000/- dated 30-04-2021
	Pharmacological Group	Hormone
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Oxitocin Injection (50ml) of M/s International Pharma Labs, Lahore. (Reg. No. 074759)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	**Injectable Hormone (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.

		Shortcomings: • Provide conversion of Oxytocin from IU to grams
	Decision: Approved. The firm shall submit conversion of Oxytocin from IU to grams and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
737.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Oxytocin Injection (20 IU/ml) 100ml
	Composition	Each ml Contains: Oxytocin…20 IU
	Diary No. Date of R& I & fee	Dy.No 12763 dated 30-04-2021 Rs.20,000/- dated 30-04-2021
	Pharmacological Group	Hormone
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Oxytovetz Injection (100ml) of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 111472)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	**Injectable Hormone (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. **Shortcomings:** • Provide conversion of Oxytocin from IU to grams
	Decision: Approved. The firm shall submit conversion of Oxytocin from IU to grams and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
738.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Oxytocin Injection (20 IU/ml) 250ml
	Composition	Each ml Contains: Oxytocin…20 IU
	Diary No. Date of R& I & fee	Dy.No 12765 dated 30-04-2021 Rs.20,000/- dated 30-04-2021
	Pharmacological Group	Hormone
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	250ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied pack size**
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of **Liquid Injectable Hormone LVP (Veterinary) Section** by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Provide conversion of Oxytocin from IU to grams • Evidence of applied formulation/drug already approved by DRAP **with same pack size as applied** (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Confirmation of Liquid Injectable Hormone (LVP) (Veterinary) Section from the Licensing Division.** • **Conversion of Oxytocin from IU to grams**	

	• **Evidence of applied formulation/drug already approved by DRAP with same pack size as applied (generic / me-too status) alongwith registration number, brand name and name of firm.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
739.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Oxytocin Injection (20 IU/ml) 50ml
	Composition	Each ml Contains: Oxytocin…20 IU
	Diary No. Date of R& I & fee	Dy.No 12761 dated 30-04-2021 Rs.20,000/- dated 30-04-2021
	Pharmacological Group	Hormone
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied pack size**
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	**Injectable Hormone (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. **Shortcomings:** • Provide conversion of Oxytocin from IU to grams • Evidence of applied formulation/drug already approved by DRAP **with same pack size as applied** (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Conversion of Oxytocin from IU to grams** • **Evidence of applied formulation/drug already approved by DRAP with same pack size as applied (generic / me-too status) alongwith registration number, brand name and name of firm.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
740.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Ishepa Injection 100ml
	Composition	Each ml contains: Phenoxy-2 Methyl-2 Propionic Acid…100mg
	Diary No. Date of R& I & fee	Dy.No 18258 dated 29-06-2021 Rs.30,000/- dated 15-06-2021 (slip No. 7373464612)
	Pharmacological Group	Appetizer
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Levo Rold Liquid Injection (100ml) of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. No. 109281)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.

	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
741.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Ishepa Injection 50ml
	Composition	Each ml contains: Phenoxy-2 Methyl-2 Propionic Acid…100mg
	Diary No. Date of R& I & fee	Dy.No 18256 dated 29-06-2021 Rs.30,000/- dated 15-06-2021 (slip No. 19327175621)
	Pharmacological Group	Appetizer
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Levo Rold Liquid Injection (50ml) of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. No. 109280)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
742.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Ishepa Injection 10ml
	Composition	Each ml contains: Phenoxy-2 Methyl-2 Propionic Acid…100mg
	Diary No. Date of R& I & fee	Dy.No 18255 dated 29-06-2021 Rs.30,000/- dated 15-06-2021 (slip No. 5696713681)
	Pharmacological Group	Appetizer
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Bio-Hepa Injection (10ml) of M/s Biorise Pharmaceuticals, Multan. (Reg. No. 112181)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
743.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Lasid Injection 10ml
	Composition	Each ml Contains: Furosemide…50mg
	Diary No. Date of R& I & fee	Dy.No 18254 dated 29-06-2021 Rs.30,000/- dated 14-06-2021 (slip No. 0882423856)
	Pharmacological Group	Diuretic
	Type of Form	Form 5

	Finished product Specification	BP specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Frusicon Injection (10ml) of M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi. (Reg. No. 049685)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. **Shortcomings:** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
744.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Lasid Injection 100ml
	Composition	Each ml Contains: Furosemide…50mg
	Diary No. Date of R& I & fee	Dy.No 18257 dated 29-06-2021 Rs.30,000/- dated 14-06-2021 (slip No. 431672259)
	Pharmacological Group	Diuretic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Frusicon Injection (100ml) of M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi. (Reg. No. 049685)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. **Shortcomings:** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
745.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Lasid Injection 50ml
	Composition	Each ml Contains: Furosemide…50mg
	Diary No. Date of R& I & fee	Dy.No 18254 dated 29-06-2021 Rs.30,000/- dated 14-06-2021 (slip No. 4058447505)
	Pharmacological Group	Diuretic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Frusicon Injection (50ml) of M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi. (Reg. No. 049685)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.

	Remarks of the Evaluator [X]	**Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021. **Shortcomings:** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved. The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
746.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Ispine Injection 100ml
	Composition	Each ml Contains: Atropine Sulphate…1mg
	Diary No. Date of R& I & fee	Dy.No 18260 dated 29-06-2021 Rs.30,000/- dated 14-06-2021 (slip No. 2660132564)
	Pharmacological Group	Antispasmodic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Zatropin Injection (100ml) of M/s Zakfas Pharmaceuticals (Pvt) Ltd. Multan (Reg. No.052324)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Approved.	
747.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Ispine Injection 10ml
	Composition	Each ml Contains: Atropine Sulphate…1mg
	Diary No. Date of R& I & fee	Dy.No 18261 dated 29-06-2021 Rs.30,000/- dated 14-06-2021 (slip No. 677702289321)
	Pharmacological Group	Antispasmodic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Zatropin Injection (10ml) of M/s Zakfas Pharmaceuticals (Pvt) Ltd. Multan (Reg. No.052324)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Approved.	
748.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Ispine Injection 50ml
	Composition	Each ml Contains: Atropine Sulphate…1mg
	Diary No. Date of R& I & fee	Dy.No 18262 dated 29-06-2021 Rs.30,000/- dated 14-06-2021 (slip No. 010354482393)

	Pharmacological Group	Antispasmodic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Zatropin Injection (50ml) of M/s Zakfas Pharmaceuticals (Pvt) Ltd. Multan (Reg. No.052324)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	**Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Approved.	
749.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Isflor Injection 50ml
	Composition	Each ml contains: Florfenicol…100mg
	Diary No. Date of R& I & fee	Dy.No 18264 dated 29-06-2021 Rs.30,000/- dated 15-06-2021 (slip No. 7452777534)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Vetz specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Florobak Injection (50ml) of M/s Attabak Pharmaceuticals Islamabad (Reg. No. 063838)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
750.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Isflor Injection 10ml
	Composition	Each ml contains: Florfenicol…100mg
	Diary No. Date of R& I & fee	Dy.No 18259 dated 29-06-2021 Rs.30,000/- dated 15-06-2021 (slip No. 0191006540)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Vetz specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Florobak Injection (10ml) of M/s Attabak Pharmaceuticals Islamabad (Reg. No. 063838)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
751.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.

	Brand Name +Dosage Form + Strength	Isflor Injection 100ml
	Composition	Each ml contains: Florfenicol…100mg
	Diary No. Date of R& I & fee	Dy.No 18263 dated 29-06-2021 Rs.30,000/- dated 15-06-2021 (slip No. 365035651357)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Vetz specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Florobak Injection (100ml) of M/s Attabak Pharmaceuticals Islamabad (Reg. No. 063838)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
752.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Ismecam Injection 100ml
	Composition	Each ml contains: Meloxicam…10mg
	Diary No. Date of R& I & fee	Dy.No 18265 dated 29-06-2021 Rs.30,000/- dated 15-06-2021 (slip No. 37676718063)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Mecam 10 Injection (100ml) of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK (Reg. No. 113566)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Approved.	
753.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Ismecam Injection 10ml
	Composition	Each ml contains: Meloxicam…10mg
	Diary No. Date of R& I & fee	Dy.No 18266 dated 29-06-2021 Rs.30,000/- dated 15-06-2021 (slip No. 5114768844)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Mylarise-1% Injection (10ml) of M/s Biorise Pharmaceuticals, Multan. (Reg. No.111194)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.

	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Approved.	
754.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Ismecam Injection 50ml
	Composition	Each ml contains: Meloxicam…10mg
	Diary No. Date of R& I & fee	Dy.No 18267 dated 29-06-2021 Rs.30,000/- dated 15-06-2021 (slip No. 508187741)
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Melo Grand 10 Injection (50ml) of M/s Grand Pharma (Pvt) Ltd., Islamabad. (Reg. No. 111553)
	GMP status	Inspection conducted on 03-02-2022 concluded good level of GMP compliance.
	Remarks of the Evaluator [X]	• **Liquid Injection (Veterinary)** section confirmed vide letter No. F. 2-11/2005-Lic (Vol-I) dated 15-06-2021.
	Decision: Approved.	
755.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries, Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Fentin Liquid
	Composition	Each ml contains: Florfenicol…250mg Colistin Sulphate…500000 IU
	Diary No. Date of R& I & fee	Dy.No 16120 dated 10-06-2021 Rs.30,000/- dated 09-06-2021 (slip No. 3585998190)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml; Decontrolled
	Me-too status	Flocol Liquid of M/s D-Maarson Pharmaceuticals, Rawat, Islamabad (Reg. No.074082)
	GMP status	cGMP certificate dated 30-04-2021 based on inspection conducted on 15-04-2021.
	Remarks of the Evaluator [X]	• **Liquid Section(General) (Veterinary)** confirmed vide panel inspection report based on inspection conducted on 31-03-2021 & 08-04-2021 for renewal of DML
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
756.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries, Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Kalvin B Suspension
	Composition	Each ml contains: Suphadiazine…35.500mg Sulphadimidine…28.400mg Neomycin Sulphate…1.800mg Hyoscine Methyl Bromide…0.040mg

		Pectin…7.100mg Kaolin…103.300mg Vitamin B1…0.150mg Vitamin B2…0.220mg
	Diary No. Date of R& I & fee	Dy.No 16121 dated 10-06-2021 Rs.30,000/- dated 09-06-2021 (slip No. 8220396184)
	Pharmacological Group	Antibiotic, Antidiarrheal, vitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml, 10000ml; Decontrolled
	Me-too status	Ever-X Suspension of M/s Evergreen Pharmaceuticals, Lahore (Reg. No. 072691)
	GMP status	cGMP certificate dated 30-04-2021 based on inspection conducted on 15-04-2021.
	Remarks of the Evaluator [X]	• **Liquid Section(General) (Veterinary)** confirmed vide panel inspection report based on inspection conducted on 31-03-2021 & 08-04-2021 for renewal of DML
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
757.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries, Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Tolprim Liquid
	Composition	Each ml Contains: Toltrazuril…25mg Trimethoprim…5mg
	Diary No. Date of R& I & fee	Dy.No 15135 dated 01-06-2021 Rs.30,000/- dated 31-05-2021 (slip No. 2774898646)
	Pharmacological Group	Anticoccidial, Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 150ml, 500ml, 1000ml, 2500ml, 5000ml,10000ml; Decontrolled
	Me-too status	Truecox Oral of M/s Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur. (Reg. No.073902)
	GMP status	cGMP certificate dated 30-04-2021 based on inspection conducted on 15-04-2021.
	Remarks of the Evaluator [X]	• **Liquid Section(General) (Veterinary)** confirmed vide panel inspection report based on inspection conducted on 31-03-2021 & 08-04-2021 for renewal of DML
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
758.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries, Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Sha-Colic Liquid
	Composition	Each ml contains: Oxolinic Acid…100mg
	Diary No. Date of R& I & fee	Dy.No 16123 dated 10-06-2021 Rs.30,000/- dated 09-06-2021 (slip No. 60472716605)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications

	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml; Decontrolled
	Me-too status	Vety Oxol Liquid of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No.046668)
	GMP status	cGMP certificate dated 30-04-2021 based on inspection conducted on 15-04-2021.
	Remarks of the Evaluator [X]	• **Liquid Section(General) (Veterinary)** confirmed vide panel inspection report based on inspection conducted on 31-03-2021 & 08-04-2021 for renewal of DML
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
759.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries, Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Tolmin-K Liquid
	Composition	Each ml Contains: Toltrazuril…25mg Vitamin K3…3mg
	Diary No. Date of R& I & fee	Dy.No 15137 dated 01-06-2021 Rs.30,000/- dated 31-05-2021 (slip No. 590815709)
	Pharmacological Group	Anticoccidial/ Anticoagulant
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml; Decontrolled
	Me-too status	Tolmars Liquid of M/s D-Maarson Pharmaceuticals, Rawat, Islamabad (Reg. No.075746)
	GMP status	cGMP certificate dated 30-04-2021 based on inspection conducted on 15-04-2021.
	Remarks of the Evaluator [X]	• **Liquid Section(General) (Veterinary)** confirmed vide panel inspection report based on inspection conducted on 31-03-2021 & 08-04-2021 for renewal of DML
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
760.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries, Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Prolin Powder
	Composition	Each gram contains: Amprolium HCl…500mg
	Diary No. Date of R& I & fee	Dy.No 16122 dated 10-06-2021 Rs.30,000/- dated 09-06-2021(slip No. 239451828)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm,1000gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Amrotech Powder of M/s Biorific Pharma, Islamabad. (Reg. No. 093619)
	GMP status	cGMP certificate dated 30-04-2021 based on inspection conducted on 15-04-2021.
	Remarks of the Evaluator [X]	• **Oral Powder (General) Section (Veterinary)** confirmed vide panel inspection report based on inspection conducted on 31-03-2021 & 08-04-2021 for renewal of DML

	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
761.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries, Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Hyclo-Dox Powder
	Composition	Each gm Powder Contains: Doxycycline Hyclate…500mg
	Diary No. Date of R& I & fee	Dy.No 15138 dated 01-06-2021 Rs.30,000/- dated 31-05-2021 (slip No. 5085584265)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm,1000gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Dox Plus 50% Water Soluble Powder of M/s Bio-Labs (Pvt) Ltd., Islamabad (Reg. No. 082498)
	GMP status	cGMP certificate dated 30-04-2021 based on inspection conducted on 15-04-2021.
	Remarks of the Evaluator [X]	• **Oral Powder (General) Section (Veterinary)** confirmed vide panel inspection report based on inspection conducted on 31-03-2021 & 08-04-2021 for renewal of DML
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
762.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries, Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Tetrafin Powder
	Composition	Each gram contains: Oxytetracycline HCl…30% Florfenicol…30%
	Diary No. Date of R& I & fee	Dy.No 16119 dated 10-06-2021 Rs.30,000/- dated 09-06-2021 (slip No. 902470820588)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm,1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Ampronil-50 Oral Powder of M/s Westmont Pharmaceutical Industry, Gujar Khan, Distt. Rawalpindi (Reg. No. 063747)
	GMP status	cGMP certificate dated 30-04-2021 based on inspection conducted on 15-04-2021.
	Remarks of the Evaluator [X]	• **Oral Powder (General) Section (Veterinary)** confirmed vide panel inspection report based on inspection conducted on 31-03-2021 & 08-04-2021 for renewal of DML
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
763.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries, Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Fosfo-In Powder
	Composition	Each gram contains:

		Fosfomycin Calcium…200mg Tylosin Tartrate…50mg Fructose 1,6 Diphosphate…180mg Sodium Phosphate…150mg Magnesium Phosphate…100mg Sodium Chloride q.s.…1000mg
	Diary No. Date of R& I & fee	Dy.No 15136 dated 01-06-2021 Rs.30,000/- dated 31-05-2021 (slip No. 827925786524)
	Pharmacological Group	Antimicrobial, antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm,1000gm, 2500gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Fofact Powder of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No.075626)
	GMP status	cGMP certificate dated 30-04-2021 based on inspection conducted on 15-04-2021.
	Remarks of the Evaluator [x]	**Oral Powder (General) Section (Veterinary)** confirmed vide panel inspection report based on inspection conducted on 31-03-2021 & 08-04-2021 for renewal of DML • The reference formulation is **Each gram contains:** **Fosfomycin Calcium …200mg** **Tylosin as Tartrate…50mg** **Fructose 1,6 Diphosphate…180mg** **Sodium Phosphate…150mg** **Magnesium Phosphate…100mg** **Sodium Chloride q.s…1000mg** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved with following label claim. **Each gram contains:** **Fosfomycin Calcium …200mg** **Tylosin as Tartrate…50mg** **Fructose 1,6 Diphosphate…180mg** **Sodium Phosphate…150mg** **Magnesium Phosphate…100mg** **Sodium Chloride q.s…1000mg** **The firm shall submit fee of Rs.30000/- for correction in formulation (salt form) and finished product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
764.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Vital Forte Injection 50ml
	Composition	Each ml contains: Vitamin A…100,000 IU Vitamin D3…40,000 IU Vitamin E…40mg
	Diary No. Date of R& I & fee	Dy.No 16761 dated 16-06-2021 Rs.30,000/- dated 10-06-2021 (slip No. 7003236989)
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled

	Me-too status	ADE-Max Injection (50ml) of M/s Nawan Laboratories (Pvt) Ltd, Karachi (Reg. No. 058990)
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator [X]	**Injectable vial (General) Veterinary section** confirmed vide cGMP certificate based upon evaluation conducted on 24-01-2023 and 25-01-2023
	Decision: Approved.	
765.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Bro-Enc 10% Liquid
	Composition	Each ml contains: Enrofloxacin…100mg Colistin Sulphate…500000 IU
	Diary No. Date of R& I & fee	Dy.No 16765 dated 16-06-2021 Rs.30,000/- dated 14-06-2021 (slip No. 6478438358)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml: Decontrolled
	Me-too status	Enrocol 10% Liquid of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 046656)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Oral Liquid (Veterinary) section** confirmed vide letter No. F. 1-31/2010-Lic dated 01-08-2012.
	Decision: Approved.	
766.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Brotil-30 Injection 500ml
	Composition	Each ml Contains: Tilmicosin…300mg
	Diary No. Date of R& I & fee	Dy.No 16767 dated 16-06-2021 Rs.30,000/- dated 14-06-2021 (slip No. 031810452211)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	500ml: Decontrolled
	Me-too status	Tilcolina Injection (500ml) of M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi (Reg. No.049674)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	**Shortcomings:** • Approval of Injectable LVP (General) Veterinary section by CLB • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Deferred for following: • **Confirmation of Injectable LVP (General) Veterinary section from the Licensing Division.** • **Fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	

	The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
767.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Brolinc-40 Powder
	Composition	Each gram contains: Lincomycin HCl Eq. to Lincomycin…400mg
	Diary No. Date of R& I & fee	Dy.No 16762 dated 16-06-2021 Rs.30,000/- dated 14-06-2021 (slip No. 6761419455)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	500gm,1000gm, 2500gm; Decontrolled
	Me-too status	Lincosel-40 Oral Powder of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No.089826)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Dry powder suspension (General) section** confirmed vide letter No. F. 1-31/2010-Lic dated 25-11-2016.
	Decision: Approved.	
768.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Bro-Ft 20 Powder
	Composition	Each gram contains: Calcium Fosfomycin…20% Tylosin Tartrate…5%
	Diary No. Date of R& I & fee	Dy.No 16763 dated 16-06-2021 Rs.30,000/- dated 14-06-2021 (slip No. 028686167)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	200gm, 1000gm, 5000gm, 40000gm; Decontrolled
	Me-too status	Sinfos Oral Powder of M/s Neotech Pharmaceuticals (Pvt) Ltd. Chak Hinda Kamoke. (Reg. No. 111426)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Dry powder suspension (General) section** confirmed vide letter No. F. 1-31/2010-Lic dated 25-11-2016. **Shortcomings:** • The reference formulation is **Each gram contains:** **Fosfomycin Calcium …200mg** **Tylosin as Tartrate…50mg** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved with following label claim: **Each gram contains:** **Fosfomycin Calcium …200mg** **Tylosin as Tartrate…50mg**	

	The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
769.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Dropsynil Powder
	Composition	Each gram contains: Oxytetracycline HCl…200mg Neomycin Sulphate…300mg
	Diary No. Date of R& I & fee	Dy.No 16768 dated 16-06-2021 Rs.30,000/- dated 14-06-2021 (slip No. 48602689781)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm; Decontrolled
	Me-too status	Tetrin-Neo Powder of M/s Univet Pharmaceuticals (Pvt) Ltd., Rawalpindi. (Reg. No. 034599)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Dry powder suspension (General) section** confirmed vide letter No. F. 1-31/2010-Lic dated 25-11-2016.
	Decision: Approved.	
770.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Proliam Oral Powder
	Composition	Each gram contains: Amprolium HCl…200mg Ethopabate…20mg
	Diary No. Date of R& I & fee	Dy.No 16766 dated 16-06-2021 Rs.30,000/- dated 14-06-2021 (slip No. 21899575)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm; Decontrolled
	Me-too status	Ethoprol Powder of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 049617)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Dry powder suspension (General) section** confirmed vide letter No. F. 1-31/2010-Lic dated 25-11-2016.
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
771.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	D-Dox 20 Powder
	Composition	Each gram Contains: Doxycycline Hyclate…200mg Tylosin Tartrate…100mg Colistin Sulphate…25mg Bromhexine HCl…5mg

	Diary No. Date of R& I & fee	Dy.No 16764 dated 16-06-2021 Rs.30,000/- dated 14-06-2021 (slip No. 166111741285)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm; Decontrolled
	Me-too status	Tycoon-D Water Soluble Powder of M/s Wimits Pharmaceuticals, Lahore (Reg. No. 078315)
	GMP status	Inspection conducted on 11-03-2022 concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [X]	• **Dry powder suspension (General) section** confirmed vide letter No. F. 1-31/2010-Lic dated 25-11-2016. **Shortcomings:** • The reference formulation is **Each gram Contains:** **Doxycycline Hyclate…200mg** **Tylosin as Tartrate…100mg** **Colistin Sulphate…25mg** **Bromhexine HCl…5mg** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved with following label claim: **Each gram Contains:** **Doxycycline Hyclate…200mg** **Tylosin as Tartrate…100mg** **Colistin Sulphate…25mg** **Bromhexine HCl…5mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
772.	Name and address of manufacturer / Applicant	M/s Noble Pharma, Plot No. B-1 Old Industrial Area, Mirpur, Azad Kashmir
	Brand Name +Dosage Form + Strength	Nobitox Oral Powder
	Composition	Each gram contains: Sodium Benzoate…500mg Ethanol Beta Amino Phosphoric Acid…100mg Vitamin A…10,000, IU Vitamin E…2.5mg Vitamin K3…1mg Vitamin C…2.5mg
	Diary No. Date of R& I & fee	Dy.No 14110 dated 25-05-2021 Rs.30,000/- dated 25-05-2021 (slip No. 51063527174)
	Pharmacological Group	Antibacterial/ diuretic
	Type of Form	Form 5
	Finished product Specification	Inhouse specifications
	Pack size & Demanded Price	100gm,250gm, 500gm, 1000gm; Decontrolled
	Me-too status	Antitox Water Soluble Powder of M/s Cherry Pharmaceutica, Lahore. (Reg. No.044924)
	GMP status	Panel inspection of M/s Noble Pharma, Azad Kashmir has been carried out on 09-02-2022. **It was observed to do a lot of improvements in HVAC, Pharmaceutical Quality systems including documentation and other quality related areas. The firm submitted improvements in these areas**. A detailed

		report would be submitted later on after verification of same through onsite inspection.
	Remarks of the Evaluator [X]	• **Veterinary Oral Powder (General)** section confirmed vide letter No.F. 5-2/2007-Lic dated 08-07-2015 **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Provide conversion of Vitamin A from IU to grams.
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **Latest GMP inspection report conducted within the period of last three years** • **Conversion of Vitamin A from IU to grams.** • **Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
773.	Name and address of manufacturer / Applicant	M/s Noble Pharma, Plot No. B-1 Old Industrial Area, Mirpur, Azad Kashmir
	Brand Name +Dosage Form + Strength	Nobiflor-C 25% Solution
	Composition	Each ml contains: Florfenicol…250mg Colistin Sulphate…50000 IU
	Diary No. Date of R& I & fee	Dy.No 18239 dated 29-06-2021 Rs.30,000/- dated 29-06-2021 (slip No. 51063527174)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Inhouse specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	Panel inspection of M/s Noble Pharma, Azad Kashmir has been carried out on 09-02-2022. **It was observed to do a lot of improvements in HVAC, Pharmaceutical Quality systems including documentation and other quality related areas. The firm submitted improvements in these areas. A detailed report would be submitted later on after verification of same through onsite inspection.**
	Remarks of the Evaluator [X]	Approval of **Veterinary Oral Liquid (General)** section confirmed vide letter No.F. 5-2/2007-Lic dated 08-07-2015. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Provide conversion of Colistin Sulphate from IU to grams. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Latest GMP inspection report conducted within the period of last three years.** • **Provide conversion of Colistin Sulphate from IU to grams.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
774.	Name and address of manufacturer / Applicant	M/s Noble Pharma, Plot No. B-1 Old Industrial Area, Mirpur, Azad Kashmir

	Brand Name +Dosage Form + Strength	Nobihepa Injection
	Composition	Each 100ml Solution Contains: Phenoxy-2-Methyl-2-prpionic acid…10gm
	Diary No. Date of R& I & fee	Dy.No 18238 dated 29-06-2021 Rs.30,000/- dated 29-06-2021 (slip No. 44094410)
	Pharmacological Group	Indigestion, Alimentary toxicosis, Ketosis, hepatic failure, inappetence, tympany, as an adjuvant in specific therapy of gestor-intestinal parasitism
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml vial: Decontrolled
	Me-too status	Hepagen -Injectable Solution (100ml, 50ml) of M/s Prix Pharmaceutical Lahore. (Reg. No. 012896)
	GMP status	Panel inspection of M/s Noble Pharma, Azad Kashmir has been carried out on 09-02-2022. **It was observed to do a lot of improvements in HVAC, Pharmaceutical Quality systems including documentation and other quality related areas. The firm submitted improvements in these areas. A detailed report would be submitted later on after verification of same through onsite inspection.**
	Remarks of the Evaluator [x]	Approval of **Veterinary Liquid Vial injection (General)** section confirmed vide letter No.F. 5-2/2007-Lic dated 08-07-2015. **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • The firm shall submit fee of Rs. 7500/- for correction/pre-approval change in pharmacological group as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter. • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, both 50ml and 100ml pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier.
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **Latest GMP inspection report conducted within the period of last three years** • **Choice of only one pack size** • **Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
775.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd. 21 Km, Ferozpur Road, Lahore.
	Brand Name +Dosage Form + Strength	Nortin-20 Solution
	Composition	Each ml Contains: **Norfloxacin**…200mg
	Diary No. Date of R& I & fee	Dy.No 15369 dated 02-06-2021 Rs.30,000/- dated 02-06-2021 (slip No. 162071626)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml,1000ml: Decontrolled
	Me-too status	Manster B 90 Oral Liquid of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 071097)

	GMP status	Inspection conducted on 20-02-2020 concludes that the firm follows the basic parameters of GMP and production was according to GMP requirements.
	Remarks of the Evaluator [X]	**Veterinary Oral Liquid Section (General)** confirmed vide panel inspection report dated 31-03-2022 for renewal of DML
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
776.	Name and address of manufacturer / Applicant	M/s Moreno Iglisias Research Labs (Pvt) Ltd. 21 Km, Ferozpur Road, Lahore.
	Brand Name +Dosage Form + Strength	Fucotyle Dry Powder
	Composition	Each gram contains: Fosfomycin Calcium…200mg Tylosin Tartrate…100mg Fructose…180mg Sodium Phosphate…150mg Magnesium Sulphate…100mg
	Diary No. Date of R& I & fee	Dy.No 15388 dated 02-06-2021 Rs.30,000/- dated 02-06-2021 (slip No. 0493497506)
	Pharmacological Group	Antibiotic combination
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm,1000gm: Decontrolled
	Me-too status	Fosfo-20 Oral Powder of M/s Evergreen Pharmaceuticals, Lahore. (Reg. No. 088861)
	GMP status	Inspection conducted on 20-02-2020 concludes that the firm follows the basic parameters of GMP and production was according to GMP requirements.
	Remarks of the Evaluator [X]	**Veterinary Dry Powder Section (General)** confirmed vide panel inspection report dated 31-03-2022 for renewal of DML **Shortcomings:** • The reference formulation is **Each gm contains:** **Fosfomycin Calcium …200mg** **Tylosin as Tartrate…100mg** **Fructose 1,6 Diphosphate…180mg** **Sodium Phosphate…150mg** **Magnesium Phosphate…100mg** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved with following label claim. **Each gram contains:** **Fosfomycin Calcium …200mg** **Tylosin as Tartrate…100mg** **Fructose 1,6 Diphosphate…180mg** **Sodium Phosphate…150mg** **Magnesium Phosphate…100mg** **The firm shall submit the following before issuance of registration letter:** • **Latest GMP inspection report conducted within the period of last three years.** • **Fee of Rs.30000/- for correction in formulation (salt form) and finished product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
777.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Oxyway-20 LA Injection 100ml

	Composition	Each ml contains: Oxytetracycline HCl eq. to Oxytetracycline…200mg
	Diary No. Date of R& I & fee	Dy.No 17784 dated 25-06-2021 Rs.30,000/- dated 18-06-2021 (slip No. 33460737124)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	100ml; N/A
	Me-too status	Levamycin-20% Injection (100ml) of M/s Biorise Pharmaceuticals, Multan. (Reg. No. 113401)
	GMP status	
	Remarks of the Evaluator [X]	**Liquid Injectable (General) Veterinary section** confirmed vide panel inspection report based on inspection dated 13-06-2018, 10-10-2018, and 11-12-2018 for renewal of DML **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
778.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd., Plot No 5, Pharmacity, 30-km Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Oxyway-20 LA Injection 50ml
	Composition	Each ml contains: Oxytetracycline HCl eq. to Oxytetracycline…200mg
	Diary No. Date of R& I & fee	Dy.No 17783 dated 25-06-2021 Rs.30,000/- dated 18-06-2021 (slip No. 69408073)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml; N/A
	Me-too status	Levamycin-20% Injection (50ml) of M/s Biorise Pharmaceuticals, Multan. (Reg. No. 113400)
	GMP status	
	Remarks of the Evaluator [X]	**Liquid Injectable (General) Veterinary section** confirmed vide panel inspection report based on inspection dated 13-06-2018, 10-10-2018, and 11-12-2018 for renewal of DML **Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years)
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
779.	Name and address of manufacturer / Applicant	M/s Attabak Pharmaceutical Industries, Plot No. 5-C, I-10/3 Indsutrial Area Islamabad.
	Brand Name +Dosage Form + Strength	Flumebak Bolus
	Composition	Each bolus contains: Flumequine…350mg
	Diary No. Date of R& I & fee	Dy.No 13831 dated 24-05-2021 Rs.30,000/- dated 20-05-2021 (slip No. 822033636)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5

	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	4 x 5's, 10 x 5's, and 20 x 5's; Decontrolled
	Me-too status	Flumiquin Bolus of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 043585) .
	GMP status	cGMP certificate based on panel inspection dated 08-02-2021 recommended for renewal of DML
	Remarks of the Evaluator [X]	Approval of **Bolus (Veterinary)** section confirmed vide certificate No. F. 3-69/2021- Addl. Dir. (QA&LT-I)-5 dated 04-03-2021
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
780.	Name and address of manufacturer / Applicant	M/s Attabak Pharmaceutical Industries, Plot No. 5-C, I-10/3 Indsutrial Area Islamabad.
	Brand Name +Dosage Form + Strength	Fosfabak-Plus Powder
	Composition	Each gram Contains: Fosfomycin Calcium…200mg Tylosin Tartrate…50mg Dextrose…180mg Sodium Phosphate…150mg Magnesium phosphate…100mg Sodium Chloride q.s.…1000mg
	Diary No. Date of R& I & fee	Dy.No 15140 dated 01-06-2021 Rs.30,000/- dated 31-05-2021 (slip No. 98874800789)
	Pharmacological Group	Antibacterial/ minerals
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm, 5000gm; Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	cGMP certificate based on panel inspection dated 08-02-2021 recommended for renewal of DML
	Remarks of the Evaluator [X]	Approval of **Oral Powder Veterinary (General)** section confirmed vide letter No.F. 1-5/96-Lic dated 30-03-2021. **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
781.	Name and address of manufacturer / Applicant	M/s Attabak Pharmaceutical Industries, Plot No. 5-C, I-10/3 Indsutrial Area Islamabad.
	Brand Name +Dosage Form + Strength	Fosfatyl Powder
	Composition	Each gram Contains: Fosfomycin Calcium…200mg Tylosin Tartrate…100mg Fructose…180mg Sodium Phosphate…150mg Magnesium Sulphate…100mg
	Diary No. Date of R& I & fee	Dy.No 15139 dated 01-06-2021 Rs.30,000/- dated 31-05-2021 (slip No. 0756684091)

	Pharmacological Group	Antibacterial/ minerals
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm, 5000gm; Decontrolled
	Me-too status	Fosfo-20 Oral Powder of M/s Evergreen Pharmaceuticals, Lahore. (Reg. No. 088861)
	GMP status	cGMP certificate based on panel inspection dated 08-02-2021 recommended for renewal of DML
	Remarks of the Evaluator [X]	Approval of **Oral Powder Veterinary (General)** section confirmed vide letter No.F. 1-5/96-Lic dated 30-03-2021. **Shortcomings:** • The reference formulation is **Each gm contains:** **Fosfomycin Calcium …200mg** **Tylosin as Tartrate…100mg** **Fructose 1,6 Diphosphate…180mg** **Sodium Phosphate…150mg** **Magnesium Phosphate…100mg** • Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved with following label claim: **Each gram contains:** **Fosfomycin Calcium …200mg** **Tylosin as Tartrate…100mg** **Fructose 1,6 Diphosphate…180mg** **Sodium Phosphate…150mg** **Magnesium Phosphate…100mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
782.	Name and address of manufacturer / Applicant	M/s Attabak Pharmaceutical Industries, Plot No. 5-C, I-10/3 Indsutrial Area Islamabad.
	Brand Name +Dosage Form + Strength	Enroflox 10 Injection 50ml
	Composition	Each ml Contains: Enrofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 15142 dated 01-06-2021 Rs.30,000/- dated 31-05-2021 (slip No. 9290624637)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Enflox-10% Injection (50ml) of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 112212)
	GMP status	cGMP certificate based on panel inspection dated 08-02-2021 recommended for renewal of DML
	Remarks of the Evaluator [X]	Approval of **Liquid Injectable Veterinary (General)** section confirmed vide letter No.F. 1-5/96-Lic dated 30-03-2021.
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
783.	Name and address of manufacturer / Applicant	M/s Attabak Pharmaceutical Industries, Plot No. 5-C, I-10/3 Indsutrial Area Islamabad.
	Brand Name +Dosage Form + Strength	Enroflox 20 Injection 50ml

	Composition	Each ml Contains: Enrofloxacin…200mg
	Diary No. Date of R& I & fee	Dy.No 15143 dated 01-06-2021 Rs.30,000/- dated 31-05-2021 (slip No. 1434110012)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Enflox-20% Injection (50ml) of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 112216)
	GMP status	cGMP certificate based on panel inspection dated 08-02-2021 recommended for renewal of DML
	Remarks of the Evaluator [X]	Approval of **Liquid Injectable Veterinary (General)** section confirmed vide letter No.F. 1-5/96-Lic dated 30-03-2021.
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
784.	Name and address of manufacturer / Applicant	M/s Attabak Pharmaceutical Industries, Plot No. 5-C, I-10/3 Indsutrial Area Islamabad.
	Brand Name +Dosage Form + Strength	Genta-15% Injection
	Composition	Each ml contains: Gentamycin as Sulphate…150mg
	Diary No. Date of R& I & fee	Dy.No 15141 dated 01-06-2021 Rs.30,000/- dated 31-05-2021 (slip No. 666224454964)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Gantasin-15% Injection (50ml) of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 112220)
	GMP status	cGMP certificate based on panel inspection dated 08-02-2021 recommended for renewal of DML
	Remarks of the Evaluator [X]	Approval of **Liquid Injectable Veterinary (General)** section confirmed vide letter No.F. 1-5/96-Lic dated 30-03-2021.
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
785.	Name and address of manufacturer / Applicant	M/s D-Haans Pharmaceuticals, Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Solurid 3.4% Oral Suspension
	Composition	Each ml contains: Oxyclozanide…34mg
	Diary No. Date of R& I & fee	Dy.No 17234 dated 21-06-2021 Rs.30,000/- dated 21-06-2021 (slip No. 478956575948)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Devour Oral Liquid of M/s Sanna Laboratories, Faisalabad (Reg. No. 069622)
	GMP status	Panel inspection dated 12-12-2019 recommended renewal of DML

	Remarks of the Evaluator [X]	Approval of **Oral Liquid Section-I Veterinary** confirmed vide panel inspection dated 12-12-2019 for renewal of DML. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
786.	Name and address of manufacturer / Applicant	M/s D-Haans Pharmaceuticals, Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Dizole 1.5% Oral Suspension
	Composition	Each ml contains: Levamisole HCl…15mg
	Diary No. Date of R& I & fee	Dy.No 17235 dated 21-06-2021 Rs.30,000/- dated 21-06-2021 (slip No. 7390291352)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Levawan Oral Liquid of M/s Prix Pharmaceutica (Pvt) Ltd., Lahore (Reg. No. 075642)
	GMP status	Panel inspection dated 12-12-2019 recommended renewal of DML
	Remarks of the Evaluator [X]	Approval of **Oral Liquid Section-I Veterinary** confirmed vide panel inspection dated 12-12-2019 for renewal of DML **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
787.	Name and address of manufacturer / Applicant	M/s D-Haans Pharmaceuticals, Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Zuril-K 28% Solution
	Composition	Each ml contains: Toltrazuril…25mg Vitamin K3…3mg
	Diary No. Date of R& I & fee	Dy.No 17236 dated 21-06-2021 Rs.30,000/- dated 21-06-2021 (slip No. 95844269052)
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Tolmars Liquid of M/s D-Maarson Pharmaceuticals, Rawat, Islamabad (Reg. No.075746)
	GMP status	Panel inspection dated 12-12-2019 recommended renewal of DML
	Remarks of the Evaluator [X]	Approval of **Oral Liquid Section-I Veterinary** confirmed vide panel inspection dated 12-12-2019 for renewal of DML **Shortcomings:**

		• Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
788.	Name and address of manufacturer / Applicant	M/s D-Haans Pharmaceuticals, Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Detoxy-Liv Oral Liquid
	Composition	Each ml Contains: **Silymarin**…21mg **Vitamin E**…15mg
	Diary No. Date of R& I & fee	Dy.No 17233 dated 21-06-2021 Rs.30,000/- dated 21-06-2021 (slip No. 925710619267)
	Pharmacological Group	Hepato-protective agent
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Hepatocare Oral Suspension of M/s Attabak Pharmaceuticals, Islamabad (Reg. No. 062167)
	GMP status	Panel inspection dated 12-12-2019 recommended renewal of DML
	Remarks of the Evaluator [X]	Approval of **Oral Liquid Section-I Veterinary** confirmed vide panel inspection dated 12-12-2019 for renewal of DML **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
789.	Name and address of manufacturer / Applicant	M/s D-Haans Pharmaceuticals, Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Trisulph-En Oral Liquid
	Composition	Each ml contains: **Enrofloxacin**…75mg **Trimethoprim**…25mg **Sulphamethoxypyridizine**…75mg **Sulphamethazine**…50mg
	Diary No. Date of R& I & fee	Dy.No 17237 dated 21-06-2021 Rs.30,000/- dated 21-06-2021 (slip No. 401182722367)
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml; Decontrolled
	Me-too status	Cinafas Oral Suspension of M/s Intervac (Pvt) Ltd., Lahore (Reg. No. 048264)
	GMP status	Panel inspection dated 12-12-2019 recommended renewal of DML
	Remarks of the Evaluator [X]	Approval of **Oral Liquid Section-I Veterinary** confirmed vide panel inspection dated 12-12-2019 for renewal of DML **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.

	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
790.	Name and address of manufacturer / Applicant	M/s D-Haans Pharmaceuticals, Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Hansymol-C W/S Powder
	Composition	Each gram Contains: Vitamin C…50mg **Paracetamol**…200mg Potassium Carbonate…125mg Sodium Bicarbonate…125mg Vitamin E…125mg
	Diary No. Date of R& I & fee	Dy.No 17240 dated 21-06-2021 Rs.30,000/- dated 21-06-2021 (slip No. 41811692460)
	Pharmacological Group	Antioxidant, Analgesic, Antipyretic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Parascorbic Powder of M/s Baariq Pharmaceuticals, Lahore. (Reg. No. 087140)
	GMP status	Panel inspection dated 12-12-2019 recommended renewal of DML
	Remarks of the Evaluator [X]	Approval of **Oral Powder Section-I Veterinary** confirmed vide panel inspection dated 12-12-2019 for renewal of DML **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
791.	Name and address of manufacturer / Applicant	M/s D-Haans Pharmaceuticals, Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Brolinc-H Oral Powder
	Composition	Each gram contains: Lincomycin HCl…50mg Spectinomycin HCl…75mg Spiramycin Adipate…25mg Bromhexine HCl…5mg
	Diary No. Date of R& I & fee	Dy.No 17242 dated 21-06-2021 Rs.30,000/- dated 21-06-2021 (slip No. 70371189217)
	Pharmacological Group	Antibacterial, bronchodilator
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Spiralinc-B Powder of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 079716)
	GMP status	Panel inspection dated 12-12-2019 recommended renewal of DML
	Remarks of the Evaluator [X]	Approval of **Oral Powder Section-I Veterinary** confirmed vide panel inspection dated 12-12-2019 for renewal of DML **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.

	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
792.	Name and address of manufacturer / Applicant	M/s D-Haans Pharmaceuticals, Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	CT-Haans 20% W/S Powder
	Composition	Each 100gm Contains: Chlortetracycline HCl…20gm
	Diary No. Date of R& I & fee	Dy.No 17241 dated 21-06-2021 Rs.30,000/- dated 21-06-2021 (slip No. 6338998509)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Cyclo-Mix 20 of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 113527)
	GMP status	Panel inspection dated 12-12-2019 recommended renewal of DML
	Remarks of the Evaluator [X]	Approval of **Oral Powder Section-I Veterinary** confirmed vide panel inspection dated 12-12-2019 for renewal of DML **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
793.	Name and address of manufacturer / Applicant	M/s D-Haans Pharmaceuticals, Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	D-Losin 50% W/S Powder
	Composition	Each gram Contains: Tylosin Tartrate…500mg
	Diary No. Date of R& I & fee	Dy.No 17238 dated 21-06-2021 Rs.30,000/- dated 21-06-2021 (slip No. 12442921579)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Tylo-50 Water Soluble Powder of M/s Symans Pharmaceuticals (Pvt) Ltd, Lahore (Reg. No. 063847)
	GMP status	Panel inspection dated 12-12-2019 recommended renewal of DML
	Remarks of the Evaluator [X]	Approval of **Oral Powder Section-I Veterinary** confirmed vide panel inspection dated 12-12-2019 for renewal of DML **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • The reference formulation is **Each gram Contains:** **Tylosin as Tartrate…500mg**

		• Firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.
	Decision: Approved with following label claim: **Each gram Contains:** **Tylosin as Tartrate…500mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in formulation and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.**	
794.	Name and address of manufacturer / Applicant	M/s D-Haans Pharmaceuticals, Plot No. 9/A, Industrial Estate, Bhimber
	Brand Name +Dosage Form + Strength	Hansy-Fon 98 W/S Powder
	Composition	Each gram contains: Trichlorfen…980mg
	Diary No. Date of R& I & fee	Dy.No 17239 dated 21-06-2021 Rs.30,000/- dated 21-06-2021 (slip No. 095958970603)
	Pharmacological Group	Anthelmentic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 25000gm; Decontrolled
	Me-too status	Trigold Water Soluble Powder of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 049700)
	GMP status	Panel inspection dated 12-12-2019 recommended renewal of DML
	Remarks of the Evaluator [X]	Approval of **Oral Powder Section-I Veterinary** confirmed vide panel inspection dated 12-12-2019 for renewal of DML **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	

b. Deferred cases

795.	Name and address of manufacturer / Applicant	M/s Baariq Pharmaceuticals, Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Toldibar Injection
	Composition	Each 100ml contains: Toldimfos Sodium…20gm Vitamin B-12…5mg
	Diary No. Date of R& I & fee	Dy.No 15018 dated 20-08-2019 Rs.20,000/- dated 19-08-2019
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml: As per SRO
	Me-too status	Tonovit Injetion (50ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd, Lahore. (Reg. No. 033253)
	GMP status	
	Remarks of the Evaluator [X]	• **Latest GMP inspection report (conducted within the period of last three years).**

		• Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.
	Decision of 324th meeting: Deferred for submission of evidence of approval of required manufacturing facility i.e**., Liquid Injection (Veterinary) section** from CLB or else while firm may transfer the registration application to by way of contract manufacturing upon submission of new Form 5, within six months. **Updated status:** **Response of the firm:** • **Liquid Injection (General) Veterinary** confirmed vide letter No. F. 1-11/2010-Lic (Vol-I) dated 14-09-2017.	
	Decision: Approved. The firm shall submit latest GMP inspection report conducted within the period of last three years and fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
796.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Bio-Bromox WSP
	Composition	Each Gram Contains: Doxycycline Hyclate…200mg Tylosin Tartrate…100mg Bromhexine HCl…24mg
	Diary No. Date of R& I & fee	Dy.No 6289 dated 16-05-2019 Rs.20,000/- dated 16-05-2019
	Pharmacological Group	Antibacterial/ Mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1Kg; As recommended by PRC (MOH)
	Me-too status	**Could not be confirmed in the applied strength.**
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• Approval of **Oral Dry powder section (veterinary)** confirmed vide panel inspection report for inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Fee Rs, 7500/- for revision of finished product specifications.
	Decision of 323rd meeting: Deferred for following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm • Finished product specifications in the light of decision taken in 267th meeting of Registration Board along with fee Rs.7500/- for revision of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. **Updated status:**	

	• The firm has now revised the formulation as per below mentioned label claim: **Each Gram Contains:** **Doxycycline HCl…200mg** **Tylosin Tartrate…100mg** **Bromhexine HCl…2.5mg** Metoo status: Deltarox D Oral Water Soluble Powder of M/s Vetrox Pharmaceutical Pvt Ltd, Toba Tek Singh. (Reg. No. 112359) • Firm has revised finished product specification from inhouse to "**as per innovator's specifications"** along with the fee of Rs. 30,000/- via deposit slip no 691698835	
	Decision: Approved with innovator's specifications and with following label claim: **Each Gram Contains:** **Doxycycline HCl…200mg** **Tylosin as Tartrate…100mg** **Bromhexine HCl…2.5mg**	
797.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Bio-Erizine WSP
	Composition	Each Gram Powder Contains: Erythromycin Thiocyanate…200mg Sulfadiazine…150mg Trimethoprim…30mg
	Diary No. Date of R& I & fee	Dy.No 7663 dated 30-05-2019 Rs.20,000/- dated 29-05-2019
	Pharmacological Group	Antibiotic/ antiprotozoal
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm and 1000gm; As recommended by PRC (MOH)
	Me-too status	**Could not be confirmed in the applied strength and combination.**
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• Approval of **Oral Dry powder section (veterinary)** confirmed vide panel inspection report for inspection dated 08-07-2021, 15-07-2021, 30-07-2021 and 03-08-2021 for renewal of DML. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Fee Rs, 7500/- for revision of finished product specifications.
	Decision of 323rd meeting: Deferred for following: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm Finished product specifications in the light of decision taken in 267th meeting of Registration Board along with fee Rs.7500/- for revision of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. **Updated status:** • The firm has now revised the formulation as per below mentioned label claim:	

	Each Gram Powder Contains: **Erythromycin Thiocyanate…100mg** **Sulfadiazine…100mg** **Trimethoprim…20mg** Metoo status: Erysul-T Oral Powder of M/s Bio-Oxime Pharmaceuticals, Faisalabad. (Reg. No. 080135) • Firm has revised finished product specification from inhouse to "**as per innovator's specifications"** along with the fee of Rs. 30,000/- via deposit slip no 99733789238	
	Decision: Approved with innovator's specifications and with following label claim: **Each Gram contains:** **Erythromycin Thiocyanate…100mg** **Sulfadiazine…100mg** **Trimethoprim…20mg**	
798.	Name and address of manufacturer / Applicant	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Bio-Chlortiam WSP
	Composition	Each 100gm powder contains: Chlortetracycline HCl eq. to Chlortetracycline Base…20gm Tiamulin Hydrogen Fumarate eq. to Tiamulin Base…36.45gm
	Diary No. Date of R& I & fee	Dy.No 8158 dated 12-06-2019 Rs.20,000/- dated 11-06-2019
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm and 1000gm; As recommended by PRC (MOH)
	Me-too status	**Could not be confirmed in applied strength.**
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [X]	• **Oral dry powder section (Veterinary)** confirmed from panel inspection report dated 10-04-2019 & 23-04-2019 for grant of GMP certificate • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Fee Rs, 7500/- for revision of finished product specifications.
	Decision of 323rd meeting: Deferred for following: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm Finished product specifications in the light of decision taken in 267th meeting of Registration Board along with fee Rs.7500/- for revision of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. **Updated status:** • The firm has now revised the formulation as per below mentioned label claim: **Each gram powder contains:** **Chlortetracycline HCl eq. to Chlortetracycline Base…100mg** **Tiamulin Hydrogen Fumarate eq. to Tiamulin Base…300mg**	

	Metoo status: SB Tiaclor Oral Powder of M/s SB Pharma Kahuta Road Islamabad. (Reg. No. 048223) • Firm has revised finished product specification from inhouse to "**as per innovator's specifications"** along with the fee of Rs. 30,000/- via deposit slip no 4651967164	
	Decision: Approved with innovator's specifications and with following label claim: **Each gram powder contains:** **Chlortetracycline HCl …100mg** **Tiamulin Hydrogen Fumarate eq. to Tiamulin Base…300mg**	
799.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Deltavetz Oral Liquid
	Composition	Each ml Contains: Deltamethrin…25mg
	Diary No. Date of R& I & fee	Dy.No 32481 dated 07-12-2020 Rs.20,000/- dated 07-12-2020
	Pharmacological Group	Ectoparasitic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 150ml, 500ml,1000ml: Decontrolled
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Shortcomings:** • Clarification regarding dosage form is required since both "**oral liquid**" and "**for external use**" are mentioned on form-5, clarify and provide accordingly, evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Provide approval of relevant manufacturing facility.
	Decision of 326th meeting: Deferred for following: • Clarification regarding dosage form is required since both "oral liquid" and "for external use" are mentioned on form-5, clarify and provide accordingly, evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • approval of relevant manufacturing facility. **Updated status:** • The firm has submitted that the applied product is **for external use only** • **Metoo status:** I-Dmeth Solution of M/s International Pharma Labs Lahore (Reg. No. 052388) • **Aerosol Spray (Veterinary) section** confirmed vide letter No. F. 2-8/2011-Lic dated 05-11-2019.	
	Decision: Approved with change of brand name. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
800.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Ivovectin Injection 200ml
	Composition	Each ml contains: Ivermectin…20mg
	Diary No. Date of R& I & fee	Dy.No 16155 dated 07-07-2020 Rs.20,000/- dated 07-07-2020
	Pharmacological Group	Anthelmintic

	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	200ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied pack size/fill volume**
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Sterile Liquid Injection (Veterinary) Section** confirmed from panel inspection report conducted on 11-04-2015 for grant of DML. **Shortcomings:** • Confirmation of relevant manufacturing facility (**LVP**) • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) **with the same pack size/ fill volume as applied,** alongwith registration number, brand name and name of firm.
	Decision of 326th meeting: Deferred for following: • Confirmation of relevant manufacturing facility (LVP) • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) with the same pack size/ fill volume as applied, alongwith registration number, brand name and name of firm. **Updated status:** • The firm has revised the demanded pack size from **200ml to 100ml** • **Metoo status:** Selmec Injection (100ml) of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore. (Reg. No. 071087) • The firm shall submit fee Rs.30000/- for revision of demanded pack size as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021	
	Decision: Approved with 100ml pack size. The firm shall submit fee Rs.30000/- for revision of demanded pack size and finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
801.	Name and address of manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd, Plot # Q-1, S.I.T.E, Kotri, Sindh.
	Brand Name +Dosage Form + Strength	Cypervetz Oral Liquid
	Composition	Each ml contains: Cypermethrin…10%
	Diary No. Date of R& I & fee	Dy.No 32479 dated 07-12-2020 Rs.20,000/- dated 07-12-2020
	Pharmacological Group	Ectoparasitic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 150ml, 500ml,1000ml: Decontrolled
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 31-5-2021 with the following conclusion: Based on the above observation their current GMP compliance level is rated as good.
	Remarks of the Evaluator [X]	**Shortcomings:** • Clarification regarding dosage form is required since both "**oral liquid**" and "**for external use**" are mentioned on form-5, clarify and provide accordingly, evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Provide approval of relevant manufacturing facility.

	Decision of 326th meeting: Deferred for following: • Clarification regarding dosage form is required since both "oral liquid" and "for external use" are mentioned on form-5, clarify and provide accordingly, evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • approval of relevant manufacturing facility. **Updated status:** • The firm has submitted that the applied product is **for external use only** • **Metoo status:** Ectorid Solution Disinfectant of M/s Symans Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 078372) • **Aerosol Spray (Veterinary) section** confirmed vide letter No. F. 2-8/2011-Lic dated 05-11-2019.	
	Decision: Approved with change of brand name. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
802.	Name and address of manufacturer / Applicant	M/s Farm Aid Pharmaceuticals, Plot No3/2 Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Cedox powder
	Composition	Each 1000gm contains: Tylosin Tartrate …100gm Doxycycline HCl …200gm Bromhexine HCl…5gm Colistin Sulphate…500 MIU
	Diary No. Date of R& I & fee	Dy.No 33435 dated 16-12-2020 Rs.20,000/- dated 09-12-2020
	Pharmacological Group	Antibacterial/ Anti-viral
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 15Kg, 20Kg, 25Kg; Decontrolled
	Me-too status	Tetravetz Powder of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh (Reg. No. 079297) **Could not be confirmed in the applied strength**
	GMP status	cGMP certificate dated 14-10-2022 based on inspection conducted on 15-04-2022.
	Remarks of the Evaluator [X]	**Oral Powder General Veterinary** section confirmed vide panel inspection dated 15-04-2022 report for renewal of DML. **Shortcomings:** • Provide conversion of Colistin Sulphate from MIU to gram • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 326th meeting: Deferred for following: • conversion of Colistin Sulphate from MIU to gram • evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. **Updated status:** • The firm has provided conversion of Colistin Sulphate (19000IU of Colistin Sulphate = 1mg) • **Metoo status:** Strick CRD 55 Water Soluble Powder of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK (Reg. No. 109130)	
	Decision: Approved. The firm shall submit fee of Rs.30000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	

803.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Trigent Injection
	Composition	Each ml Contains: Gentamycin Sulphate…30mg Trimethoprim…25mg Sulfadiazine…125mg
	Diary No. Date of R& I & fee	Dy.No 18059 dated 19-09-2019 Rs.20,000 dated 19-09-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml, 30ml, 50ml, 100ml, 250ml, 450ml, 500ml: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [x]	• **Liquid injectable (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal • Initially, multiple pack sizes (10ml, 30ml, 50ml, 100ml, 250ml, 450ml, 500ml) of injectable dosage form were demanded in a single application. Now, the firm has demanded **100ml pack size**. **Shortcoming;** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 324th meeting: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. **Updated status:** • The firm has now revised the formulation as per below mentioned label claim: **Each ml Contains:** **Gentamycin Sulphate…30mg** **Trimethoprim…25mg** **Sulfadimidine sodium…125mg** • **Metoo status:** Gentamix Injection (100ml) of M/s Breeze Pharma (Pvt.) Ltd., Islamabad. (Reg. No. 063558) • Firm has depositted fee of Rs. 30,000/- via deposit slip no 1693327650 for revision of formulation.	
	Decision: Approved with following label claim: **Each ml Contains:** **Gentamycin Sulphate…30mg** **Trimethoprim…25mg** **Sulfadimidine sodium…125mg**	
804.	Name and address of manufacturer / Applicant	M/s Decent Pharma, Plot No. 30, Street SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Kloroqueen 10% Oral Liquid
	Composition	Each ml Contains: Thiamphenicol…100mg
	Diary No. Date of R& I & fee	Dy.No 5137 dated 20-03-2020 Rs.20,000/- dated 20-03-2020
	Pharmacological Group	Antibiotic

	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 150ml, 200ml, 450ml, 500ml, 1Liter, 2.5Liter, 5Liter, 10Liter, 20Liter: Decontrolled
	Me-too status	**Could not be confirmed in the applied strength.**
	GMP status	cGMP certificate dated 12-09-2022 based on inspection conducted on 09-05-2022
	Remarks of the Evaluator [x]	• **Oral Liquid (General) section** confirmed vide panel inspection dated 10-03-2022, 21-04-2022 and 09-05-2022 report for approval of DML renewal • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 324th meeting: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. **Updated status:** • The firm has now revised the formulation as per below mentioned label claim: **Each ml Contains:** **Thiamphenicol…200mg** • **Metoo status:** Thiam Rold 20% Oral Liquid of M/s Haarolds Pharmaceuticals (Pvt) Ltd., AJK. (Reg. No. 109060) • Firm has depositted fee of Rs. 30,000/- via deposit slip no 049097276902 for revision of formulation.	
	Decision: Approved with change of brand name.	

C 02 Registration applications of newly granted DML or New section (Veterinary)
New DML

/s Acme Pharmaceuticals, Rawat, Islamabad.

C 289th meeting held on 23rd January, 2023 has considered and approved the grant of DML by way o tion with following sections.

1. **Oral Dry Powder-I**
2. **Oral Dry Powder-II**
3. **Oral Liquid-I**
4. **Oral Liquid-II**

A ly, following applications were submitted by firm for consideration of the Registration Board in it eeting.

Section	No. of Products applied	No. of Molecules applied
Oral Liquid-I	30	10
Oral Liquid-II	23	10
Oral Dry Powder-II	20	10

M below mentioned application were also applied by the firm for priority consideration however th inadvertently left from inclusion in the agenda.

	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmepro-20 Water Soluble Powder
	Composition	Each gram contains: Amprolium HCl…20%

	Diary No. Date of R& I & fee	Dy.No 6831 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Anti-protozoal/ Anticoccidial
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
	Me-too status	Harlium 20% Water Soluble Powder of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 109109)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved with following label claim: **Each gram contains:** **Amprolium HCl…200mg**	
806.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmepro-30 Water Soluble Powder
	Composition	Each gram contains: Amprolium HCl…30%
	Diary No. Date of R& I & fee	Dy.No 6832 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Anti-protozoal/ Anticoccidial
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
	Me-too status	Harlium 30% Water Soluble Powder of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber, AJK. (Reg. No. 109110)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved with following label claim: **Each gram contains:** **Amprolium HCl…300mg**	
807.	Name and address of manufacturer / Applicant	M/s Acme Pharmaceuticals, Plot No 29, St No SS-22, Rawat National Industrial Zone, RCCI Estate Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Acmepro-60 Water Soluble Powder
	Composition	Each gram contains: Amprolium HCl…60%
	Diary No. Date of R& I & fee	Dy.No 6833 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Anti-protozoal/ Anticoccidial
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg: Decontrolled
	Me-too status	Bio-Amprol 60 Powder of M/s Mallard Pharmaceutical (Pvt) Ltd. Multan. (Reg. No. 063773)
	GMP status	New DML
	Remarks of the Evaluator [X]	
	Decision: Approved with following label claim: **Each gram contains:** **Amprolium HCl…600mg**	

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

b. Export facilitation (Veterinary)

Deputy Director PRV/EFD vide letter No.1-6/2019-PR-I (EFD) dated 28-02-2023 has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision, **M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore** has submitted following applications for priority consideration/ evaluation in lieu of export facilitation, submitted before the Board for its consideration please:

808.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Pro-Up Sterile Solution for Injection
	Composition	Each ml contains: Progesterone…50mg
	Diary No. Date of R& I & fee	Dy.No 16355 dated 14-06-2021 Rs.30,000/- dated 08-06-2021
	Pharmacological Group	Steroid Hormone
	Type of Form	**Form 5D**
	Finished product Specification	USP specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	cGMP certificate dated 20-07-2020 based on inspection dated 24-01-2020
	Remarks of the Evaluator [X]	**Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board. • Stability studies data as per requirement of the Registration Board
	Decision: Registration Board decided to reject the application since the firm has not submitted stability study data of 3 batches of the drug product before the lapse of deadline decided by DRAP Authority i.e. till 31st December 2022.	

b. Deputy Director PRV/EFD vide letter No.1-6/2019-PR-I (EFD) dated 28-02-2023 has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision, **M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore** has achieved the benchmark of **134105.00 USD** during the fiscal Year **2019-2020** and **329260.00 USD** during the fiscal year **2020-2021.** Following applications submitted by the firm for priority consideration/ evaluation in lieu of export facilitation are submitted before the Board for its consideration please:

809.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Enersel Injection 50ml
	Composition	Each ml Contains: L-Arginine HCl...1.42mg

		L-Cysteine HCl...0.02mg Monosodium Glutamate...0.08mg L-Histidine HCl...0.02mg L-Isoleucine HCl...0.525mg L-Leucine.....0.6mg L-Lysine HCl...0.525mg DL-Methionine...0.525mg L-Threonine.....0.35mg L-Tryptophan...0.175mg L-Phenylalnine...0.35mg L-Valine.....0.525mg Thiamine HCl...0.1mg Riboflavin...0.05mg Pyridoxine HCl...0.1mg Nicotinamide.....3mg Dextrose...50mg Calcium Chloride...2mg Potassium Chloride...2mg Magnesium Sulphate...2mg Sodium Acetate...7.5mg D-Pantothenol...0.1mg
	Diary No. Date of R& I & fee	Dy.No 703 dated 09-01-2023 Rs.30,000/- dated 06-12-2022
	Pharmacological Group	Vitamins, amino acids & mineral supplements
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied pack size**
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator [X]	• **Liquid Injectable Vial-I General (Veterinary) and Liquid Injectable Vial-II General (Veterinary) section** confirmed vide panel inspection report for grant of additional sections based on inspection dated 14-03-2022. **Shortcomings:** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	

Case no. 04 Registration applications of import cases

a. New Cases (Veterinary)

810.	Name and address of Applicant	M/s Better Traders International, 23-Z, Saifullah Shaheed Road, Madina Town, Faisalabad, Pakistan
	Detail of Drug Sale License	Name: M/s Better Traders International Address: 24-Z/E, Saifullah Shaheed Road, Madina Town, Faisalabad, Pakistan. Validity: 15-02-2022. Status: License to sell drugs as a distributor (Form No.11).
	Name and address of manufacturer	M/s RTD (Rural Technology Development) Veterinary Medicine Joint Stock Company.

		Truong An Industrial Zone, An Khanh, Hoai Duc, Ha Noi, Vietnam
	Name and address of marketing authorization holder	M/s RTD (Rural Technology Development) Veterinary Medicine Joint Stock Company. Truong An Industrial Zone, An Khanh, Hoai Duc, Ha Noi, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 1621 Dated 12-01-2021
	Fee including differential fee	**Rs : 50,000** Dated 12-01-2021
	Brand Name +Dosage Form + Strength	RTD-Hohenstop powder
	Composition	Active Ingredients per unit Contains: Tiamulin…100g Doxycycline HCl…25g
	Finished Product Specification	Inhouse
	Pharmacological Group	Antimicrobial
	Shelf life	03 Years
	Demanded Price	Decontrolled
	Pack size	100gm, 500gm, 1Kg, 2Kg, 5Kg, 10Kg
	International availability	Not provided
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	• Scanned copy of GMP certificate No. 01/19/GCN-GMP dated 18-03-2019 issued by Department of Animal Health Ministry of Agriculture and Rural Development Vietnam **Validity: 5 Years** • Originally legalized FSC No. 1119/2019/QLT-CFS dated 09-10-2019 issued by Department of Animal Health Vietnam, confirms free sale status of the applied product in country of origin. **Validity: 2 years** • Scanned copy of legalized authorization letter dated 16-08-2019 between PLH and Applicant
	Remarks of the Evaluator [X]	Firm has claimed shelf life of **3 years** however, provided only **24months** real time stability studies data of three batches at zone IV-A conditions. **Shortcomings:** • Provide valid copy of DSL • Provide valid legalized original letter of authorization (LOA) since already submitted LOA is scanned copy. • Provide valid legalized original FSC since already submitted FSC is **expired now but valid upon submission**. • Submit 06 months accelerated stability studies data as per zone-IV-A conditions. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • The address of the applicant mentioned on form 5A is not the same as mentioned on copy of DSL, clarify.

	Decision: Deferred for following: • **Valid copy of DSL** • **Valid legalized original letter of authorization (LOA) since already submitted LOA is scanned copy.** • **Valid legalized original FSC since already submitted FSC is expired now but valid upon submission.** • **06 months accelerated and complete real time stability studies data, upto claimed shelf life, of three batches at zone IV-A conditions.** • **Label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Clarification regarding address of the applicant since the address mentioned on form 5A is not the same as mentioned on copy of DSL.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
811.	Name and address of Applicant	M/s U.M. Enterprises, Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan
	Detail of Drug Sale License	Name: M/s U.M. Enterprises, Address: Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan Date of issuance: 21-03-2023. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Arab Veterinary Industrial Co. "AVICO" P.O.Box 150906, Amman 11115-Jordan
	Name and address of marketing authorization holder	M/s Arab Veterinary Industrial Co. "AVICO" P.O.Box 150906, Amman 11115-Jordan
	Name of exporting country	Jordan
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 2647 Dated 22-01-2021
	Fee including differential fee	Rs : 1,00,000 Dated 22-01-2021
	Brand Name +Dosage Form + Strength	Diaban Suspension
	Composition	Each ml contains: Sulphadimidine as Sodium…35.5mg Sulphadiazine as Sodium…35.5mg Streptomycin as Sulphate...6.06mg Neomycin Sulphate...1.8mg Hyoscine as Hydro Bromide...0.0316mg Sodium as Chloride...4.43mg Calcium as Gluconate...0.196mg Magnesium as Sulphate...0.059mg Potassium as Chloride...1.9mg Kaolin...103.3mg Pectin...5.32mg Glycine...20.9mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotics / Minerals
	Shelf life	02 Years
	Demanded Price	N/A
	Pack size	225ml
	International availability	Scourban Oral Anti-Diarrhoeal Suspension (**approved in APVMA Australia)**
	Me-too status	Not provided

	Detail of certificates attached	• Original Legalized COPP NO. 9374 dated 05-10-2020 issued by the Ministry of Agriculture, The Hashemite Kingdom of Jordan **confirms GMP status and Free sale status of applied product in country of origin.**
	Remarks of the Evaluator [X]	• Provided 06 month accelerated and 24months real time stability studies data of three batches at zone IV-A conditions. **Shortcomings**: • Provide original legalized Letter of authorization/ sole agency certificate.
	Decision: Deferred for original legalized Letter of authorization/ sole agency certificate.	
812.	Name and address of Applicant	M/s Brand Station, House No. 89-A2, Wapda Town, Extension, Iqbal Town Lahore.
	Detail of Drug Sale License	**Not provided**
	Name and address of manufacturer	M/s Asia Animal Pharmaceutical Co., Ltd. No. 130, 1A Highway, Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam
	Name and address of marketing authorization holder	M/s Asia Animal Pharmaceutical Co., Ltd. No. 130, 1A Highway, Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 2649 Dated 22-01-2021
	Fee including differential fee	Rs : 100,000 Dated 22-01-2021
	Brand Name +Dosage Form + Strength	Tylo-Dox Soluble Powder
	Composition	Each gram contains: Tylosin Tartrate…20mg Doxycycline Hyclate…40mg
	Finished Product Specification	**Not provided**
	Pharmacological Group	Antibiotics
	Shelf life	03 Years
	Demanded Price	Decontrolled
	Pack size	1 x 100gm, 50 x 100gm
	International availability	Not provided
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	• Copy of GMP certificate No. 16/17/GCN-GMP dated 01-08-2017 issued by Department of Animal Health Ministry of Agriculture and Rural Development Vietnam **Validity: 5 Years** ➢ Free sale certificate and letter of authorization/ sole agency certificate are **NOT PROVIDED**
	Remarks of the Evaluator [X]	**Shortcomings:** • Tylosin Tartrate…20gm and Doxycycline Hyclate…40gm /Kg is mentioned on label claim in Form-5A while Tylosin Tartrate…20gm and Doxycycline Hyclate…40gm /100gm is mentioned in rest of the dossier; clarification regarding applied strength is required. • Provide valid copy of DSL • Provide valid legalized original letter of authorization (LOA)/ sole agency certificate and Free sale certificate (FSC).

		• Provide valid legalized original GMP certificate since already submitted copy is **expired now but valid upon submission**. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Provide full description of the specifications and analytical methods necessary to assure the identity, strength, quality, purity and homogeneity throughout the shelf life of the drug product. • Provide 06 month accelerated and 36-month real time stability studies data of three batches at zone IV-A/IV-B conditions upto claimed shelf life. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Clarification regarding applied strength, since Tylosin Tartrate…20gm and Doxycycline Hyclate…40gm /Kg is mentioned on label claim in Form-5A while Tylosin Tartrate…20gm and Doxycycline Hyclate…40gm /100gm is mentioned in rest of the dossier** • **Valid copy of DSL** • **Valid legalized original letter of authorization (LOA)/ sole agency certificate and Free sale certificate (FSC).** • **Valid legalized original GMP certificate since already submitted copy is expired now but valid upon submission.** • **Label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** • **Full description of the specifications and analytical methods necessary to assure the identity, strength, quality, purity and homogeneity throughout the shelf life of the drug product.** • **06 month accelerated and 36-month real time stability studies data of three batches at zone IV-A/IV-B conditions upto claimed shelf life.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
813.	Name and address of Applicant	M/s Brand Station, House No. 89-A2, Wapda Town, Extension, Iqbal Town Lahore.
	Detail of Drug Sale License	**Not provided**
	Name and address of manufacturer	M/s Asia Animal Pharmaceutical Co., Ltd. No. 130, 1A Highway, Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam
	Name and address of marketing authorization holder	M/s Asia Animal Pharmaceutical Co., Ltd. No. 130, 1A Highway, Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 2676 Dated 21-01-2021
	Fee including differential fee	Rs : 100,000 Dated 21-01-2021
	Brand Name +Dosage Form + Strength	Tilco 250 Oral Solution
	Composition	Each ml contains: Tilmicosin Phosphate…250mg

	Finished Product Specification	**Not provided**
	Pharmacological Group	Antibiotic
	Shelf life	03 Years
	Demanded Price	Decontrolled
	Pack size	1Liter
	International availability	Not provided
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	• Copy of GMP certificate No. 16/17/GCN-GMP dated 01-08-2017 issued by Department of Animal Health Ministry of Agriculture and Rural Development Vietnam **Validity: 5 Years** ➢ Free sale certificate and letter of authorization/ sole agency certificate are **NOT PROVIDED**
	Remarks of the Evaluator [X]	**Shortcomings:** • Tilmicosin Phosphate…250mg/ml is mentioned on label claim in Form-5A and rest of the dossier while Tilmicosin Phosphate…250gm /ml is mentioned on cover letter; clarification regarding applied strength is required. • Provide valid copy of DSL • Provide valid legalized original letter of authorization (LOA)/ sole agency certificate and Free sale certificate (FSC). • Provide valid legalized original GMP certificate since already submitted copy is **expired now but valid upon submission**. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Provide full description of the specifications and analytical methods necessary to assure the identity, strength, quality, purity and homogeneity throughout the shelf life of the drug product. • Provide 06 month accelerated and 36-month real time stability studies data of three batches at zone IV-A/IV-B conditions upto claimed shelf life. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Clarification regarding applied strength, since Tilmicosin Phosphate…250mg/ml is mentioned on label claim in Form-5A and rest of the dossier while Tilmicosin Phosphate…250gm /ml is mentioned on cover letter** • **Valid copy of DSL** • **Valid legalized original letter of authorization (LOA)/ sole agency certificate and Free sale certificate (FSC).** • **Valid legalized original GMP certificate since already submitted copy is expired now but valid upon submission.** • **Label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** • **Full description of the specifications and analytical methods necessary to assure the identity, strength, quality, purity and homogeneity throughout the shelf life of the drug product.** • **06 month accelerated and 36-month real time stability studies data of three batches at zone IV-A/IV-B conditions upto claimed shelf life.**	

	• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
814.	Name and address of Applicant	M/s Brand Station, House No. 89-A2, Wapda Town, Extension, Iqbal Town Lahore.
	Detail of Drug Sale License	**Not provided**
	Name and address of manufacturer	M/s Asia Animal Pharmaceutical Co., Ltd. No. 130, 1A Highway, Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam
	Name and address of marketing authorization holder	M/s Asia Animal Pharmaceutical Co., Ltd. No. 130, 1A Highway, Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 2477 Dated 21-01-2021
	Fee including differential fee	Rs : 100,000 Dated 20-01-2021
	Brand Name +Dosage Form + Strength	Neotesol Soluble Powder
	Composition	Each gram contains: Neomycin Sulphate…720mg
	Finished Product Specification	**Not provided**
	Pharmacological Group	Antibiotic
	Shelf life	03 Years
	Demanded Price	Decontrolled
	Pack size	1000gm
	International availability	N/A
	Me-too status	Breno-Cin Oral Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No.113526)
	Detail of certificates attached	• Copy of GMP certificate No. 16/17/GCN-GMP dated 01-08-2017 issued by Department of Animal Health Ministry of Agriculture and Rural Development Vietnam **Validity: 5 Years** ➢ Free sale certificate and letter of authorization/ sole agency certificate are **NOT PROVIDED**
	Remarks of the Evaluator [X]	**Shortcomings:** • Provide valid copy of DSL • Provide valid legalized original letter of authorization (LOA)/ sole agency certificate and Free sale certificate (FSC). • Provide valid legalized original GMP certificate since already submitted copy is **expired now but valid upon submission**. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Provide full description of the specifications and analytical methods necessary to assure the identity, strength, quality, purity and homogeneity throughout the shelf life of the drug product.

		• Provide 06 month accelerated and 36-month real time stability studies data of three batches at zone IV-A/IV-B conditions upto claimed shelf life.
	Decision: Deferred for following: • **Valid copy of DSL** • **Valid legalized original letter of authorization (LOA)/ sole agency certificate and Free sale certificate (FSC).** • **Valid legalized original GMP certificate since already submitted copy is expired now but valid upon submission.** • **Label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** • **Full description of the specifications and analytical methods necessary to assure the identity, strength, quality, purity and homogeneity throughout the shelf life of the drug product.** • **06 month accelerated and 36-month real time stability studies data of three batches at zone IV-A/IV-B conditions upto claimed shelf life.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
815.	Name and address of Applicant	M/s Brand Station, House No. 89-A2, Wapda Town, Extension, Iqbal Town Lahore.
	Detail of Drug Sale License	**Not provided**
	Name and address of manufacturer	M/s Asia Animal Pharmaceutical Co., Ltd. No. 130, 1A Highway, Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam
	Name and address of marketing authorization holder	M/s Asia Animal Pharmaceutical Co., Ltd. No. 130, 1A Highway, Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 2648 Dated 22-01-2021
	Fee including differential fee	Rs : 100,000 Dated 22-01-2021
	Brand Name +Dosage Form + Strength	Flor-Oral Oral Solution
	Composition	Each ml contains: Florfenicol…230mg
	Finished Product Specification	**Not provided**
	Pharmacological Group	Antibacterial
	Shelf life	03 Years
	Demanded Price	Decontrolled
	Pack size	1Liter
	International availability	N/A
	Me-too status	Floskill-23% Liquid of M/s Bioskils Pharmaceuticals, Sadhoke, District Gujranwala. (Reg. No. 113510)
	Detail of certificates attached	• Copy of GMP certificate No. 16/17/GCN-GMP dated 01-08-2017 issued by Department of Animal Health Ministry of Agriculture and Rural Development Vietnam **Validity: 5 Years** ➢ Free sale certificate and letter of authorization/ sole agency certificate are **NOT PROVIDED**
	Remarks of the Evaluator [X]	**Shortcomings:** • Provide valid copy of DSL • Provide valid legalized original letter of authorization (LOA)/ sole agency certificate and Free sale certificate (FSC).

		• Provide valid legalized original GMP certificate since already submitted copy is **expired now but valid upon submission**. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Provide full description of the specifications and analytical methods necessary to assure the identity, strength, quality, purity and homogeneity throughout the shelf life of the drug product. • Provide 06 month accelerated and 36-month real time stability studies data of three batches at zone IV-A/IV-B conditions upto claimed shelf life.
	Decision: Deferred for following: • **Valid copy of DSL** • **Valid legalized original letter of authorization (LOA)/ sole agency certificate and Free sale certificate (FSC).** • **Valid legalized original GMP certificate since already submitted copy is expired now but valid upon submission.** • **Label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** • **Full description of the specifications and analytical methods necessary to assure the identity, strength, quality, purity and homogeneity throughout the shelf life of the drug product.** • **06 month accelerated and 36-month real time stability studies data of three batches at zone IV-A/IV-B conditions upto claimed shelf life.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
816.	Name and address of Applicant	M/s Ghazi Brothers, Ghazi House, D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi-75350, Pakistan
	Detail of Drug Sale License	Name: M/s Ghazi Brothers Address: D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi Validity: 29-06-2023. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Tairgi Tread-Lia Baile na Sceilge teo T/A Ballinskelligs Veterinary Products, Ballinskelligs Co. Kerry V23XR52, Ireland
	Name and address of marketing authorization holder	M/s Warburton Technology Limited, 36 Fitzwilliam Square Dublin 2, Ireland
	Name of exporting country	Ireland
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 1681 Dated 13-01-2021
	Fee including differential fee	**Rs : 50,000** Dated 13-01-2021
	Brand Name +Dosage Form + Strength	Multimin 90 Solution for injection for cattles
	Composition	Each ml contains: Zinc Eq. to 74.68mg of Zinc Oxide…60mg Manganese Eq. to 20.92mg of Manganese Carbonate…10mg Copper Eq. to 26.09mg of Copper Carbonate…15mg Selenium Eq. to 10.95mg of Sodium Selenite…5mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Mineral supplement
	Shelf life	30 months

	Demanded Price	Decontrolled
	Pack size	100ml and 500ml
	International availability	**Ireland approved**
	Me-too status	N/A
	Detail of certificates attached	➢ Copy of Free sale certificate No. FSC-19-0029 dated 19-11-2019 issued by Health Products Regulatory Authority (HPRA), Ireland. ➢ Copy of GMP certificate No. 21196/V10956 dated 11-05-2018 issued by Health Products Regulatory Authority (HPRA), Ireland. ➢ Copy of Letter of Authorization (LoA) dated 06-03-2020 provided **Validity: July 01, 2022.**
	Remarks of the Evaluator [X]	Provided 06 months accelerated and **only 24 months** long term stability studies data as per zone-IV-A conditions **Shortcomings:** • Provide original legalized valid Power of attorney/sole agency certificate since the already submitted copy is **expired now but valid upon submission** • Provide original legalized valid GMP certificate of the manufacturer abroad since more than 3 years have elapsed since the date of inspection. • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, both **100ml and 500ml** pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier. • Revised form 5A stating correct name and address of manufacturer abroad (including contract manufacturers, if any) since ***M/s Warburton Technology Limited, 36 Fitzwilliam Square Dublin 2, Ireland*** is written on form-5A while copy of GMP certificate of ***M/s Tairgi Tread-Lia Baile na Sceilge teo T/A Ballinskelligs Veterinary Products, Ballinskelligs Co. Kerry V23XR52, Ireland*** is provided
	Decision: Deferred for following: • **Original legalized valid Power of attorney/sole agency certificate since the already submitted copy is expired now but valid upon submission** • **Original legalized valid GMP certificate of the manufacturer abroad since more than 3 years have elapsed since the date of inspection.** • **Choice of only one pack size** • **Revised form 5A stating correct name and address of manufacturer abroad (including contract manufacturers, if any) since *M/s Warburton Technology Limited, 36 Fitzwilliam Square Dublin 2, Ireland* is written on form-5A while copy of GMP certificate of *M/s Tairgi Tread-Lia Baile na Sceilge teo T/A Ballinskelligs Veterinary Products, Ballinskelligs Co. Kerry V23XR52, Ireland*** • **Complete real time stability studies data, upto claimed shelf life, of three batches at zone IV-A conditions.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
817.	Name and address of Applicant	M/s QAS International, 42-A, 1st Floor, Olivia Plaza, Commercial Area, Block A, Phase 2, City Housing, Gujranwala
	Detail of Drug Sale License	Name: M/s QAS International

		Address: Opposite Kings Mall, Near Wapda Town, GT Road, Tehsil and District, Gujranwala Validity: **22-09-2019.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Super's Diana S.L. CTRA C.17, 17 KM, 08150 Parets Del Valles, Barcelona, Spain
	Name and address of marketing authorization holder	M/s Super's Diana S.L. CTRA C.17, 17 KM, 08150 Parets Del Valles, Barcelona, Spain
	Name of exporting country	Spain
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 1623 Dated 12-01-2021
	Fee including differential fee	Rs : 100,000 Dated 12-01-2021
	Brand Name +Dosage Form + Strength	Qaslink 4.4% Oral Powder
	Composition	Each gm contains: Lincomycin HCl…44mg
	Finished Product Specification	USP specifications
	Pharmacological Group	Antibacterial
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	25Kg
	International availability	**CIMAvet, Spain approved**
	Me-too status	Colink Powder of M/s Mili Vet Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 112200)
	Detail of certificates attached	➢ Original legalized COPP dated 29-01-2019 issued by Spanish agency of Medicines and sanitary products, Spain confirming the free sale status in exporting country as well as GMP status of the manufacturer ➢ Copy of legalized sole distributor agreement dated 28-02-2019 between applicant and MAH.
	Remarks of the Evaluator [X]	Provided 06 months accelerated and 24 months long term stability studies data as per zone-IV-A conditions **Shortcomings:** • Provide **copy of valid DSL** • Provide original legalized valid Power of attorney/sole distributor agreement since the already submitted is photocopy. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Revised form 5A stating correct address of applicant (as per valid DSL) along with clarification since ***42-A, 1st Floor, Olivia Plaza, Commercial Area, Block A, Phase 2, City Housing, Gujranwala*** is written on form-5A while on copy of DSL ***Opposite Kings Mall, Near Wapda Town, GT Road, Tehsil and District, Gujranwala*** is mentioned
	Decision: Deferred for following: • **Copy of valid DSL** • **Original legalized valid Power of attorney/sole distributor agreement since the already submitted is photocopy.** • **Label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** • **Revised form 5A stating correct address of applicant (as per valid DSL) along with clarification since *42-A, 1st Floor, Olivia Plaza, Commercial Area, Block A, Phase 2, City***	

	Housing, Gujranwala **is written on form-5A while on copy of DSL** ***Opposite Kings Mall, Near Wapda Town, GT Road, Tehsil and District, Gujranwala*** **is mentioned** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
818.	Name and address of Applicant	M/s Al-Asar Enterprises (Pakistan), Gulshan E Ghulab Colony, Behind Abdullah Heart Care, Pull Wasil Suraj, Miani Road, District Multan, Pakistan
	Detail of Drug Sale License	Name: M/s Al-Asar Enterprises Address: Gulshan E Ghulab Colony, Behind Abdullah Heart Care, Pull Wasil Suraj, Miani Road, District Multan, Pakistan Validity: **05-08-2027.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Vemedim Veterinary Drugs and Probiotics Co. Ltd (Vemedim Animal Health), Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District, Hau Giang Province, Viet Nam.
	Name and address of marketing authorization holder	M/s Vemedim Veterinary Drugs and Probiotics Co. Ltd (Vemedim Animal Health), Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District, Hau Giang Province, Viet Nam.
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 1951 Dated 15-01-2021
	Fee including differential fee	Rs : 100,000 Dated 14-01-2021
	Brand Name +Dosage Form + Strength	Doramax Solution for Injection
	Composition	Each ml contains: Doramectin…10mg
	Finished Product Specification	Inhouse specifications
	Pharmacological Group	Antiparasitic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	50ml
	International availability	N/A
	Me-too status	Doracent Injection (50ml) of M/s Decent Pharma, Rawat, Islamabad (Reg. No. 099434)
	Detail of certificates attached	➢ Original legalized FSC Ref. No. 1046/2020/QLT-CFS dated 11-09-2020 issued by Department of Animal Health of Vietnam confirming the free sale status in exporting country Validity: 2years • Scanned copy of GMP certificate No. 32/18/GCN-GMP dated 16-10-2018 issued by Department of Animal Health Ministry of Agriculture and Rural Development Vietnam ➢ Scanned copy of legalized distribution agreement No. 01/VEMEDIM.ALASAR.2020 dated 24-03-2020 between applicant and MAH.
	Remarks of the Evaluator [X]	Provided 06 months accelerated and 36 months long term stability studies data as per zone-IV-B conditions **Shortcomings:** • Provide original legalized valid GMP certificate and Power of attorney/sole distributor agreement since the already submitted are scanned copies.

		• Provide original legalized valid Free Sale certificate since the already submitted FSC is **expired now but valid upon submission.**
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **original legalized valid GMP certificate and Power of attorney/sole distributor agreement since the already submitted are scanned copies.** • **original legalized valid Free Sale certificate since the already submitted FSC is expired now but valid upon submission.** • **Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
819.	Name and address of Applicant	M/s Al-Asar Enterprises (Pakistan), Gulshan E Ghulab Colony, Behind Abdullah Heart Care, Pull Wasil Suraj, Miani Road, District Multan, Pakistan
	Detail of Drug Sale License	Name: M/s Al-Asar Enterprises Address: Gulshan E Ghulab Colony, Behind Abdullah Heart Care, Pull Wasil Suraj, Miani Road, District Multan, Pakistan Validity: **05-08-2027.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Vemedim Veterinary Drugs and Probiotics Co. Ltd (Vemedim Animal Health), Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District, Hau Giang Province, Viet Nam.
	Name and address of marketing authorization holder	M/s Vemedim Veterinary Drugs and Probiotics Co. Ltd (Vemedim Animal Health), Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District, Hau Giang Province, Viet Nam.
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 1950 Dated 15-01-2021
	Fee including differential fee	Rs : 100,000 Dated 14-01-2021
	Brand Name +Dosage Form + Strength	Tilmo Vime 250 Oral Solution
	Composition	Each ml contains: Tilmicosin as Phosphate…250mg
	Finished Product Specification	Inhouse specifications
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	1Liter
	International availability	N/A
	Me-too status	Kptil Oral 25% Oral Liquid of M/s Krypton Pharma (Pvt) Ltd., Faisalabad. (Reg. No. 113415)
	Detail of certificates attached	➢ Original legalized FSC Ref. No. 606/2020/QLT-CFS dated 30-06-2020 issued by Department of Animal Health of Vietnam confirming the free sale status in exporting country Validity: 2years • Scanned copy of GMP certificate No. 32/18/GCN-GMP dated 16-10-2018 issued by Department of Animal Health Ministry of Agriculture and Rural Development Vietnam ➢ Scanned copy of legalized distribution agreement No. 01/VEMEDIM.ALASAR.2020 dated 24-03-2020 between applicant and MAH.

	Remarks of the Evaluator [X]	Provided 06 months accelerated and 36 months long term stability studies data as per zone-IV-B conditions **Shortcomings:** • Provide original legalized valid GMP certificate and Power of attorney/sole distributor agreement since the already submitted are scanned copies. • Provide original legalized valid Free Sale certificate since the already submitted FSC is **expired now but valid upon submission.**
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **original legalized valid GMP certificate and Power of attorney/sole distributor agreement since the already submitted are scanned copies.** • **original legalized valid Free Sale certificate since the already submitted FSC is expired now but valid upon submission.** • **Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
820.	Name and address of Applicant	M/s Al-Asar Enterprises (Pakistan), Gulshan E Ghulab Colony, Behind Abdullah Heart Care, Pull Wasil Suraj, Miani Road, District Multan, Pakistan
	Detail of Drug Sale License	Name: M/s Al-Asar Enterprises Address: Gulshan E Ghulab Colony, Behind Abdullah Heart Care, Pull Wasil Suraj, Miani Road, District Multan, Pakistan Validity: **05-08-2027.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Vemedim Veterinary Drugs and Probiotics Co. Ltd (Vemedim Animal Health), Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District, Hau Giang Province, Viet Nam.
	Name and address of marketing authorization holder	M/s Vemedim Veterinary Drugs and Probiotics Co. Ltd (Vemedim Animal Health), Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District, Hau Giang Province, Viet Nam.
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 1947 Dated 15-01-2021
	Fee including differential fee	Rs : 100,000 Dated 14-01-2021
	Brand Name +Dosage Form + Strength	Preso Suspension for Injection
	Composition	Each ml Contains: Prednisolone Acetate…10mg
	Finished Product Specification	Inhouse specifications
	Pharmacological Group	Glucocorticoid
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	10ml, 20ml, 50ml and 100ml
	International availability	N/A
	Me-too status	**Could not be confirmed in the applied pack size**
	Detail of certificates attached	➢ Original legalized FSC Ref. No. 610/2020/QLT-CFS dated 30-06-2020 issued by Department of Animal Health of Vietnam confirming the free sale status in exporting country Validity: 2years • Scanned copy of GMP certificate No. 32/18/GCN-GMP dated 16-10-2018 issued by Department of Animal Health Ministry of Agriculture and Rural Development Vietnam

		➢ Scanned copy of legalized distribution agreement No. 01/VEMEDIM.ALASAR.2020 dated 24-03-2020 between applicant and MAH.
	Remarks of the Evaluator [X]	Provided 06 months accelerated and 36 months long term stability studies data as per zone-IV-B conditions **Shortcomings:** • Provide original legalized valid GMP certificate and Power of attorney/sole distributor agreement since the already submitted are scanned copies. • Provide original legalized valid Free Sale certificate since the already submitted FSC is **expired now but valid upon submission.** • Evidence of applied formulation/drug already approved by DRAP **with same pack size as applied** (generic / me-too status) alongwith registration number, brand name and name of firm. • Confirmation of **manufacturing facility**. • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier.
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
821.	Name and address of Applicant	M/s Al-Asar Enterprises (Pakistan), Gulshan E Ghulab Colony, Behind Abdullah Heart Care, Pull Wasil Suraj, Miani Road, District Multan, Pakistan
	Detail of Drug Sale License	Name: M/s Al-Asar Enterprises Address: Gulshan E Ghulab Colony, Behind Abdullah Heart Care, Pull Wasil Suraj, Miani Road, District Multan, Pakistan Validity: **05-08-2027.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Vemedim Veterinary Drugs and Probiotics Co. Ltd (Vemedim Animal Health), Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District, Hau Giang Province, Viet Nam.
	Name and address of marketing authorization holder	M/s Vemedim Veterinary Drugs and Probiotics Co. Ltd (Vemedim Animal Health), Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District, Hau Giang Province, Viet Nam.
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 1949 Dated 15-01-2021
	Fee including differential fee	Rs : 100,000 Dated 14-01-2021
	Brand Name +Dosage Form + Strength	OTC 20% LA Solution for Injection
	Composition	Each ml Contains: Oxytetracycline as Oxytetracycline Dihydrate…200mg
	Finished Product Specification	Inhouse specifications
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	10ml, 20ml, 50ml and 100ml
	International availability	N/A
	Me-too status	**Could not be confirmed in the applied pack size**

	Detail of certificates attached	➢ Original legalized FSC Ref. No. 609/2020/QLT-CFS dated **30-06-2020** issued by Department of Animal Health of Vietnam confirming the free sale status in exporting country Validity: **2years** • Scanned copy of GMP certificate No. 32/18/GCN-GMP dated 16-10-2018 issued by Department of Animal Health Ministry of Agriculture and Rural Development Vietnam ➢ Scanned copy of legalized distribution agreement No. 01/VEMEDIM.ALASAR.2020 dated 24-03-2020 between applicant and MAH.
	Remarks of the Evaluator [X]	Provided 06 months accelerated and 36 months long term stability studies data as per zone-IV-B conditions **Shortcomings:** • Provide original legalized valid GMP certificate and Power of attorney/sole distributor agreement since the already submitted are scanned copies. • Provide original legalized valid Free Sale certificate since the already submitted FSC is **expired now but valid upon submission.** • Evidence of applied formulation/drug already approved by DRAP **with same pack size as applied** (generic / me-too status) alongwith registration number, brand name and name of firm. • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier.
	Decision: Deferred for following: • **Original legalized valid GMP certificate and Power of attorney/sole distributor agreement since the already submitted are scanned copies.** • **Original legalized valid Free Sale certificate since the already submitted FSC is expired now but valid upon submission.** • **Evidence of applied formulation/drug already approved by DRAP with same pack size as applied (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Choice of only one pack size** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
822.	Name and address of Applicant	M/s Al-Asar Enterprises (Pakistan), Gulshan E Ghulab Colony, Behind Abdullah Heart Care, Pull Wasil Suraj, Miani Road, District Multan, Pakistan
	Detail of Drug Sale License	Name: M/s Al-Asar Enterprises Address: Gulshan E Ghulab Colony, Behind Abdullah Heart Care, Pull Wasil Suraj, Miani Road, District Multan, Pakistan Validity: **05-08-2027.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Vemedim Veterinary Drugs and Probiotics Co. Ltd (Vemedim Animal Health), Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District, Hau Giang Province, Viet Nam.
	Name and address of marketing authorization holder	M/s Vemedim Veterinary Drugs and Probiotics Co. Ltd (Vemedim Animal Health), Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District, Hau Giang Province, Viet Nam.

	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 1948 Dated 15-01-2021
	Fee including differential fee	Rs : 100,000 Dated 14-01-2021
	Brand Name +Dosage Form + Strength	Amoxi 500 WSP for Oral Solution
	Composition	Each gram Contains: Amoxicillin Trihydrate 500mg eq to Amoxicillin.....436mg
	Finished Product Specification	Inhouse specifications
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	1000gm
	International availability	Approved in Spanish Agency for Medicines and Health Products
	Me-too status	Espemox 500mg/G Powder of M/s Poul Med Enterprises, Karachi. (Reg. No. 101523)
	Detail of certificates attached	➢ Original legalized FSC Ref. No. 605/2020/QLT-CFS dated 30-06-2020 issued by Department of Animal Health of Vietnam confirming the free sale status in exporting country Validity: 2years • Scanned copy of GMP certificate No. 05/19/GCN-GMP dated 16-08-2019 issued by Department of Animal Health Ministry of Agriculture and Rural Development Vietnam ➢ Scanned copy of legalized distribution agreement No. 01/VEMEDIM.ALASAR.2020 dated 24-03-2020 between applicant and MAH.
	Remarks of the Evaluator [X]	Provided 06 months accelerated and 36 months long term stability studies data as per zone-IV-B conditions **Shortcomings:** • Provide original legalized valid GMP certificate and Power of attorney/sole distributor agreement since the already submitted are scanned copies. • Provide original legalized valid Free Sale certificate since the already submitted FSC is **expired now but valid upon submission.** • Confirmation of **manufacturing facility**.
	Decision: Deferred for following: • **Original legalized valid GMP certificate and Power of attorney/sole distributor agreement since the already submitted are scanned copies.** • **Original legalized valid Free Sale certificate since the already submitted FSC is expired now but valid upon submission.** • **Confirmation of dedicated manufacturing facility**. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
823.	Name and address of Applicant	M/s Al-Asar Enterprises (Pakistan), Gulshan E Ghulab Colony, Behind Abdullah Heart Care, Pull Wasil Suraj, Miani Road, District Multan, Pakistan
	Detail of Drug Sale License	Name: M/s Al-Asar Enterprises Address: Gulshan E Ghulab Colony, Behind Abdullah Heart Care, Pull Wasil Suraj, Miani Road, District Multan, Pakistan Validity: **05-08-2027.** Status: License to sell drugs as a Distributor (Form No.11).

	Name and address of manufacturer	M/s Vemedim Veterinary Drugs and Probiotics Co. Ltd (Vemedim Animal Health), Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District, Hau Giang Province, Viet Nam.
	Name and address of marketing authorization holder	M/s Vemedim Veterinary Drugs and Probiotics Co. Ltd (Vemedim Animal Health), Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District, Hau Giang Province, Viet Nam.
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 6952 Dated 02-03-2021
	Fee including differential fee	Rs : 100,000 Dated 02-03-2021
	Brand Name +Dosage Form + Strength	Vimelinspec Powder for Oral Solution
	Composition	Each gram contains: Lincomycin as Lincomycin HCl…222mg Spectinomycin as Spectinomycin Sulphate…444.7mg
	Finished Product Specification	Inhouse specifications
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	1000gm
	International availability	N/A
	Me-too status	**Could not be confirmed in the applied strength**
	Detail of certificates attached	➢ Original legalized FSC Ref. No. 1047/2020/QLT-CFS dated 11-09-2020 issued by Department of Animal Health of Vietnam confirming the free sale status in exporting country Validity: 2years ➢ Scanned copy of GMP certificate No. 32/18/GCN-GMP dated 16-10-2018 issued by Department of Animal Health Ministry of Agriculture and Rural Development Vietnam ➢ Scanned copy of legalized distribution agreement No. 01/VEMEDIM.ALASAR.2020 dated 24-03-2020 between applicant and MAH.
	Remarks of the Evaluator [X]	Provided 06 months accelerated and 36 months long term stability studies data as per zone-IV-B conditions **Shortcomings:** • Provide original legalized valid GMP certificate and Power of attorney/sole distributor agreement since the already submitted are scanned copies. • Provide original legalized valid Free Sale certificate since the already submitted FSC is **expired now but valid upon submission.** • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Original legalized valid GMP certificate and Power of attorney/sole distributor agreement since the already submitted are scanned copies.** • **Original legalized valid Free Sale certificate since the already submitted FSC is expired now but valid upon submission.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	

	The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
824.	Name and address of Applicant	M/s Al-Asar Enterprises (Pakistan), Gulshan E Ghulab Colony, Behind Abdullah Heart Care, Pull Wasil Suraj, Miani Road, District Multan, Pakistan
	Detail of Drug Sale License	Name: M/s Al-Asar Enterprises Address: Gulshan E Ghulab Colony, Behind Abdullah Heart Care, Pull Wasil Suraj, Miani Road, District Multan, Pakistan Validity: **05-08-2027.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Vemedim Veterinary Drugs and Probiotics Co. Ltd (Vemedim Animal Health), Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District, Hau Giang Province, Viet Nam.
	Name and address of marketing authorization holder	M/s Vemedim Veterinary Drugs and Probiotics Co. Ltd (Vemedim Animal Health), Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District, Hau Giang Province, Viet Nam.
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 6953 Dated 02-03-2021
	Fee including differential fee	Rs : 100,000 Dated 02-03-2021
	Brand Name +Dosage Form + Strength	Vimedox 500 Powder for Oral Solution
	Composition	Each gram Contains: Doxycycline Hyclate…500mg
	Finished Product Specification	Inhouse specifications
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	1000gm
	International availability	N/A
	Me-too status	Doxline 50 Powder of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK.(Reg. No. 112322)
	Detail of certificates attached	➢ Original legalized FSC Ref. No. 608/2020/QLT-CFS dated 30-06-2020 issued by Department of Animal Health of Vietnam confirming the free sale status in exporting country Validity: 2years ➢ Scanned copy of GMP certificate No. 32/18/GCN-GMP dated 16-10-2018 issued by Department of Animal Health Ministry of Agriculture and Rural Development Vietnam ➢ Scanned copy of legalized distribution agreement No. 01/VEMEDIM.ALASAR.2020 dated 24-03-2020 between applicant and MAH.
	Remarks of the Evaluator [X]	Provided 06 months accelerated and 36 months long term stability studies data as per zone-IV-B conditions **Shortcomings:** • Provide original legalized valid GMP certificate and Power of attorney/sole distributor agreement since the already submitted are scanned copies. • Provide original legalized valid Free Sale certificate since the already submitted FSC is **expired now but valid upon submission.**

	Decision: Approved. The firm shall submit following before issuance of registration letter: • **original legalized valid GMP certificate and Power of attorney/sole distributor agreement since the already submitted are scanned copies.** • **original legalized valid Free Sale certificate since the already submitted FSC is expired now but valid upon submission.** • **Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
825.	Name and address of Applicant	M/s Al-Asar Enterprises (Pakistan), Gulshan E Ghulab Colony, Behind Abdullah Heart Care, Pull Wasil Suraj, Miani Road, District Multan, Pakistan
	Detail of Drug Sale License	Name: M/s Al-Asar Enterprises Address: Gulshan E Ghulab Colony, Behind Abdullah Heart Care, Pull Wasil Suraj, Miani Road, District Multan, Pakistan Validity: **05-08-2027.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Vemedim Veterinary Drugs and Probiotics Co. Ltd (Vemedim Animal Health), Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District, Hau Giang Province, Viet Nam.
	Name and address of marketing authorization holder	M/s Vemedim Veterinary Drugs and Probiotics Co. Ltd (Vemedim Animal Health), Song Hau Industrial Zone, Dong Phu Commune, Chau Thanh District, Hau Giang Province, Viet Nam.
	Name of exporting country	Vietnam
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 6951 Dated 02-03-2021
	Fee including differential fee	Rs : 100,000 Dated 02-03-2021
	Brand Name +Dosage Form + Strength	Vimenro 20% Solution for Injection
	Composition	Each ml Contains: Enrofloxacin…200mg
	Finished Product Specification	Inhouse specifications
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	Enropro 20% Injection (100ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 112252)
	Detail of certificates attached	➢ Original legalized FSC Ref. No. 611/2020/QLT-CFS dated 30-06-2020 issued by Department of Animal Health of Vietnam confirming the free sale status in exporting country Validity: 2years • Scanned copy of GMP certificate No. 32/18/GCN-GMP dated 16-10-2018 issued by Department of Animal Health Ministry of Agriculture and Rural Development Vietnam ➢ Scanned copy of legalized distribution agreement No. 01/VEMEDIM.ALASAR.2020 dated 24-03-2020 between applicant and MAH.
	Remarks of the Evaluator [X]	Provided 06 months accelerated and 36 months long term stability studies data as per zone-IV-B conditions **Shortcomings:**

		• Provide original legalized valid GMP certificate and Power of attorney/sole distributor agreement since the already submitted are scanned copies. • Provide original legalized valid Free Sale certificate since the already submitted FSC is **expired now but valid upon submission.**
	Decision: Approved. The firm shall submit following before issuance of registration letter: • **original legalized valid GMP certificate and Power of attorney/sole distributor agreement since the already submitted are scanned copies.** • **original legalized valid Free Sale certificate since the already submitted FSC is expired now but valid upon submission.** • **Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
826.	Name and address of Applicant	M/s Vety Care Pvt Ltd., Plot # 77, Street No. 6, I-10/3, Islamabad
	Detail of Drug Sale License	Not provided
	Name and address of manufacturer	M/s Intervet International B.V. Wim De Korversaraat 35, 5831 AN Boxmeer, Netherlands
	Name and address of marketing authorization holder	M/s Intervet International B.V. Wim De Korversaraat 35, 5831 AN Boxmeer, Netherlands
	Name of exporting country	**Netherlands**
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 6612 Dated 01-03-2021
	Fee including differential fee	Rs : 1,00,000 Dated 26-02-2021
	Brand Name +Dosage Form + Strength	Mastijet Forte Intramammary Suspension
	Composition	Each 8gram Contains: Tetracycline HCl…200mg Neomycin Base as Sulphate…250mg Bacitracin…2000 IU Prednisolone…10mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibacterial and Corticosteroid
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	Not demanded
	International availability	N/A
	Me-too status	MASTIJET Syringe of M/s Progressive Associate, Karachi. (Reg. No. 014162)
	Detail of certificates attached	• Original legalized CoPP BD/2020/No. of Certificate 254273 dated 12-11-2020 issued by Ministry of Agriculture, Nature and Food Quality of the Netherlands **does not confirm free sale status of the product in country of origin** • Original legalized GMP certificate No. NL/V 20/0012 based on inspection conducted on 16-07-2020 issued by Ministry of Agriculture, Nature and Food Quality of the Netherlands. (**scope of provided GMP certificate does not cover manufacturing lines of steroids**) • Letter of authorization not provided
	Remarks of the Evaluator [X]	• Provide valid copy of DSL • CoPP is provided which **does not confirm free sale status of the product in country of origin;** Submit legalized original valid FSC.

		• The **scope of provided GMP certificate does not cover manufacturing lines of steroids;** Submit legalized original relevant GMP certificate. • Provide legalized original valid Letter of authorization/sole agency agreement between product license holder and distributor. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Demanded Pack size is not mentioned in form-5A. ➢ **The initial stability studies of Mastijet Forte were performed at 25ºC/60% RH covering 24 months. However, when a decrease in the content of Bacitracin and Prednisolone was observed the storage conditions were finally changed to "store at 2-8ºC". Consequently, only 24 months study results for storage at 5ºC (±3ºC) are presented.**
	Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters	
827.	Name and address of Applicant	M/s ZS Biotech, 50-C, Madina Block, Awan Town, Multan Road, Lahore, Pakistan.
	Detail of Drug Sale License	Name: M/s ZS Biotech Address: House No. 22-A, Hidayat Ullah Block, Mustafa Town, Wahdat Road, District Lahore. **Validity: 22-01-2022.** Status: License to sell drugs as a distributor (Form No.11).
	Name and address of manufacturer	M/s Farmabase Saude Animal LTDA., Av. Emilio Marconato, n˚ 1000 Chacara primavera-Jaguariuna, Brazil
	Name and address of marketing authorization holder	M/s Farmabase Saude Animal LTDA., Av. Emilio Marconato, n˚ 1000 Chacara primavera-Jaguariuna, Brazil
	Name of exporting country	Brazil
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 7849 Dated 10-03-2021
	Fee including differential fee	Rs : 1,00,000 Dated 10-03-2021
	Brand Name +Dosage Form + Strength	Enrofarm Solution (500ml Sachet)
	Composition	Each ml Contains: Enrofloxacin…100mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antimicrobial
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	500ml
	International availability	N/A
	Me-too status	Mycomas Solution for Use in Drinking Water of M/s Orient Animal Health (Pvt) Ltd., Karachi. (Reg. No. 113543)
	Detail of certificates attached	• Scanned copy of FSC dated 02-05-2018 issued by the Ministry of Agriculture, Livestock, and Food Supply Livestock confirms free sale status of the product in country of origin. The manufacturer complies with GMP.

		• Copy of legalized distribution agreement made on 13-06-2018 between the applicant and product license holder is provided.
	Remarks of the Evaluator [X]	Provided 06 months accelerated and 24 months long term stability studies data as per zone-IV-A conditions **Shortcomings:** • Provide copy of valid DSL • Submit legalized original valid FSC, since the already submitted scanned copy is ***expired now but valid upon submission.*** • Submit legalized original valid GMP certificate. • Provide legalized original valid distribution agreement between product license holder and distributor, since already submitted is photocopy. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Revised form 5A stating correct address of applicant (as per valid DSL) along with clarification since ***50-C, Madina Block, Awan Town, Multan Road, Lahore*** is written on form-5A while on copy of DSL ***House No. 22-A, Hidayat Ullah Block, Mustafa Town, Wahdat Road, District Lahore*** is mentioned
	Decision: Deferred for following: • **Copy of valid DSL** • **Legalized original valid FSC, since the already submitted scanned copy is *expired now but valid upon submission.*** • **Legalized original valid GMP certificate.** • **Legalized original valid distribution agreement between product license holder and distributor, since already submitted is photocopy.** • **Label in accordance with The Drugs (Labeling and Packing) Rules, 1986.** • **Revised form 5A stating correct address of applicant (as per valid DSL) along with clarification since *50-C, Madina Block, Awan Town, Multan Road, Lahore* is written on form-5A while on copy of DSL *House No. 22-A, Hidayat Ullah Block, Mustafa Town, Wahdat Road, District Lahore* is mentioned** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	

b. Deferred cases

i. Veterinary

828.	Name and address of Applicant	M/s Atzan Pharmaceuticals, 13-E, Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan
	Detail of Drug Sale License	Name: M/s Atzan Pharmaceutical Address: 13-E, Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan. Validity: **14 April, 2020.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Farma Vet OOD. 40 Otets Paisiy Street, Shumen 9700, Bulgaria
	Name and address of marketing authorization holder	M/s Farma Vet OOD. 40 Otets Paisiy Street, Shumen 9700, Bulgaria
	Name of exporting country	Bulgaria

	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 20575 Dated 19-08-2020
	Fee including differential fee	Rs : 1,00,000 Dated 19-08-2020
	Brand Name +Dosage Form + Strength	Cypermethrin Farma
	Composition	Each 100ml Contains: Cypermethrin…10gm
	Finished Product Specification	Inhouse
	Pharmacological Group	Ectoparasiticides for topical use
	Shelf life	2 Years
	Demanded Price	Decontrolled
	Pack size	1L, 5L, 10L
	International availability	N/A
	Me-too status	Cypercid Liquid of M/s Eterna Pharma (Pvt) Ltd., Mirpur, AJK. (Reg. No. 112138)
	Detail of certificates attached	➢ Original Legalized Free Sale Certificate issued by Bulgarian Food Safety Agency at the Ministry of Agriculture, Food and Forestry confirms free sale status of the applied product in exporting country. Date of issuance: 13-04-2020 ➢ Original legalized GMP certificate No. 102/2019/GMP issued on 29-05-2019 by Bulgarian Food Safety Agency Ministry of Agriculture, Food and Forestry Bulgaria. (Original in Tylofarm- Water Soluble Powder dossier) ➢ Copy of Letter of Authorization dated 05-03-2020 (Original in Tylofarm- Water Soluble Powder dossier)
	Remarks of the Evaluator [X]	• Provide valid copy of DSL • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. ➢ 6 months accelerated and 24 months long term stability studies data has been submitted as per zone-IV-A conditions.
	Decision of 326th meeting: Deferred for following: • valid copy of DSL • Label in accordance with The Drugs (Labeling and Packing) Rules, 1986 **Updated status:** • The firm has submitted copy of DSL (Form-11) valid till 07-11-2027 • The firm has now provided label in accordance with The Drugs (Labeling and Packing) Rules, 1986	
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
829.	Name and address of Applicant	M/s Atzan Pharmaceuticals, 13-E, Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan
	Detail of Drug Sale License	Name: M/s Atzan Pharmaceutical Address: 13-E, Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan. Validity: **14 April, 2020.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Farma Vet OOD. 40 Otets Paisiy Street, Shumen 9700, Bulgaria
	Name and address of marketing authorization holder	M/s Farma Vet OOD. 40 Otets Paisiy Street, Shumen 9700, Bulgaria

	Name of exporting country	Bulgaria
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 20576 Dated 19-08-2020
	Fee including differential fee	Rs : 1,00,000 Dated 19-08-2020
	Brand Name +Dosage Form + Strength	Tylofarm- Water Soluble Powder
	Composition	Each 100gram Contains: Tylosin Tartrate…40,000,000 IU (50g)
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibacterial
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	1Kg, 5Kg, 10Kg, 25Kg
	International availability	N/A
	Me-too status	Tylo-50 Water Soluble Powder of M/s Symans Pharmaceuticals (Pvt) Ltd, Lahore. (Reg. No. 063847)
	Detail of certificates attached	➢ Original Legalized Free Sale Certificate issued by Bulgarian Food Safety Agency at the Ministry of Agriculture, Food and Forestry confirms free sale status of the applied product in exporting country. Date of issuance: 23-02-2020 ➢ Original legalized GMP certificate No. 102/2019/GMP issued on 29-05-2019 by Bulgarian Food Safety Agency Ministry of Agriculture, Food and Forestry Bulgaria. ➢ Original legalized Letter of Authorization dated 05-03-2020
	Remarks of the Evaluator [X]	**Shortcomings:** • Provide valid copy of DSL • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. ➢ 6 months accelerated and 36 months long term stability studies data has been submitted as per zone-IV-A conditions.
	Decision of 326th meeting: Deferred for following: • valid copy of DSL • Label in accordance with The Drugs (Labeling and Packing) Rules, 1986 **Updated status:** • The firm has submitted copy of DSL (Form-11) valid till 07-11-2027 • The firm has now provided label in accordance with The Drugs (Labeling and Packing) Rules, 1986	
	Decision: Approved. The firm shall submit full fee of Rs.150,000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
830.	Name and address of Applicant	M/s Ghazi Brothers, Ghazi House, D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi-75350, Pakistan
	Detail of Drug Sale License	Name: M/s Ghazi Brothers Address: D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi Validity: 29-06-2023. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Zhummadian Huazhong Chia Tai. No.2019, Leshan Road, High Technology Development Zone, Zhumadian, Henan, China

	Name and address of marketing authorization holder	M/s Zhummadian Huazhong Chia Tai. No.2019, Leshan Road, High Technology Development Zone, Zhumadian, Henan, China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24963 Dated 24-09-2020
	Fee including differential fee	**Rs : 50,000** Dated 23-09-2020
	Brand Name +Dosage Form + Strength	Tylomax 10% Premix
	Composition	Each Kg contains: Tylosin Phosphate…100gm
	Finished Product Specification	Chinese Pharmacopeia
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	25Kg
	International availability	Not provided
	Me-too status	Ty-Mix 10 Premix of M/s Breeze Pharma Islamabad. (Reg. No. 059160)
	Detail of certificates attached	➢ Original Legalized Free Sale Certificate No. 201100B0/021525 issued by Animal Husbandry Bureau of Zhumadian City, Henan Province China Date of issuance: 02-04-2020 Validity: **01-04-2024** ➢ Original Legalized GMP Certificate No. (2019) GMP16018 issued by Bureau of Animal Husbandry, Henan Province China Date of issuance: 21-05-2019 Validity: **20-05-2024** ➢ Photocopy of Power of Attorney dated 12-03-2019 for the applied product
	Remarks of the Evaluator [X]	• 06 months accelerated and 36 months long term stability studies data has been submitted as per zone-IV-A conditions. **Shortcomings:** • Differential fee Rs. 50,000/- for registration of generic drug product. • The provided Letter of Authorization (LOA)/ sole agency certificate is copy**,** Provide legalized valid original LOA from product license holder.
	Decision of 326th meeting: Deferred for following: • Differential fee Rs. 50,000/- for registration of generic drug product. • Original legalized valid Letter of Authorization (LOA)/ sole agency certificate from product license holder **Updated status:** • The firm has not deposited differential fee Rs. 50,000/- for registration of generic drug product. • The firm has provided reference to the dossier Tylomax 22% considered in 322nd meeting of the Registration Board for Original legalized valid Power of attorney dated 12-03-2019.	
	Decision: Approvd with innovator's specifications and firm shall submit full fee of Rs.150,000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
831.	Name and address of Applicant	M/s Samara Stores, 17 Qamar Market Unit No 7, Latifabad, Hyderabad, Pakistan
	Detail of Drug Sale License	**Not provided**

	Name and address of manufacturer	M/s The Arab Pecticides & Veterinary Drugs Mfg. Co. Factory/El-Hassan Industrial Estate-Ibrid
	Name and address of marketing authorization holder	M/s The Arab Pecticides & Veterinary Drugs Mfg. Co. Factory/El-Hassan Industrial Estate-Ibrid
	Name of exporting country	Jordan
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 15556 Dated 26-08-2019
	Fee including differential fee	Rs : 100,000 Dated 26-08-2019
	Brand Name +Dosage Form + Strength	Bisolvet 2% Oral Solution
	Composition	Each 1ml Contains: Bromhexine HCl…20mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Expectorant
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	500ml, 1L, 2.5L
	International availability	N/A
	Me-too status	**Could not be confirmed in the applied strength**
	Detail of certificates attached	➢ Original Legalized Free Sale Certificate No. 003473 issued by minister of Agriculture and Minister of Environment Jordan declaring the free sale of applied product in country of origin Date of issuance: 08-04-2019 ➢ Original legalized GMP certificate No. 003479 dated 08-04-2019 issued by minister of Agriculture and Minister of Environment Jordan, with validity: 3 years. ➢ Letter of Authorization/Sole Agency Certificate between PLH and Applicant **is not provided**
	Remarks of the Evaluator [X]	• 06 months accelerated and 36 months long term stability studies data has been submitted as per zone-IV-A conditions. **Shortcomings:** • Provide valid copy of DSL • Provide original legalized valid GMP certificate since the already submitted is expired now but valid upon submission. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Provide Letter of Authorization/Sole Agency Certificate between PLH and Applicant
	Decision of 324th meeting: Deferred for following: • Provide valid copy of DSL • Provide original legalized valid GMP certificate since the already submitted is expired now but valid upon submission. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Provide Letter of Authorization/Sole Agency Certificate between PLH and Applicant **Updated status:** • The firm has submitted copy of DSL (Form-7-A) valid till 07-01-2024 • Original legalized GMP certificate No. 000949 dated 24-01-2023 issued by Ministry of Agriculture- Veterinary and Animal Health Department Jordan, with **validity: 3 years.**	

	• **Metoo status:** Avixin-M 2% Oral Liquid of M/S. U.M. Enterprises, Karachi. (Reg. No. 099038) • Provided **photocopy** of Letter of Authorization **(not legalized)** for the applied product between PLH and Applicant.	
	Decision: Deferred for original legalized valid Letter of Authorization (LoA) for the applied product between PLH and Applicant. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
832.	Name and address of Applicant	M/s Ghazi Brothers, Ghazi House, D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi-75350, Pakistan
	Detail of Drug Sale License	Name: M/s Ghazi Brothers Address: D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road, Karachi Date of issuance: 24-12-2018. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Zhummadian Huazhong Chia Tai. No.2019, Leshan Road, High Technology Development Zone, Zhumadian, Henan, China
	Name and address of marketing authorization holder	M/s Zhummadian Huazhong Chia Tai. No.2019, Leshan Road, High Technology Development Zone, Zhumadian, Henan, China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 6285 Dated 16-05-2019
	Fee including differential fee	**Rs : 50,000** Dated 15-05-2019
	Brand Name +Dosage Form + Strength	Tylomax 22% Granules
	Composition	Each Kg contains: Tylosin Phosphate…220gm
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	25Kg
	International availability	Not provided
	Me-too status	Could not be confirmed
	Detail of certificates attached	➢ Original Legalized Free Sale Certificate No. 191100B0/018162 issued by Animal Husbandry Bureau of Zhumadian City, Henan Province China Date of issuance: 12-03-2019 Validity: 20-02-2024 ➢ Originally legalized copy of GMP certificate No. (2014) Shou Yao GMP No.156 issued on 28-02-2019 and valid till **31-07-2019** confirms GMP status ➢ Original Legalized Power of attorney dated 12-03-2019
	Remarks of the Evaluator [X]	• 06 months accelerated and 36 months long term stability studies data has been submitted as per zone-IV-A conditions. **Shortcomings:** • Submitted copy of GMP certificate is expired now but valid upon submission, provide legalized original valid GMP certificate of the manufacturer. • Provide valid copy of DSL

		• Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 322nd meeting: Deferred for following: • Legalized original valid GMP certificate of the manufacturer. • Valid copy of DSL • Finished product specifications in the light of decision taken in 267th meeting of Registration Board. • Differential fee Rs. 50,000/- for registration of imported drug. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. **Updated status:** • The firm has provided reference to the dossier Tylomax 10% considered in 326th meeting of the Registration Board for Original Legalized **GMP** Certificate No. (2019) GMP16018 issued by Bureau of Animal Husbandry, Henan Province China; Date of issuance: 21-05-2019 and **Validity: 20-05-2024** • The firm has provided copy of DSL (Form No.7) valid till **29-06-2023.** • Firm has revised finished product specification from inhouse to "**as per innovator's specifications"** without submission of requisite fee. • The firm has not deposited differential fee Rs. 50,000/- for registration of generic drug product. • Metoo status: Tyro Premix Powder of M/s Epla Laboratories (Pvt) Ltd Karachi. (Reg. No. 023463)	
	Decision: Approvd with innovator's specifications. The firm shall submit fee of Rs.150,000/- for correction in formulation (salt form), as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
833.	Name and address of Applicant	M/s U.M. Enterprises, Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan
	Detail of Drug Sale License	Name: M/s U.M. Enterprises, Address: Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan Date of issuance: 21-03-2023. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Arab Veterinary Industrial Co. "AVICO" P.O.Box 150906, Amman 11115-Jordan
	Name and address of marketing authorization holder	M/s Arab Veterinary Industrial Co. "AVICO" P.O.Box 150906, Amman 11115-Jordan
	Name of exporting country	Jordan
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 26140 Dated 05-12-2019
	Fee including differential fee	Rs : 1,00,000 Dated 05-12-2019
	Brand Name +Dosage Form + Strength	Trimectin Cattle Suspension
	Composition	Each ml Contains: Ivermectin…2mg Triclabendazole…120mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Anthelmintic
	Shelf life	03 Years

	Demanded Price	N/A
	Pack size	100ml, 500ml, 1Liter
	International availability	N/A
	Me-too status	Not provided
	Detail of certificates attached	• Original Legalized COPP NO. 8343 dated 25-09-2019 issued by the Ministry of Agriculture, The Hashemite Kingdom of Jordan confirms GMP status and Free sale status of applied product in country of origin. • Original Legalized GMP certificate No**:** 008342 **Certified by:** Director of Veterinary & Animal Health, Ministry of Agriculture, The Hashemite Kingdom of Jordan. **Issued on:** 25/09/2019 **Validity**: 3 years • Original legalized Power of attorney from Arab Veterinary Industrial Co. "AVICO" P.O Box 150906 Amman 11115-Jordan & U.M. Enterprises, 18 C 3rd Floor Dolmen Estate Block-7, Shaheed e Millat Road, Karachi.
	Remarks of the Evaluator [x]	• Provided 06 month accelerated and 36months real time stability studies data of three batches at zone IV-A conditions. **Shortcomings**: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 322nd meeting: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. **Updated status:** • The firm has submitted that metoo/ generic of the applied product is not registered but the applied formulation is **approved in Australia** • **RRA status**: Fasimec Cattle Oral Flukicide and Broad Spectrum Drench Ivermectin .....2.0g/L Triclabendazole.....120.0g/L	
	Decision: Approved. Fee of Rs. 7500/- for correction/pre-approval change in finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.	
834.	Name and address of Applicant	M/s U.M. Enterprises, Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan
	Detail of Drug Sale License	Name: M/s U.M. Enterprises, Address: Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan Date of issuance: 21-03-2023. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Arab Veterinary Industrial Co. "AVICO" P.O.Box 150906, Amman 11115-Jordan
	Name and address of marketing authorization holder	M/s Arab Veterinary Industrial Co. "AVICO" P.O.Box 150906, Amman 11115-Jordan
	Name of exporting country	Jordan
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 4031 Dated 19-04-2019
	Fee including differential fee	Rs : 1,00,000 Dated 01-04-2019
	Brand Name +Dosage Form + Strength	Coliprim Injection

	Composition	Each 1ml Contains: Trimethoprim…40mg Sulphadiazine Sodium…200mg
	Finished Product Specification	Manufacturer's specifications
	Pharmacological Group	Antibiotic
	Shelf life	02 Years
	Demanded Price	N/A
	Pack size	50ml, 100ml and 250ml
	International availability	N/A
	Me-too status	Not provided
	Detail of certificates attached	• Photocopy of Legalized GMP certificate: reference to file submitted in December 2019. Certificate No: 000304 Certified by: Ministry of Agriculture/The Veterinary Department- Pharmacy & Drugs Control Division/ In The Hashemite Kingdom of Jordan. Issued on: 11/01/2017 • Legalized Original free sale certificate: Certificate No: 002232 Certified by: Ministry Of Agriculture/The Veterinary Department- Pharmacy & Drugs Control Division/ In The Hashmite Kingdom of Jordan certifies that Coliprim Injection manufactured by Avico is registered & freely sold in Jordan with the same name & Composition and pack size of **100ml.** Issued on: 10-03-2019 Letter of Authorization (Photocopy) Arab Veterinary Industrial Co. "AVICO" P.O Box 150906 Amman 11115- Jordan & U.M. Enterprises, 18 C 3rd Floor Dolmen Estate Block-7, Shaheed e Millat Road, Karachi. Issued on: 12th of June, 2012
	Remarks of the Evaluator [X]	• The submitted photocopy of letter of Authorization (LOA) and GMP certificate are **expired now, but valid upon submission,** Provide legalized valid original LOA and GMP certificate. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Submit Rs.7500/- for revision of finished product Specifications. • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes of injectable dosage form are demanded in a single application. So clarification is required for which pack size/ fill volume you want to apply this dossier. • Provide 06 months accelerated and real time stability studies data upto claimed shelf life of three batches at zone IV-A conditions as per requirement of 278th meeting of Registration Board.
	Decision of 322nd meeting: Deferred for following: • Legalized valid original LOA	

	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Finished product specifications in the light of decision taken in 267th meeting of Registration Board. • Submit Rs.7500/- for revision of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • Demanded pack size. • 06 months accelerated and real time stability studies data upto claimed shelf life of three batches at zone IV-A conditions **Updated status:** • Legalized original Power of Attorney from AVICO Jordan to M/s UM Enterprises. • The firm has submitted that metoo/ generic of the applied product is not registered but the applied formulation is **approved in The Netherlands** • **RRA status**: Diatrim Solution for injection 200mg/ml + 40mg/ml • Firm has submitted **Inhouse** finished product specification along with the fee of Rs. 7,500/- via deposit slip no 108012945 • Demanded pack size: **100ml** • Provided 06 months accelerated and 24 months real time stability studies data of three batches at zone IV-A conditions Remarks of the Evaluator [x]: • Provide legalized valid original GMP certificate before issuance of registration letter, since the original legalized GMP submitted with Trimectin Cattle suspension was valid till 24-09-2022	
	Decision: Approved. The firm shall submit oridginal legalized valid GMP certificate before issuance of registration letter.	
835.	Name and address of Applicant	M/s U.M. Enterprises, Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan
	Detail of Drug Sale License	Name: M/s U.M. Enterprises, Address: Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan Date of issuance: 01-09-2021. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Qilu Animal Health Products Co. Ltd. No. 243, Gongye North Road, Jinan, Shandong, China
	Name and address of marketing authorization holder	M/s Qilu Animal Health Products Co. Ltd. No. 243, Gongye North Road, Jinan, Shandong, China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 2271 Dated 01-04-2019
	Fee including differential fee	Rs : 1,00,000 Dated 01-04-2019
	Brand Name +Dosage Form + Strength	Flor 30 Solution for Injection
	Composition	Each ml Contains: Florfenicol…300mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	24 months
	Demanded Price	N/A
	Pack size	50ml
	International availability	N/A
	Me-too status	Florfenicen Injectable Solution of M/s Mustafa Brothers, Faisalabad. (Reg. No.103910)
	Detail of certificates attached	**CERTIFICATE OF PHARMACEUTICAL PRODUCT**

		Certified by: Bureau of Animal Husbandry & Veterinary of Shandong Province, China **Product License NO:** Vet. Drug No. (2014)150252540 **Issued on:** 06/11/2018 **Free sale:** Free sale of the product in exporting country: Yes confirms from COPP GMP certificate No.: 151100B0/17202 Validity: 10-07-2019 **Authorization Letter** 11-12-2017 Validity: 3 years
	Remarks of the Evaluator [X]	**Shortcomings:** • The submitted photocopy of letter of Authorization (LOA) and GMP certificate are **expired now, but valid upon submission,** Provide legalized valid original LOA and GMP certificate. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Submit Rs.7500/- for revision of finished product specifications. • Provide accelerated and real time stability studies data of three batches at zone IV-A conditions as per requirement of 278th meeting of Registration Board. The firm has submitted vide letter no. UME-10/2022.DOC-021 dated 07-10-2022 that all the deficiencies were duly notified to the supplier and will be addressed at the earliest possible time. Kindly give us a **time extension** to furnish the requisite information/documents from the principal as the legalized and notarized documents may take time from the principal.
	Decision of 322nd Meeting: Deferred for following: • Legalized valid original LOA and GMP certificate. • Finished product specifications in the light of decision taken in 267th meeting of Registration Board. • Fee Rs.7500/- for revision of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • 06 months accelerated and real time stability studies data upto claimed shelf life of three batches at zone IV-A conditions. **Updated status:** • Firm has submitted scanned copies of Legalized LoA dated 20-08-2022 (original in oxyplan 20 solution Injection application) and GMP certificate No. (2018)GMP15036 valid till 21-11-2023 • The firm has submitted **Chinese Pharmacopoeia** specifications alongwith fee Rs. 7500/- vide slip No. 5357273482 for correction/ pre-approval change of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • Provided 06 months accelerated and 24 months real time stability studies data of three batches at zone IV-A conditions	
	Decision: Approved. The firm shall submit oridginal legalized valid GMP certificate before issuance of registration letter.	
836.	Name and address of Applicant	M/s U.M. Enterprises, Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan
	Detail of Drug Sale License	Name: M/s U.M. Enterprises, Address: Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan

		Date of issuance: 01-09-2021. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Qilu Animal Health Products Co. Ltd. No. 243, Gongye North Road, Jinan, Shandong, China
	Name and address of marketing authorization holder	M/s Qilu Animal Health Products Co. Ltd. No. 243, Gongye North Road, Jinan, Shandong, China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 2267 Dated 01-04-2019
	Fee including differential fee	Rs : 1,00,000 Dated 01-04-2019
	Brand Name +Dosage Form + Strength	Ceftihyde RTU Injection
	Composition	Each ml contains: Ceftiofur HCl eq. to Ceftiofur…50mg
	Finished Product Specification	As per innovator's specifications
	Pharmacological Group	Antibiotic
	Shelf life	24 months
	Demanded Price	N/A
	Pack size	50ml
	International availability	N/A
	Me-too status	Cefur-RTU Injection of M/s Nawan Laboratories (Pvt) Ltd., Karachi. (Reg. No.049605)
	Detail of certificates attached	**CERTIFICATE OF PHARMACEUTICAL PRODUCT** **Certified by:** Bureau of Animal Husbandry & Veterinary of Shandong Province, China **NO:** Vet. Drug No. (2014)150252292 **Issued on:** 06/11/2018 **Free sale:** Free sale of the product in exporting country: Yes confirms from COPP GMP certificate No.: 151100B0/17202 Validity: 10-07-2019 **Authorization Letter** 11-12-2017 Validity: 3 years
	Remarks of the Evaluator [x]	**Shortcomings:** • The submitted photocopy of letter of Authorization (LOA) and GMP certificate are expired now, but valid upon submission, Provide legalized valid original LOA and GMP certificate. • Provide accelerated and real time stability studies data of three batches at zone IV-A conditions as per requirement of 278th meeting of Registration Board. The firm has submitted vide letter no. UME-10/2022.DOC-021 dated 07-10-2022 that all the deficiencies were duly notified to the supplier and will be addressed at the earliest possible time. Kindly give us a **time extension** to furnish the requisite information/documents from the principal as the legalized and notarized documents may take time from the principal.
	Decision of 322nd Meeting: Deferred for following: • Legalized valid original LOA and GMP certificate. • 06 months accelerated and real time stability studies data upto claimed shelf life of three batches at zone IV-A conditions. **Updated status:**	

	• Firm has submitted scanned copies of Legalized LoA dated 20-08-2022 (original in oxyplan 20 solution Injection application) and GMP certificate No. (2018)GMP15036 valid till 21-11-2023 • Provided 06 months accelerated and 24 months real time stability studies data of three batches at zone IV-A conditions	
	Decision: Approved. The firm shall submit oridginal legalized valid GMP certificate before issuance of registration letter.	
837.	Name and address of Applicant	M/s U.M. Enterprises, Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan
	Detail of Drug Sale License	Name: M/s U.M. Enterprises, Address: Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan Date of issuance: 01-09-2021. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Qilu Animal Health Products Co. Ltd. No. 243, Gongye North Road, Jinan, Shandong, China
	Name and address of marketing authorization holder	M/s Qilu Animal Health Products Co. Ltd. No. 243, Gongye North Road, Jinan, Shandong, China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 227169 Dated 01-04-2019
	Fee including differential fee	Rs : 1,00,000 Dated 01-04-2019
	Brand Name +Dosage Form + Strength	Flumeglu Solution for Injection
	Composition	Each ml contains: Flunixin Meglumine…50mg
	Finished Product Specification	USP
	Pharmacological Group	Non-steroidal anti-inflammatory drug
	Shelf life	24 months
	Demanded Price	N/A
	Pack size	50ml
	International availability	N/A
	Me-too status	Logon Injection of M/s S.J & G Fazul Ellahie (Pvt.) Ltd, Karachi. (Reg. No.097927)
	Detail of certificates attached	**CERTIFICATE OF PHARMACEUTICAL PRODUCT** **Certified by:** Bureau of Animal Husbandry & Veterinary of Shandong Province, China **NO:** Vet. Drug No. (2014)150252102 **Issued on:** 06/11/2018 **Free sale:** Free sale of the product in exporting country: Yes confirms from COPP GMP certificate No.: 151100B0/17202 Validity: 10-07-2019 **Authorization Letter** 11-12-2017 Validity: 3 years
	Remarks of the Evaluator [X]	**Shortcomings:** • The submitted original letter of Authorization (LOA) and copy of GMP certificate are **expired now, but valid upon submission,** Provide legalized valid original LOA and GMP certificate. • Provide accelerated and real time stability studies data of three batches at zone IV-A conditions as per requirement of 278th meeting of Registration Board.

		• Revise label claim on form 5A in line with reference product and composition in CoPP. Submit full fee of registration for revision of label claim. The firm has submitted vide letter no. UME-10/2022.DOC-021 dated 07-10-2022 that all the deficiencies were duly notified to the supplier and will be addressed at the earliest possible time. Kindly give us a **time extension** to furnish the requisite information/documents from the principal as the legalized and notarized documents may take time from the principal.
	Decision of 322nd Meeting: Deferred for following: • Legalized valid original LOA and GMP certificate. • Finished product specifications in the light of decision taken in 267th meeting of Registration Board. • Revision of label claim on form 5A in line with reference product and composition in CoPP. • Fee Rs. 100,000/- for correction/ pre-approval change of formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • 06 months accelerated and real time stability studies data upto claimed shelf life of three batches at zone IV-A conditions. **Updated status:** • Firm has submitted scanned copies of Legalized LoA dated 20-08-2022 (original in oxyplan 20 solution Injection application) and GMP certificate No. (2018)GMP15036 valid till 21-11-2023 • The firm has revised formulation as per following label claim **Each ml contains:** **Flunixin Meglumine eq. to Flunixin…50mg** • The firm has submitted Fee Rs. 150,000/- vide slip No. 7677703022 for correction/ pre-approval change of formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • Provided 06 months accelerated and 24 months real time stability studies data of three batches at zone IV-A conditions	
	Decision: Approved with following label claim: **Each ml contains:** **Flunixin Meglumine eq. to Flunixin…50mg** **The firm shall submit oridginal legalized valid GMP certificate before issuance of registration letter.**	
838.	Name and address of Applicant	M/s U.M. Enterprises, Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan
	Detail of Drug Sale License	Name: M/s U.M. Enterprises, Address: Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan Date of issuance: 01-09-2021. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Qilu Animal Health Products Co. Ltd. No. 243, Gongye North Road, Jinan, Shandong, China
	Name and address of marketing authorization holder	M/s Qilu Animal Health Products Co. Ltd. No. 243, Gongye North Road, Jinan, Shandong, China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 2268 Dated 01-04-2019
	Fee including differential fee	Rs : 1,00,000 Dated 01-04-2019
	Brand Name +Dosage Form + Strength	Enroplan 10 Solution for Injection

	Composition	Each ml contains: Enrofloxacin…100mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	24 months
	Demanded Price	N/A
	Pack size	100ml
	International availability	N/A
	Me-too status	Floxa-10 Injection of M/s Evergreen Pharmaceuticals, Lahore. (Reg. No.102192)
	Detail of certificates attached	**CERTIFICATE OF PHARMACEUTICAL PRODUCT** **Certified by:** Bureau of Animal Husbandry & Veterinary of Shandong Province, China **NO:** Vet. Drug No. (2014)150252523 **Issued on:** 06/11/2018 **Free sale:** Free sale of the product in exporting country: Yes confirms from COPP GMP certificate No.: 151100B0/17202 Validity: 10-07-2019 **Authorization Letter** 11-12-2017 Validity: 3 years
	Remarks of the Evaluator [x]	**Shortcomings:** • The submitted photocopy of letter of Authorization (LOA) and GMP certificate **are expired now, but valid upon submission,** Provide legalized valid original LOA and GMP certificate. • Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Submit Rs.7500/- for revision of finished product specifications. • Provide accelerated and real time stability studies data of three batches at zone IV-A conditions as per requirement of 278th meeting of Registration Board. The firm has submitted vide letter no. UME-10/2022.DOC-021 dated 07-10-2022 that all the deficiencies were duly notified to the supplier and will be addressed at the earliest possible time. Kindly give us a **time extension** to furnish the requisite information/documents from the principal as the legalized and notarized documents may take time from the principal.
	Decision of 322nd Meeting: Deferred for following: • Legalized valid original LOA and GMP certificate. • Finished product specifications in the light of decision taken in 267th meeting of Registration Board. • Fee Rs.7500/- for revision of finished product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • 06 months accelerated and real time stability studies data upto claimed shelf life of three batches at zone IV-A conditions. **Updated status:** • Firm has submitted scanned copies of Legalized LoA dated 20-08-2022 (original in oxyplan 20 solution Injection application) and GMP certificate No. (2018)GMP15036 valid till 21-11-2023	

	• The firm has submitted **Chinese Pharmacopoeia** specifications alongwith fee Rs. 7500/- vide slip No. 6765347727 for correction/ pre-approval change of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • Provided 06 months accelerated and 24 months real time stability studies data of three batches at zone IV-A conditions	
	Decision: Approved. The firm shall submit oridginal legalized valid GMP certificate before issuance of registration letter.	
839.	Name and address of Applicant	M/s U.M. Enterprises, Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan
	Detail of Drug Sale License	Name: M/s U.M. Enterprises, Address: Plot No. 12, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan Date of issuance: 01-09-2021. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Qilu Animal Health Products Co. Ltd. No. 243, Gongye North Road, Jinan, Shandong, China
	Name and address of marketing authorization holder	M/s Qilu Animal Health Products Co. Ltd. No. 243, Gongye North Road, Jinan, Shandong, China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 2270 Dated 01-04-2019
	Fee including differential fee	Rs : 1,00,000 Dated 01-04-2019
	Brand Name +Dosage Form + Strength	Oxyplan 20 Solution for Injection
	Composition	Each ml contains: Oxytetracycline…200mg
	Finished Product Specification	**Chinese pharmacopoeial specifications**
	Pharmacological Group	Antibiotic
	Shelf life	24 months
	Demanded Price	N/A
	Pack size	100ml
	International availability	N/A
	Me-too status	Oxy-LA Injection of M/s Selmore Pharmaceuticals (Pvt.) Ltd., Lahore. (Reg. No.035014) (confirm salt form)
	Detail of certificates attached	**CERTIFICATE OF PHARMACEUTICAL PRODUCT** **Certified by:** Bureau of Animal Husbandry & Veterinary of Shandong Province, China **Product License NO:** Vet. Drug No. (2014)150252787 **Issued on:** 06/11/2018 **Free sale:** Free sale of the product in exporting country: Yes confirms from COPP GMP certificate No.: 151100B0/17202 Validity: **10-07-2019** **Authorization Letter** 11-12-2017 Validity: 3 years
	Remarks of the Evaluator [X]	**Shortcomings:** • The submitted photocopy of letter of Authorization (LOA) and GMP certificate are expired now, but valid upon submission, Provide legalized valid original LOA and GMP certificate. • Clarification regarding salt form of API applied in this dossier is required; and revise label claim and master formula in line with reference product, accordingly.

		• Provide evidence of pharmacopoeial reference of finished product specification. In case, the product is non pharmacopoeial, submit product specification in the light of decision taken in 267th meeting of Registration Board. • Submit full fee of registration for revision of finished product specifications, label claim and master formula. • Provide accelerated and real time stability studies data of three batches at zone IV-A conditions as per requirement of 278th meeting of Registration Board. The firm has submitted vide letter no. UME-10/2022.DOC-021 dated 07-10-2022 that all the deficiencies were duly notified to the supplier and will be addressed at the earliest possible time. Kindly give us a **time extension** to furnish the requisite information/documents from the principal as the legalized and notarized documents may take time from the principal.
	Decision of 322nd Meeting: Deferred for following: • Legalized valid original LOA and GMP certificate. • Finished product specifications in the light of decision taken in 267th meeting of Registration Board. • Clarification regarding salt form of API and revise label claim and master formula in line with reference product, accordingly • Fee Rs. 100,000/- for correction/ pre-approval change of formulation and finished product specification as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • 06 months accelerated and real time stability studies data upto claimed shelf life of three batches at zone IV-A conditions. **Updated status:** • Firm has submitted original Legalized LoA dated 20-08-2022 and scanned copy of GMP certificate No. (2018)GMP15036 valid till 21-11-2023 • The firm has revised formulation as per following label claim **Each ml contains:** **Oxytetracycline as base…200mg** • The firm has submitted Fee Rs. 150,000/- vide slip No. 98945081819 for correction/ pre-approval change of formulation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021. • Provided 06 months accelerated and 24 months real time stability studies data of three batches at zone IV-A conditions	
	Decision: Approved	
840.	Name and address of Applicant	M/s Orient Animal Health Pvt Ltd. Commercial # 6, Block-A, 1st Floor, Kazimabad, Near Masjid-e-Hira, Model Colony, Karachi, Pakistan
	Detail of Drug Sale License	Name: M/s Orient Animal Health Pvt Ltd, Address: Commercial # 6, Block-A, 1st Floor, Kazimabad, Near Masjid-e-Hira, Model Colony, Karachi Validity: 22-10-2020. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Divasa-Farmavic, S.A. Ctra. Sant Hipolit, Km.71, Gurb-Vic, 08503 Barcelona, Spain
	Name and address of marketing authorization holder	M/s EMDOKA bvba. John Lijsenstraat 16, B-2321 Hoogstraten Belgium
	Name of exporting country	Belgium
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 23842 Dated 15-09-2020
	Fee including differential fee	Rs : 100,000 Dated 15-09-2020

	Brand Name +Dosage Form + Strength	Halagon 0.5mg/ml Oral Solution
	Composition	Each ml contains: Halofuginone as Lactate…0.5mg
	Finished Product Specification	Eur. Ph
	Pharmacological Group	Antiprotozoal
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	Not demanded
	International availability	Belgium approved
	Me-too status	-
	Detail of certificates attached	➢ Original legalized Certificate of Medicinal Product Certificate No. 02/19/136092 Issued on 20-09-2019, Certified by *European Medicine Agency*. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturer. ➢ Originally legalized GMP certificate No. ES/084HV/18 dated 13-07-2018 issued by Spanish agency of Medicines and Medical Devices, Spain Validity: 19-04-2020 **(expired even upon submission)** ➢ Originally legalized sole agency certificate dated 26-09-2019 from PLH attached in Emdactilin 150 Solution For Injection file
	Remarks of the Evaluator [X]	➢ 6 months accelerated and 36 months long term stability studies data has been submitted as per zone-IV-A conditions. ➢ The applied formulation is non-pharmacopoeial. **Shortcomings:** • The already submitted GMP is **expired even upon submission,** Provide • Choice of pack size. • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision of 326th Meeting: Deferred for submission of following • copy of valid DSL • original legalized valid GMP certificate • demanded pack size • Label in accordance with The Drugs (Labelling and Packing) Rules, 1986. **Updated status:** • The firm has provided copy of DSL (Form No.7) valid till **22-10-2024.** • Originally legalized GMP certificate No. ES/165HV/21 dated 11-11-2021 issued by Spanish agency of Medicines and sanitary products, Spain Validity: 21-04-2024 • Demanded pack sizes: **290ml, 490ml, and 980ml** • Proposed Product label **does not have" URDU "Inscription** as required under the drugs (labelling and packaging) rules.	
	Decision: Approved with 250ml pack size. The firm shall submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986 before issuance of registration letter.	
841.	Name and address of Applicant	M/s Orient Animal Health Pvt Ltd. Commercial # 6, Block-A, 1st Floor, Kazimabad, Near Masjid-e-Hira, Model Colony, Karachi, Pakistan
	Detail of Drug Sale License	Name: M/s Orient Animal Health Pvt Ltd, Address: Commercial # 6, Block-A, 1st Floor, Kazimabad, Near Masjid-e-Hira, Model Colony, Karachi

		Validity: 22-10-2020. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Produlab Pharma BV. Forellenweg 16, NL-4941 SJ Raamsdonksveer, The Netherlands
	Name and address of marketing authorization holder	M/s EMDOKA bvba. John Lijsenstraat 16, B-2321 Hoogstraten Belgium
	Name of exporting country	Belgium
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 23843 Dated 15-09-2020
	Fee including differential fee	Rs : 100,000 Dated 15-09-2020
	Brand Name +Dosage Form + Strength	Emdactilin 150 Solution For Injection
	Composition	Each ml Contains: 149.01mg of Spectinomycin HCl Pentahydrate Eq. To Spectinomycin…100mg 56.70mg Lincomycin HCl Monohydrate Eq. To Lincomycin…50mg
	Finished Product Specification	Eur. Ph
	Pharmacological Group	Antibacterial
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	100ml, 250ml
	International availability	Belgium approved
	Me-too status	-
	Detail of certificates attached	➢ Original legalized Certificate of Pharmaceutical Product Certificate No. 000030 Issued on 23-05-2019, Certified by *Federal Agency for medicines and health products – famhp, Eurostation II, Victor Hortaplein 40/40, 1060 Brussels, Belgium*. The CoPP confirms free sale status of the product in exporting country ➢ Originally legalized copy of GMP certificate No. NL/V/17/0021 dated **05-10-2017** issued by the state Secretary of Economic Affairs, Head of the Veterinary Medicinal Products Unit, The Netherlands. ➢ Originally legalized sole agency certificate dated 26-09-2019 from PLH.
	Remarks of the Evaluator [X]	6 months accelerated and 24 months long term stability studies data has been submitted as per zone-IV-A conditions. **Shortcomings:** • The already submitted GMP is **expired now but valid upon submission,** Provide legalized valid original GMP certificate. • Choice of one pack size. • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision of 326th Meeting: Deferred for submission of following • copy of valid DSL • original legalized valid GMP certificate • demanded pack size • Label in accordance with The Drugs (Labeling and Packing) Rules, 1986. **Updated status:** • The firm has provided copy of DSL (Form No.7) valid till **22-10-2024.**	

	• Originally legalized GMP certificate No. NL/V/20/0007 dated 06-05-2020 issued by the state The Minister of Agriculture, Nature and Food Quality, Head of the Veterinary Medicinal Products Unit, The Netherlands. • Demanded pack sizes: **250ml** • Proposed Product label **does not have" URDU "Inscription** as required under the drugs (labelling and packaging) rules.
	Decision: Approved with 250ml pack size. The firm shall submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986 before issuance of registration letter.

Agenda of Evaluator PEC-XI

Case No. 01: Routine Registration application of Human Drugs on Form 5F (Local)

842.	Name, address of Applicant / Marketing Authorization Holder	M/s Axis Pharmaceuticals., 3-B Value Additional City, 1.5 Km Khurrianwala – Sahianwala Road, Faisalabad – Pakistan
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals., 3-B Value Additional City, 1.5 Km Khurrianwala – Sahianwala Road, Faisalabad – Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted cGMP certificate issued on 06-07-2020 based on inspection conducted on 09-06-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-20/2006-Lic (Vol-II) dated 30-06-2020 which specifies Tablet section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3187, dated; 02.02.2022
	Details of fee submitted	PKR 30,000/-: 04-01-2022 (deposit slip # 014147644702)
	The proposed proprietary name / brand name	**Trubax 125mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Terbinafine (as HCl)……..125mg
	Pharmaceutical form of applied drug	Immediate Release Tablet
	Pharmacotherapeutic Group of (API)	Antifungals for systemic use
	Reference to Finished product specifications	USP specification
	Proposed Pack size	10’s
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	LAMISIL terbinafine 125mg (as hydrochloride) tablet blister pack, TGA approved
	For generic drugs (me-too status)	Lamisil 125mg Tablet by M/s Novartis Pharma (Reg#13208)
	Name and address of API manufacturer	Shandong Boyuan Pharmaceutical Co., Ltd., Qiangjin Street, Jibei Economic Development Zone, Jinan City China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification,, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40 º ± 2 º C /75% ± 5% RH for 6 months. The real time stability data is conducted at 30 ºC ± 2 º C / 65% ± 5% RH for 36 months. (Batch No. 150401TH, 150402TH & 150403TH)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation / verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted results of pharmaceutical equivalence for their product against Lamisil tablet 125mg by M/s GSK OTC Pvt. Ltd (mfgr) / Novartis Pharma (MAH) by performing quality tests (Friability, Hardness test, moisture content, disintegration time, dissolution time, assay) CDP has been performed against the same brand that is Lamisil tablet 125mg by M/s GSK OTC Pvt. Ltd (mfgr) / Novartis Pharma (MAH), in Acid media (pH 1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8) and citrate buffer pH 3 (USP Medium). The values for f2 are in the acceptable range.

	Analytical method validation/verification of product	Firm has submitted method verification studies including specificity, accuracy, precision and system suitability	
STABILITY STUDY DATA			
Manufacturer of API	Shandong Boyuan Pharmaceutical Co., Ltd., Qiangjin Street, Jibei Economic Development Zone, Jinan City China		
API Lot No.	210105T		
Description of Pack (Container closure system)	Alu – PVC Blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3, (Months)		
Batch No.	T-005	T-006	T-007
Batch Size	5000 tablets	5000 tablets	5000 tablets
Manufacturing Date	07 – 2021	07 – 2021	07 – 2021
Date of Initiation	03-08-2021	03-08-2021	03-08-2021
No. of Batches	03		
Administrative Portion			
7.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted	
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate of M/s Shandong Boyuan Pharmaceutical Co., Ltd., Qiangjin Street, Jibei Economic Development Zone, Jinan City China issued by Shandong Food and Drug Administration valid upto 25-08-2021	
9.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice No. BY210222 dated 22-02-2021 for import of 4.7Kg of Terbinafine HCl in name of M/s Axis Pharmaceuticals attested by AD (I&E) DRAP Lahore dated 25-02-2021.	
10.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted copy of data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted	
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted	

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.1	Clarification is required as application is submitted by Axis Pharmaceuticals while name	The firm submitted that there was a Typographic error, which was later corrected. Correct copy of DML is submitted

	mentioned on DML is Axis Pharmaceuticals (Pvt) Ltd.	
1.6.5	• Valid GMP certificate / DML of drug substance manufacturer issued by relevant regulatory authority of country of origin is required	The firm has submitted copy of GMP Certificate of M/s Shandong Boyuan Pharmaceutical Co., Ltd., Qiangjin Street, Jibei Economic Development Zone, Jinan City China issued by Shandong Food and Drug Administration valid upto 27-05-2025 *However the submitted cGMP certificate could not be verified from NMPA website*
3.2.S.4	• Clarification is required as Drug substance manufacturer has claimed EP specification while drug product manufacturer has claimed BP • Clarification is required as drug substance manufacturer has claimed assay of drug substance by HPLC instead of titration as recommended by EP. • Drug substance manufacturer has set limit of assay as 98-102% instead of 99-101% as recommended by EP • The drug product manufacturer has performed assay by simple titration instead of potentiometric titration as recommended by BP. • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required.	• Both Ph.Eur. & BP specifications as well as analytical procedure are same. Moreover, a comparison is provided herewith.

Parameter	**Ph.Eur.**	**BP**	**USP**	**Results Axis**	**Mfgr.**
Appearance	White or almost white powder.	White or almost white powder.	White or almost white powder.	Complies	Complies
Solubility	Very slightly or slightly soluble in water. Freely soluble in ethanol & methanol. Slightly soluble in acetone.	Very slightly or slightly soluble in water. Freely soluble in ethanol & methanol. Slightly soluble in acetone.	Very slightly or slightly soluble in water. Freely soluble in ethanol & methanol. Slightly soluble in acetone.	Complies	Complies
Identification	IR	IR	IR	Complies	Complies
Loss on Drying	NMT 0.5%	NMT 0.5%	NMT 0.5%	0.1%	0.08%
Sulphated Ash	NMT 0.1%	NMT 0.1%	NMT 0.1%	0.05%	0.04%
Content	99.0 – 101.0 %	99.0 – 101.0 %	98.0 – 102.0 %	99.60 %	99.60 %

Copy of monographs & CoA by drug substance manufacturer and drug product manufacturer are submitted.

		• Specification & analytical procedure by drug substance manufacturer as provided in DMF is as per USP. However, the material provided by the DS manufacture also complies Ph.Eur./BP specification as well USP specifications. It is important to note that we have implemented **more stringent specification.** • Both the techniques follow similar principle & yield comparable/equivalent results as can be seen from the table below. **Parameter** / **Direct Titration** / **Potentiometric Titration** Assay / 99.60 % / 99.58 % Therefore, direct titration method was adopted using freshly prepared reagents, analytical method of drug substance was appropriately validated & complies acceptance criteria. • Copy of revised specification & analytical procedure is submitted.
3.2.P.1	• Justification is required for using colloidal silicon dioxide in formulation which is not used by innovator product	The firm submitted that it is compatible with Terbinafine and stated that the said ingredients are not novel & routinely used in tablet product development. Therefore, to harmonize both strengths of drug product the said ingredients were incorporated in formulation. Terbinafine tends to stick during compression therefore colloidal silicon dioxide was used as a glidant to facilitate powder flow.
3.2.P.2	• Justification is required for not performing uniformity of dosage units test in pharmaceutical equivalence as recommended by USP	The firm submitted that the quantity of Terbinafine is more than 25mg and greater than 25% in drug product. Therefore, uniformity of dosage unit was performed by weight variation as per USP <905> Uniformity of dosage unit.
3.2.P.5	• Justification is required as drug substance follow EP/BP specifications while drug product follows USP specifications • Justification is required for using different chromatographic conditions i.e. ratio of mobile phase, injection volume and column specifications in assay (Buffer pH3:ACN, 40;60), (20ul), (C8, (4.6x250mm), 5um) than that recommended by USP(ACN: Buffer, 2;3) (5ul) (3.9x15cm), 5um packing L7)	• The firm submitted that Drug substance complies Ph.Eur./BP specification and also USP specification but drug product complies USP specification based on stringent specification & analytical procedure which was appropriately verified. Moreover, drug substance specification will be aligned from next lot upon commercialization with drug product specification i.e. USP. • Analytical method was adopted form USP and it was verified as per actual practice. Moreover, the changes made were in accordance with USP <621> Chromatography and system suitability parameters were evaluated during method validation that complies the acceptance criteria.
3.2.P.6	• The firm has submitted COA of reference standard which follow EP specification and COA from drug product manufacturer which follow BP specification while finished	Drug substance complies Ph.Eur./BP specification as well as USP specification. Dug product complies USP specification based on stringent specification & analytical procedure which was appropriately verified. Moreover, drug substance specification will be aligned from next lot upon commercialization with drug product specification i.e. USP.

	product follow USP specifications, clarify	
3.2.P.8	• Submit 6th month time point stability data of the applied product • The applied product is tablet while in description of pack in stability summary sheet collapsible Alu-tube, packed in carton is written, clarify • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	• Firm has submitted stability data of applied product at 6th month time point • The firm submitted that there was Typographic error, tablets are packed in Alu-PVC blisters as can be seen from Stability Protocol and Stability Data • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

843.	Name, address of Applicant / Marketing Authorization Holder	M/s Axis Pharmaceuticals., 3-B Value Additional City, 1.5 Km Khurrianwala – Sahianwala Road, Faisalabad – Pakistan
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals., 3-B Value Additional City, 1.5 Km Khurrianwala – Sahianwala Road, Faisalabad – Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted cGMP certificate issued on 06-07-2020 based on inspection conducted on 09-06-2020.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-20/2006-Lic (Vol-II) dated 30-06-2020 which specifies Tablet section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3188, dated; 02.02.2022
	Details of fee submitted	PKR 30,000/-: 04-01-2022 (deposit slip # 64291093698)
	The proposed proprietary name / brand name	**Trubax 250mg tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Terbinafine (as HCl)……..250mg
	Pharmaceutical form of applied drug	Immediate Release Tablet
	Pharmacotherapeutic Group of (API)	Antifungals for systemic use

	Reference to Finished product specifications	USP specification
	Proposed Pack size	10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LAMISIL terbinafine 250mg (as hydrochloride) tablet blister pack, TGA approved
	For generic drugs (me-too status)	Lamisil 250mg Tablet by M/s Novartis Pharma (Reg#13209)
	Name and address of API manufacturer	Shandong Boyuan Pharmaceutical Co., Ltd., Qiangjin Street, Jibei Economic Development Zone, Jinan City China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40 º ± 2 º C /75% ± 5% RH for 6 months. The real time stability data is conducted at 30 ºC ± 2 º C / 65% ± 5% RH for 36 months. (Batch No. 150401TH, 150402TH & 150403TH)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability study.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted results of pharmaceutical equivalence for their product against Lamisil tablet 250mg by M/s GSK OTC Pvt. Ltd (mfgr) / Novartis Pharma (MAH) by performing quality tests (Friability, Hardness test, moisture content, disintegration time, dissolution time, assay) CDP has been performed against the same brand that is Lamisil tablet 250mg by M/s GSK OTC Pvt. Ltd (mfgr) / Novartis Pharma (MAH), in Acid media (pH

		1.2), acetate buffer (pH 4.5), Phosphate Buffer (pH 6.8) and citrate buffer pH 3 (USP Medium). The values for f2 are in the acceptable range.	
	Analytical method validation/verification of product	Firm has submitted method verification studies including specificity, accuracy, precision and system suitability	
STABILITY STUDY DATA			
Manufacturer of API		Shandong Boyuan Pharmaceutical Co., Ltd., Qiangjin Street, Jibei Economic Development Zone, Jinan City China	
API Lot No.		210105T	
Description of Pack (Container closure system)		Alu – PVC Blister	
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Period		Real time: 3 months Accelerated: 3 months	
Frequency		Accelerated: 0, 3 (Months) Real Time: 0, 3, (Months)	
Batch No.		T-002	T-003	T-004
Batch Size		1000 tablets	1000 tablets	1000 tablets
Manufacturing Date		07 – 2021	07 – 2021	08 – 2021
Date of Initiation		08-2021	08-2021	08-2021
No. of Batches		03		
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate of Shandong Boyuan Pharmaceutical Co., Ltd., Qiangjin Street, Jibei Economic Development Zone, Jinan City China issued by Shandong Food and Drug Administration valid upto 25-08-2021	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice No. BY210222 dated 22-02-2021 for import of 4.7Kg of Terbinafine HCl in name of M/s Axis Pharmaceuticals attested by AD (I&E) DRAP Lahore dated 25-02-2021.	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted copy of data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted	
Remarks of Evaluator [XI]:			

<table>
<tr><th>Section</th><th>Observations</th><th>Response</th></tr>
<tr><td>1.3.1</td><td>Clarification is required as application is submitted by Axis Pharmaceuticals while name mentioned on DML is Axis Pharmaceuticals (Pvt) Ltd.</td><td>The firm submitted that there was a Typographic error, which was later corrected. Correct copy of DML is submitted</td></tr>
<tr><td>1.6.5</td><td>• Valid GMP certificate / DML of drug substance manufacturer issued by relevant regulatory authority of country of origin is required</td><td>The firm has submitted copy of GMP Certificate of M/s Shandong Boyuan Pharmaceutical Co., Ltd., Qiangjin Street, Jibei Economic Development Zone, Jinan City China issued by Shandong Food and Drug Administration valid upto 27-05-2025
However the submitted cGMP certificate could not be verified from NMPA website</td></tr>
<tr><td>3.2.S.4</td><td>• Clarification is required as Drug substance manufacturer has claimed EP specification while drug product manufacturer has claimed BP
• Clarification is required as drug substance manufacturer has claimed assay of drug substance by HPLC instead of titration as recommended by EP.
• Drug substance manufacturer has set limit of assay as 98-102% instead of 99-101% as recommended by EP
• The drug product manufacturer has performed assay by simple titration instead of potentiometric titration as recommended by BP.
• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required.</td><td>• Both Ph.Eur. & BP specifications as well as analytical procedure are same. Moreover, a comparison is provided herewith.
<table>
<tr><th>Parameter</th><th>Ph.Eur.</th><th>BP</th><th>USP</th><th>Results Axis</th><th>Mfgr.</th></tr>
<tr><td>Appearance</td><td>White or almost white powder.</td><td>White or almost white powder.</td><td>White or almost white powder.</td><td>Complies</td><td>Complies</td></tr>
<tr><td>Solubility</td><td>Very slightly or slightly soluble in water. Freely soluble in ethanol & methanol. Slightly soluble in acetone.</td><td>Very slightly or slightly soluble in water. Freely soluble in ethanol & methanol. Slightly soluble in acetone.</td><td>Very slightly or slightly soluble in water. Freely soluble in ethanol & methanol. Slightly soluble in acetone.</td><td>Complies</td><td>Complies</td></tr>
<tr><td>Identification</td><td>IR</td><td>IR</td><td>IR</td><td>Complies</td><td>Complies</td></tr>
<tr><td>Loss on Drying</td><td>NMT 0.5%</td><td>NMT 0.5%</td><td>NMT 0.5%</td><td>0.1%</td><td>0.08 %</td></tr>
<tr><td>Sulphated Ash</td><td>NMT 0.1%</td><td>NMT 0.1%</td><td>NMT 0.1%</td><td>0.05%</td><td>0.04 %</td></tr>
<tr><td>Content</td><td>99.0 – 101.0 %</td><td>99.0 – 101.0 %</td><td>98.0 – 102.0 %</td><td>99.60 %</td><td>99.60%</td></tr>
</table></td></tr>
</table>

		Copy of monographs & CoA by drug substance manufacturer and drug product manufacturer are submitted. • Specification & analytical procedure by drug substance manufacturer as provided in DMF is as per USP. However, the material provided by the DS manufacture also complies Ph.Eur./BP specification as well USP specifications. It is important to note that we have implemented **more stringent specification.** • Both the techniques follow similar principle & yield comparable/equivalent results as can be seen from the table below. **Parameter** / **Direct Titration** / **Potentiometric Titration** Assay / 99.60 % / 99.58 % Therefore, direct titration method was adopted using freshly prepared reagents, analytical method of drug substance was appropriately validated & complies acceptance criteria. • Copy of revised specification & analytical procedure is submitted.
3.2.P.1	• Justification is required for using Lactose monohydrate in formulation which is not used by innovator product	The firm submitted that it is compatible with Terbinafine and stated that the said ingredients are not novel & routinely used in tablet product development. Therefore, to harmonize both strengths of drug product the said ingredients were incorporated in formulation. Lactose was added as bulking agent to facilitate granulation of Terbinafine.
3.2.P.2	• Justification is required for not performing uniformity of dosage units test in pharmaceutical equivalence as recommended by USP	The firm submitted that the quantity of Terbinafine is more than 25mg and greater than 25% in drug product. Therefore, uniformity of dosage unit was performed by weight variation as per USP <905> Uniformity of dosage unit.
3.2.P.5	• Justification is required as drug substance follow EP/BP specifications while drug product follows USP specifications • Justification is required for using different chromatographic conditions i.e. ratio of mobile phase, injection volume and column specifications in assay (Buffer pH3:ACN, 40;60), (20ul), (C8, (4.6x250mm), 5um) than that recommended by USP(ACN: Buffer, 2;3) (5ul) (3.9x15cm), 5um packing L7)	• The firm submitted that Drug substance complies Ph.Eur./BP specification and also USP specification but drug product complies USP specification based on stringent specification & analytical procedure which was appropriately verified. Moreover, drug substance specification will be aligned from next lot upon commercialization with drug product specification i.e. USP. • Analytical method was adopted form USP and it was verified as per actual practice. Moreover, the changes made were in accordance with USP <621> Chromatography and system suitability parameters were evaluated during method validation that complies the acceptance criteria.
3.2.P.6	• The firm has submitted COA of reference standard which follow EP specification and COA from drug product manufacturer which follow BP specification	Drug substance complies Ph.Eur./BP specification as well as USP specification. Dug product complies USP specification based on stringent specification & analytical procedure which was appropriately verified. Moreover, drug substance specification will be aligned

	while finished product follow USP specifications, clarify	from next lot upon commercialization with drug product specification i.e. USP.
3.2.P.8	• Submit 6th month time point stability data of the applied product • The applied product is tablet while in description of pack in stability summary sheet collapsible Alu-tube, packed in carton is written, clarify • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	• Firm has submitted stability data of applied product at 6th month time point • The firm submitted that there was Typographic error, tablets are packed in Alu-PVC blisters as can be seen from Stability Protocol and Stability Data • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

844.	Name, address of Applicant / Marketing Authorization Holder	M/s Caliph Pharmaceuticals (Pvt) Ltd. Plot No 17, Special Industrial Zone (EPZ), Risalpur
	Name, address of Manufacturing site.	M/s Caliph Pharmaceuticals (Pvt) Ltd. Plot No 17, Special Industrial Zone (EPZ), Risalpur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Fir has submitted copy of GMP certificate issued on 02-03-2021 based on inspection conducted on 02-03-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 3-6/2005-Lic (Vol-I) dated 17-01-2019 which specifies Tablet section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3334 dated 03/02/2022
	Details of fee submitted	PKR 30,000/-: dated 11/01/2022 (Slip#741189664890)
	The proposed proprietary name / brand name	Lamical tablet 125mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Terbinafine (as HCl)……..125mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Antifungals for systemic use

	Reference to Finished product specifications	USP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Terbinafine 125mg Tablets by M/s Dr. Reddy's Laboratories (UK) Ltd, MHRA approved
	For generic drugs (me-too status)	Lamisil 125mg Tablet by M/s Novartis Pharma (Reg#13208)
	Name and address of API manufacturer.	M/s Saptagir Laboratories Pvt. Ltd., Sy.No. Parts of 27, 46 & 50 to 56, Ananthasagar (Vill), Chegunta (Mandal), Medak (Dist.), Telangana India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 06 months Batches: (TH0131216, TH0141216, TH0151216,)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted results of pharmaceutical equivalence for their product against Lamisil tablet 125mg by M/s Novartis Pharma Pakistan by performing quality tests (Identification, uniformity of dosage units, dissolution time, assay) CDP has been performed against the same brand that is Lamisil tablet 125mg by M/s Novartis Pharma Pakistan in Acid media (pH 1.2), acetate buffer (pH 4.5), Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm have submitted Method verification studies including accuracy, precision, specificity.
STABILITY STUDY DATA		
Manufacturer of API	M/s Saptagir Laboratories Pvt. Ltd., Sy.No. Parts of 27, 46 & 50 to 56, Ananthasagar (Vill), Chegunta (Mandal), Medak (Dist.), Telangana India.	

API Lot No.	TH0180421		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	T004	T005	T006
Batch Size	500 tab	500 tab	500 tab
Manufacturing Date	08-2021	08-2021	08-2021
Date of Initiation	11-08-2021	11-08-2021	11-08-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection for authenticity of stability data of their product by the panel on the basis of which Registration Board in 308th meeting dated 21-22nd June 2021 decided to approve registration of Dexcal (Dexlansoprazole) 30mg & 60mg capsule. Inspection date: 01st June, 2021 (Morning) The report shows that: • The HPLC software is 21 CFR compliant as per record available with the firm. • The firm showed the audit trail reports on API and product testing • Continuous power supply and monitoring are available for stability chambers
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate in name of M/s Saptagir Laboratories Pvt. Ltd., Sy.No. Parts of 27, 46 & 50 to 56, Ananthasagar (Vill), Chegunta (Mandal), Medak (Dist.), Telangana India issued by Drugs Control Administration Telangana State India valid upto 01-03-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted commercial invoice No#2122/SL/032 dated 21/07/2021 in the name of M/s Caliph Pharmaceuticals for import of 1.00Kg Terbinafine HCL (Batch No#TH0180421) attested by AD (I&E) DRAP Peshawar on 08/07/2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, summary data sheets is submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.4	• Submit valid DML as the submitted DML expires on 12-08-2022	The firm submitted that we have applied for renewal of DML on 10-08-2022 and our DML renewal is under process in Licensing Division. We are attaching copy of our application for renewal of DML**.**
1.6.5	• Valid GMP certificate / DML of drug substance manufacturer issued by relevant regulatory authority of country of origin is required	The firm has submitted copy of GMP certificate in name of M/s Saptagir Laboratories Pvt. Ltd., Sy.No. Parts of 27, 46 & 50 to 56, Ananthasagar Village, Chegunta Mandal, Medak (Dist.), Telangana state India issued by Drugs Control Administration Telangana State India valid upto one year from date of issue (date of issue; 21/02/2023).
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	Firm has submitted copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.P.1	• Justification is required for using sodium starch glycolate instead of Croscarmellose Sodium in formulation which is not used by referenced product	• The reference product containing terbinafine hydrochloride 125mg or 250mg in tablet dosage form approved in UK (MHRA) and Australia (TGA) also contains sodium starch glycolate as disintegrant. • Sodium starch glycolate as well as croscarmellose sodium both are used as tablet disintegrant. Handbook of pharmaceutical excipient defines that the incompatibility of croscarmellose sodium is strong acids or with soluble salts of iron and some other metals such as aluminum, mercury, and zinc. While the incompatibility of sodium starch glycolate is only ascorbic acid. Since sodium starch glycolate is incompatible with ascorbic acid only, which is not used in our formulation therefore our formulation is considered to be compatible. • The results of product development as well as stability studies also indicate that the formulation is compatible and stable. • The documents including product literature SmPC of MHRA and TGA as well as handbook of pharmaceutical excipient is submitted**.**
3.2.P.5	• Justify the specificity test in analytical method verification study without analyzing the standard solution	We have performed the evaluation of standard solution in method validation studies and its results were reported under in accuracy studies. As per ICH and other method validation guidelines, for assay of finished products like Tablets, specificity test is studied for blank/diluent, placebo, impurity and degradation product (forced degradation) to check whether the analytical method has the ability to quantify the analyte in the presence of these components.

		Since impurity testing and degradation products were not determined in the drug product therefore the specificity test was studied for following components: • Blank / Diluent • Placebo (to check interference of excipients) In this case the mobile phase and buffer solution was considered as blank / diluent as per the analytical method. Placebo included all excipients but without API. The acceptance criteria for both includes no interference from any of these components for the analysis of the analyte.
3.2.P.8	• Justify the batch size against the number of units required for complete stability study	Total batch size: 500 Tablets Total tablets yield: 490 Tablets Tablets placed in accelerated stability chamber: 90 Tablets placed in real-time stability study chamber: 220 Tablets used in product development studies: 60 Total tablets required till 24 months: 370 Remaining Tablets for performing any additional study: 120 Hence our batch size was sufficient to complete the stability studies of the product.
	• Submit UV spectra / absorbance of samples analysed in dissolution study during stability study. Furthermore, justify single absorbance value of sample and standard solution in dissolution studies.	As per our previous practice we have performed dissolution testing through USP method which includes UV analysis. Our UV spectroscopy equipment does not have connectivity with the computer and only gives results which are displayed on its built in screen. We have recorded all the UV values and noted in the raw data sheets developed in Excel software which are already shared in the original CTD. As per our previous practice we are performing dissolution test using a single UV reading of sample for each tablet. However, we will change our practice and will take 3 readings for sample and standard solution in future.
	• COA of all batches during the stability study at both real time and accelerated conditions at 3rd month time point is not submitted	For stability studies we are developing raw data sheets for each stability time point while COA is generated only at batch release. Our same practice has been accepted by the Drug Registration Board for our various CTD applications considered in previous meetings. We therefore request that as per previous practice our raw data sheets may be considered along with stability summary sheets since they also contain the similar information as well.
	• Submit 6th month time point stability study data of the applied product	Firm has submitted 6th month time point stability study data of the applied product

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
845.	Name, address of Applicant / Marketing Authorization Holder	M/s Caliph Pharmaceuticals (Pvt) Ltd. Plot No 17, Special Industrial Zone (EPZ), Risalpur
	Name, address of Manufacturing site.	M/s Caliph Pharmaceuticals (Pvt) Ltd. Plot No 17, Special Industrial Zone (EPZ), Risalpur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Fir has submitted copy of GMP certificate issued on 02-03-2021 based on inspection conducted on 02-03-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 3-6/2005-Lic (Vol-I) dated 17-01-2019 which specifies Tablet section (General)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3335 dated 03/02/2022
	Details of fee submitted	PKR 30,000/-: dated 11/01/2022 (Slip#12146173590)
	The proposed proprietary name / brand name	Lamical tablet 250mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Terbinafine (as HCl)……..250mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Antifungals for systemic use
	Reference to Finished product specifications	USP specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lamisil Tablets 250mg by M/s Novartis Pharmaceuticals, MHRA approved
	For generic drugs (me-too status)	Lamisil 250mg Tablet by M/s Novartis Pharma (Reg#13209)
	Name and address of API manufacturer.	M/s Saptagir Laboratories Pvt. Ltd., Sy.No. Parts of 27, 46 & 50 to 56, Ananthasagar (Vill), Chegunta (Mandal), Medak (Dist.), Telangana India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.

	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months Batches: (TH0131216, TH0141216, TH0151216,)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted results of pharmaceutical equivalence for their product against Lamisil tablet 250mg by M/s Novartis Pharma Pakistan by performing quality tests (Identification, uniformity of dosage units, dissolution time, assay) CDP has been performed against the same brand that is Lamisil tablet 250mg by M/s Novartis Pharma Pakistan in Acid media (pH 1.2), acetate buffer (pH 4.5), Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm have submitted Method verification studies including accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Saptagir Laboratories Pvt. Ltd., Sy.No. Parts of 27, 46 & 50 to 56, Ananthasagar (Vill), Chegunta (Mandal), Medak (Dist.), Telangana India.		
API Lot No.	TH0180421		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	T001	T002	T003
Batch Size	500 tab	500 tab	500 tab
Manufacturing Date	08-2021	08-2021	08-2021
Date of Initiation	11-08-2021	11-08-2021	11-08-2021
No. of Batches	03		
Administrative Portion			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection for authenticity of stability data of their product by the panel on the basis of which Registration Board in 308th meeting dated 21-22nd June 2021 decided to approve registration of Dexcal (Dexlansoprazole) 30mg & 60mg capsule. Inspection date: 01st June, 2021 (Morning) The report shows that: • The HPLC software is 21 CFR compliant as per record available with the firm. • The firm showed the audit trail reports on API and product testing • Continuous power supply and monitoring are available for stability chambers
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm has submitted copy of GMP certificate in name of M/s Saptagir Laboratories Pvt. Ltd., Sy.No. Parts of 27, 46 & 50 to 56, Ananthasagar (Vill), Chegunta (Mandal), Medak (Dist.), Telangana India issued by Drugs Control Administration Telangana State India valid upto 01-03-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted commercial invoice No#2122/SL/032 dated 21/07/2021 in the name of M/s Caliph Pharmaceuticals for import of 1.00Kg Terbinafine HCL (Batch No#TH0180421) attested by AD (I&E) DRAP Peshawar on 08/07/2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, summary data sheets is submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator XI:

Section	Observations	Response
1.3.4	• Submit valid DML as the submitted DML expires on 12-08-2022	The firm submitted that we have applied for renewal of DML on 10-08-2022 and our DML renewal is under process in Licensing Division. We are attaching copy of our application for renewal of DML**.**
1.6.5	• Valid GMP certificate / DML of drug substance manufacturer issued by relevant regulatory authority of country of origin is required	The firm has submitted copy of GMP certificate in name of M/s Saptagir Laboratories Pvt. Ltd., Sy.No. Parts of 27, 46 & 50 to 56, Ananthasagar Village, Chegunta Mandal, Medak (Dist.), Telangana state India issued by Drugs Control Administration Telangana State India valid upto one year from date of issue (date of issue; 21/02/2023).
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which	Firm has submitted copy of Batch Manufacturing Record (BMR) for all the batches of drug product

	stability studies data is provided in Module 3 section 3.2.P.8.3>	for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.P.5	• Justify the specificity test in analytical method verification study without analyzing the standard solution	We have performed the evaluation of standard solution in method validation studies and its results were reported under in accuracy studies. As per ICH and other method validation guidelines, for assay of finished products like Tablets, specificity test is studied for blank/diluent, placebo, impurity and degradation product (forced degradation) to check whether the analytical method has the ability to quantify the analyte in the presence of these components. Since impurity testing and degradation products were not determined in the drug product therefore the specificity test was studied for following components: • Blank / Diluent • Placebo (to check interference of excipients) In this case the mobile phase and buffer solution was considered as blank / diluent as per the analytical method. Placebo included all excipients but without API. The acceptance criteria for both includes no interference from any of these components for the analysis of the analyte.
3.2.P.8	• Justify the batch size against the number of units required for complete stability study	Total batch size: 500 Tablets Total tablets yield: 490 Tablets Tablets placed in accelerated stability chamber: 90 Tablets placed in real-time stability study chamber: 220 Tablets used in product development studies: 60 Total tablets required till 24 months: 370 Remaining Tablets for performing any additional study: 120 Hence our batch size was sufficient to complete the stability studies of the product.
	• Submit UV spectra / absorbance of samples analysed in dissolution study during stability study. Furthermore, justify single absorbance value of sample and standard solution in dissolution studies.	As per our previous practice we have performed dissolution testing through USP method which includes UV analysis. Our UV spectroscopy equipment does not have connectivity with the computer and only gives results which are displayed on its built in screen. We have recorded all the UV values and noted in the raw data sheets developed in Excel software which are already shared in the original CTD. As per our previous practice we are performing dissolution test using a single UV reading of sample for each tablet. However, we will change our practice and will take 3 readings for sample and standard solution in future.
	• COA of all batches during the stability study at both real time and	For stability studies we are developing raw data sheets for each stability time point while COA is generated only at batch release. Our same practice has been accepted by the Drug

	accelerated conditions at 3rd month time point is not submitted	Registration Board for our various CTD applications considered in previous meetings. We therefore request that as per previous practice our raw data sheets may be considered along with stability summary sheets since they also contain the similar information as well.
	• Submit 6th month time point stability study data of the applied product	Firm has submitted 6th month time point stability study data of the applied product

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

846.	Name, address of Applicant / Marketing Authorization Holder	M/s Daneen Pharma (Pvt.) Ltd., 27-Sundar Industrial Estate, Sundar Raiwand RD Lahore
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd., 44-45B Korangi Creek Road Karachi
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-12/93-Lic (Vol-V) dated 20-09-2021 which specifies Liquid Injection (Ampoule, Vial, Infusion) (General) section
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3625 dated 08-02-2022
	Details of fee submitted	PKR 75,000/-: dated: 04-01-2022 (Deposit sip#98940276970)
	The proposed proprietary name / brand name	**Irfen Injection 100mg/2ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml ampoule contains: Ferric hydroxide polymaltose complex equivalent to Iron(III)……100mg
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Use to treat Iron deficiency
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	5's x2ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ferrosig Injection 100mg/2ml by M/s Sigma Company Limited., TGA Approved

	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	Biofer S.p.A. Legal headquarters and manufacturing site: Via Canina, 2 - 41036 MEDOLLA (MO), Italy
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: Real time: 30 ± 2°C / 65 ± 5% RH) for 36 months Accelerated: 40 ± 2°C / 75 ± 5% RH for 6 months Batches: (FPJ 002 FP 01, FPJ 003 FP 01, FPJ 004 FP 01)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand that is Hemafer 100mg/2ml Injection by M/s UNI-PHARMAKLEON LAORATORIES S.A by performing quality tests (Identification, pH, Assay)
	Analytical method validation/verification of product	Firm has submitted method validation studies including Specificity, Linearity, Accuracy, Precision-Repeatability, Intermediate Precision, Robustness.

STABILITY STUDY DATA	
Manufacturer of API	Biofer S.p.A. Legal headquarters and manufacturing site: Via Canina, 2 - 41036 MEDOLLA (MO), Italy
API Lot No.	FPJ014FV20
Description of Pack (Container closure system)	Amber glass Type I ampoule
Stability Storage Condition	Real time: 30°C ± 2°C /65%± 5%RH Accelerated: 40°C ± 2°C / 75%± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	21SB(A)-098-01	21SB(A)-099-02	21SB(A)-100-03
Batch Size	500ampoules	500ampoules	500ampoules
Manufacturing Date	06-2021	06-2021	06-2021
Date of Initiation	15-07-2021	15-07-2021	15-07-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted Copy of GMP certificate in name of Biofer S.p.A. Legal headquarters and manufacturing site: Via Canina, 2 - 41036 MEDOLLA (MO), Italy issued by Italian Medicines Agency valid upto three years from the date of inspection (date of inspection 28/06/2019)
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) for three months is submitted

THERAPEUTIC INDICATIONS

FERROSIG is indicated for the treatment of iron deficiency anaemia in the following circumstances:

- When oral therapy is contraindicated.
- When enteric absorption of iron is defective.
- When patient non-compliance or persistent gastrointestinal intolerance makes oral therapy impractical.

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted	• Firm has submitted copy of panel inspection report of the applicant for renewal of DML dated 08-02-2021 & 27-10-2021 wherein panel recommends the grant of renewal of DML by way of formulation to M/s Daneen Pharma (Pvt.) Ltd., 27-Sundar Industrial Estate, Sundar Raiwand RD Lahore • *GMP inspection report/ GMP certificate of the manufacturing unit is not submitted*
1.5.5	• Submit correct Pharmacological class of the drug substance with proper reference	• Parenteral iron preparations. Anti-anaemic
1.6.5	• Valid GMP certificate / DML of drug substance manufacturer issued by relevant regulatory authority of country of origin is required	The firm submitted clarification from AIFA Italy stating that due to restrictions caused by covid-19, the period of validity of the GMP certificate is automatically extended until the end of 2023. Onsite inspections will resume as soon as there

		is a consensus that the period of public health crisis has passed
3.2.S.4	• Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required.	• Not submitted
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided.	According to Biofer MOA no working standard are required for release analysis of the API Ferric Hydroxide Polymaltose Complex so, we cannot provide any CoA.
3.2.S.7	• Results of Assay test for iron is not submitted in stability study of drug substance, clarify	Firm submitted revised stability study data of drug substance wherein Assay test for iron has been performed. Stability study conditions: Real time: 30 ± 2°C / 65 ± 5% RH) for 60 months Accelerated: 40 ± 2°C / 75 ± 5% RH for 6 months Batches: (FPJ 001 FV 17, FPJ 005 FV 16, FPJ 006 FP 15)
3.2.P.1	• Justification is required for not using hydrochloric acid or sodium hydroxide for pH adjustment in formulation	• In development of Genfer Injection 100mg/2ml, the active substance (Ferric Hydroxide Polymaltose Complex Inj.Grade) is dissolved in water for injection and mix until homogenization of solution will be formed. Then Check the pH of the solution. pH limit = 5.2 – 6.50. • The pH of the solution observed in the range as described above therefore no need to the addition of HCl or NaOH for pH adjustment in the formulation. • The product kept on stability and no changes observed in pH of the formulation and any other physical and chemical parameters. • Stability studies also demonstrated that the formulation is stable without the addition of pH adjusting agents.
3.2.P.2	• Submit details of country of origin of reference product against which pharmaceutical equivalence studies have been performed. • Justification is required for not performing test for bacterial endotoxin and particulate matter in pharmaceutical equivalence as submitted in finished product specifications	• The firm submitted details of country of origin: UNI-PHARMA KLEON TSETIS Pharmaceutical Laboratory S.A 14Km National Road 1, GR-145 64K, Kifissia GREECE. • The firm submitted that we have also conducted pharmaceutical equivalence against Ferrosig 100mg/2ml injection by M/s Sigma Company Limited Rowville, VIC, 3176 Australia by performing quality test (Appearance, Identification, pH, Assay, BET, Particulate matter) • The firm has submitted revised pharmaceutical equivalence report wherein results of test for bacterial endotoxin and particulate matter has been submitted
3.2.P.5.2	• You have applied for innovator specifications in module 1 section 1.5.6 while in-house specification in this section, justify?	The firm submitted that this is typographic error and submitted revise specification stating innovator specifications

3.2.P.6 3.2.P.8	• COA of primary / secondary reference standard including source and lot number shall be provided. • You have written liraglutide on initial page of summary sheet while applied product is ferric hydroxide polymaltose complex, clarify? • Compliance Record of HPLC software 21CFR & audit trail reports on product testing is required • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) upto 6th months is required • Submit documents for the procurement of API with approval from DRAP (in case of import). • Submit 6th month stability data of applied product	The firm submitted that we have conducted assay of Iron by complexometric titration, in this method working standard is not required. • The firm submitted that this is typographic error and submitted corrected summary reports. • Audit trial is not applicable as product testing is carried out via titration method • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted • Firm has submitted copy of invoice for import of 01Kg of Ferric Hydroxide Polymaltose Complex (Batch No# FPJ014FV20) in name of M/s Genix Pharma (Pvt.) Ltd., attested by AD (I&E) DRAP Karachi dated 26-04-2021. • Firm has also submitted copy of form 6 for import of 01Kg of Ferric Hydroxide Polymaltose Complex in name of M/s Genix Pharma (Pvt.) Ltd., attested by AD (I&E) DRAP Karachi dated 26-04-2021. • 6th month stability data of applied product is submitted
Decision: Deferred for submission of following: • **Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer.** • **GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years** • **Fee of Rs. 7,500/- for correction/pre-approval change in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**		

Case No. 02; Registration application of Human drugs on Form 5-F on export facilitation

Assistant director PR-I/EFD vide letter No.F.1-6/2019-PR-I (EFD) dated 28-02-2023 has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the *pharmaceutical* i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm have achieved the benchmark of more than **100,000 USD** during the **fiscal Year 2020-2021** and submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.,

847.	Name, address of Applicant / Marketing Authorization Holder	M/s Nabiqasim Industries (Pvt.) Ltd., 17 / 24, Korangi Industrial Area, Karachi – Pakistan.
	Name, address of Manufacturing site.	M/s Nabiqasim Industries (Pvt.) Ltd., 17 / 24, Korangi Industrial Area, Karachi – Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate issued on 28-05-2022 based on inspection conducted on 27-05-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-20/85-Lic (Vol-V) dated 27-04-2020 which specifies Tablet (General) section

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy No. 603 dated 06/01/2023
	Details of fee submitted	PKR 30,000/-: dated 13/12/2022 (Deposit silp#2655263793)
	The proposed proprietary name / brand name	GLEMPA-M XR Tablet 5mg/1000mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Empagliflozin ……5mg Metformin HCl USP (extended release)…1000mg
	Pharmaceutical form of applied drug	Film coated tablet for oral use
	Pharmacotherapeutic Group of (API)	Type 2 Diabetes Mellitus, antidiabetic agent
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SYNJARDY XR Tablet (5mg/1000mg, 10mg/1000mg, 12.5mg/1000mg, 25mg/1000mg) USFDA Approved.
	For generic drugs (me-too status)	Xenglu-Met XR Tablet 5mg/1000mg by M/s Hilton Pharma, (Reg#105268)
	Name and address of API manufacturer.	**Empagliflozin:** Zhejiang Hongyuan Pharmaceuticals Co., Ltd., Chem & API's Industrial Zone, Linhai, Zhejiang Province, China. **Metformin Hydrochloride:** Aarti Drugs Limited., Plot No. 211-213, Road No. 2, G.I.D.C., Sarigam, Dist; Valsad Gujarat , India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	**Empagliflozin:** The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Metformin:**

		The firm as submitted details of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (Z1215-170601, Z1215-170602, Z1215-170603) **Metformin HCl:** Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (MEF/1410027, MEF/1410028, MEF/1410029)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted Pharmaceutical Equivalence studies against XENGLU-MET XR Tablet 5mg/1000mg by M/s Hilton Pharma, by performing quality tests (Description, Identification, Dissolution and Assay). CDP has been performed against the same brand that is XENGLU-MET XR Tablet 5mg/1000mg by M/s Hilton Pharma, in Acid media (0.1N) (pH 1.2), Acetate Buffer (4.5) & Phosphate Buffer (6.8). The values f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted method validation studies including linearity, range, accuracy, precision, specificity, LOD, LOQ, system suitability, robustness and forced degradation studies.

STABILITY STUDY DATA	
Manufacturer of API	**Empagliflozin:** Zhejiang Hongyuan Pharmaceuticals Co., Ltd., Chem & API's Industrial Zone, Linhai, Zhejiang Province, China. **Metformin Hydrochloride:** Aarti Drugs Limited., Plot No. 211-213, Road No. 2, G.I.D.C., Sarigam, Dist; Valsad Gujarat , India
API Lot No.	**Empagliflozin:** EPG20211101 **Metformin HCl:** MEF/11113625
Description of Pack	Alu-Alu blister packed in unit carton.

(Container closure system)			
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	583DS01	583DS02	
Batch Size	5000 tablets	5000 tablets	
Manufacturing Date	14-07-2022	15-07-2022	
Date of Initiation	05-08-2022	05-08-2022	
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** The firm has submitted copy of GMP certificate of M/s Zhejiang Hongyuan Pharmaceuticals Co., Ltd., Chem & API's Industrial Zone, Linhai, Zhejiang P.R. China issued by Linhai Medical and Chemical Industry Administration valid upto 29th December 2023. Firm has submitted copy of DML (Zhe20090508) in name of Zhejiang Hongyuan Pharmaceuticals Co., Ltd., Chem & API's Industrial Zone, Linhai, Zhejiang, China issued by Zhejiang Food and Drug Administration valid upto 13th January 2024 **Metformin HCl:** Firm has submitted Copy of GMP certificate in name of Aarti Drugs Limited (Unit-II)., Plot No. 211-213, Road No. 2, G.I.D.C., at & post Sarigam, Dist; Valsad, Gujarat state , India issued by Commissioner Food & Drugs control Administration, Gandhinagar India valid upto 19-03-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of invoice for import of 30kg Empagliflozin attested by AD (I&E) DRAP Karachi office dated 24-12-2021 Firm has submitted copy of form 6 for import of Empagliflozin attested by AD (I&E) DRAP Karachi office dated 17-12-2021 **Metformin HCl:** Firm has submitted copy of invoice EXP/2810/21-22 Dated: 10-12-2021 for import of 3000kg Metformin HCL USP attested by AD (I&E) DRAP Karachi office dated 03-11-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.6.5	• Valid GMP certificate of drug substance manufacturer (empagliflozin & metformin) issued by relevant regulatory authority of country of origin is required • The address mentioned in submitted GMP certificate of M/s Zhejiang Hongyuan Pharmaceuticals Co., Ltd is different than that available on NMPA website, clarify	• The firm submitted that at the time of dossier submission previously submitted GMP certificate of Metformin HCl API, manufacturer: AARTI Drugs Limited was valid till 19-03-2023. *However, renewal application of GMP certificate dated 27-01-2023 received from manufacturer is submitted.* • Firm has not submitted copy of GMP certificate of drug substance manufacturer for empagliflozin issued by relevant regulatory authority of country of origin • The firm submitted that address mentioned on Manufacturing License is same as mentioned on NMPA website (Chem & API's Industrial Zone, Linhai, Zhejiang, China), whereas on NMPA website the complete and detailed address has been given, furthermore, the office name, city and province are exactly same on both credentials. However, the addresses are different. **Name and address mentioned on DML:** Zhejiang Hongyuan Pharmaceuticals Co., Ltd., Chem & API's Industrial Zone, Linhai, Zhejiang, China **Name and address mentioned on NMPA website:** Zhejiang Hongyuan Pharmaceutical Co., Ltd., No. 6, Donghai Fourth Avenue, Toumen Port Economic Development Zone, Zhejiang Province, Linhai City, Taizhou City. Later the firm has submitted a Notice of change from the drug substance manufacturer declaring that description of the company's address has been changed from "Chem & API's Industrial Zone, Linhai, Zhejiang, China" to "No. 6, Donghai Fourth Avenue, Zheijiang Toumengang Economic Development Zone, Linhai City, Taizhou, Zhejiang, P.R of China." The notice further states that location of manufacturing site has not been changed and remains same with before. The GMP certificate and DML of the drug substance manufacturer verified from the NMPA website reveals that the description of the address has been changed.
3.2.S.4	Drug substance specifications for Empagliflozin shall be submitted from drug substance, manufacturer.	Drug substance specifications for Empagliflozin from drug substance manufacturer is submitted

3.2.P.2	Justification shall be submitted for not performing Pharmaceutical equivalence and CDP studies against the innovator product.	The firm submitted that Reference to CTD guidance document pharmaceutical equivalence and CDP studies can be performed against reference / comparator samples
3.2.P.5	• Justification shall be submitted that how the "specificity" of the applied method has been inferred without the performance of "Peak Purity Test (e.g., using diode array detector) to establish that analyte chromatographic peak is not attributable to more than one component". • Submitted analytical method validation report declares the details for "Empagliflozin/Linagliptin/Metformin tablet.	• Specificity of the applied method was conducted on PDA detector to establish analyte peaks are not attributable. Chromatograms representing peak purity of Metformin and Empagliflozin are submitted • We acknowledge that previously submitted analytical method validation report is of "Empagliflozin/Metformin extended release tablet". • As mentioned by you that report declares the details of "Empagliflozin / Linagliptin / Metformin HCl". It is due to the typographical error, while compiling report, mention in system suitability parameter of Metformin HCl on pahe No. 15. Corrected method validation report is submitted.
3.2.P.6	COA of primary / secondary reference standard including source and lot number used for the analysis for trial batches shall be submitted shall be provided.	• COA of reference standards used in testing are submitted **Metformin Certified Reference Material** Source: Supelco LOT No: LRAC3162 **Empagliflozin** **Till 3rd month stability studies:** Source: Zhejiang Hongyuan Pharmaceutical Co., Ltd., China Batch No. EPG211202WS **For Onward Studies** Batch No. EPG220703WS
3.2.P.8	• The commercial invoice for Metformin HCl submitted by firm has been attested by AD I&E Karachi, dated 03-11-2022, whereas trial batches have been manufactured in July 2022. Justification shall be submitted for manufacturing of trial batches prior to the release of drug substance by AD I&E. • Stability studies data for 6th month time point shall be submitted.	• The firm has submitted copy of commercial invoice of Metformin HCl attested by AD *I&E mentioning comments that previously signed date by AD I&E (03-11-2022) was a writing error, Month is mentioned as November instead of January 2022.* • The firm has also submitted copy of goods declaration • Firm has submitted 6th month time point stability study data of applied product
2.3.R	• **Justification shall be submitted for dispensed quantity of Empagliflozin & alongwith 20% overage for formulation of trial batches alongwith the performance based evidence for the referred process loss.** The firm submitted that 20% excess quantity is taken to cover for process losses as mentioned below: 1. Coating process done in R&D having R&D solid dosage unity Dr. Pharm that is equipped with three interchangeable perforated coating pans that are suitable for coating 0.8kg-10kg tablets a. Process loss occurs during spray volume setting b. Process losses occur from exhaust as also the coating pan is perforated c. Process losses occur as some of the coating material stick to the coating pan during coating process d. Process losses occur as some of the coating material remains in the hoses and pipes of spray equipment and vessel after completion of coating process	

2. Due to above losses it is a general practice to include 20% excess at coating stage. Weight gain is monitored during the process and coating process is stopped when the desired weight gain is achieved

- **Justification shall be submitted for proceeding for the Seal coating upon the Metformin HCl core tablet without establishing the extended release dissolution profile of Metformin HCl core tablet at in process stage.**
- The firm submitted that we have manufactured trial batches of the Empagliflozin/Metformin HCl XR tablet range. Trial batch testing was conducted at each stage and results were found satisfactory.
- On the basis of above reason testing of stability batches were conducted on final product only.
- Justification letter is enclose in Annexure-I along with test results of trial batches of Empagliflozin/Metformin HCl XR Tablet range for dissolution profile of Metformin HCl.
- The firm submitted justification stating that dissolution testing on Metformin HCl core tablet was done on below mentioned trial batches before proceeding to seal coating stage.
  1. Empagliflozin/Metformin HCl XR Tablet 5mg/1000mg Tablet, Batch No.:583DT01, Batch Size: 1.420kg
  2. Empagliflozin/Metformin HCl XR Tablet 10mg/1000mg Tablet, Batch No.:584DT01, Batch Size: 1.420kg
  3. Empagliflozin/Metformin HCl XR Tablet 12.5mg/1000mg Tablet, Batch No.:585DT01, Batch Size: 1.420kg
  4. Empagliflozin/Metformin HCl XR Tablet 25mg/1000mg Tablet, Batch No.:586DT01, Batch Size: 1.420kg
- Based on the satisfactory dissolution testing results of Metformin HCl core tablets of above mentioned trial batches (report submitted) and the experience with our recently registered product Empagliflozin/Linagliptin/Metformin XR Tablet range 5mg/2.5mg/1000mg, 10mg / 5mg / 1000mg, 12.5mg / 2.5mg / 1000mg, 25mg / 5mg / 1000mg which also have the same formulation as of Metformin HCl core tablet as of Metformin HCl core tablet formulation in Empagliflozin Metformin XR Tablet Range.
- Therefore, stability batches of subjected product were proceeded to seal coating stage without dissolution testing on Metformin core tablet
- **Justification shall be submitted for proceeding for the final film coating step without establishing the content of Empagliflozin at in process stage of active coating.**
- Empagliflozin API content testing was done after API coating on trial batches of Empagliflozin/Metformin HCl XR tablets range.(Justification letter and results of content of Empagliflozin are enclose in Annexure-J)
- Satisfactory results of trial batches obtained give us confidence to test the stability batches directly on finished product.
- However we commit to conduct testing the product at each stage for QC release batches.
- The firm submitted justification stating Empagliflozin content testing on Empagliflozin coated Metformin HCl XR tablet was done on below mentioned trial batches before proceeding to final coating stage.
  1. Empagliflozin/Metformin HCl XR Tablet 5mg/1000mg Tablet, Batch No.:583DT01, Batch Size: 1.420kg
  2. Empagliflozin/Metformin HCl XR Tablet 10mg/1000mg Tablet, Batch No.:584DT01, Batch Size: 1.420kg
  3. Empagliflozin/Metformin HCl XR Tablet 12.5mg/1000mg Tablet, Batch No.:585DT01, Batch Size: 1.420kg
  4. Empagliflozin/Metformin HCl XR Tablet 25mg/1000mg Tablet, Batch No.:586DT01, Batch Size: 1.420kg
- Based on the satisfactory Empagliflozin content testing results of Empagliflozin coated Metformin HCl XR tablet of above mentioned trial batches (report submitted) and on the experience with our recently registered product Empagliflozin / Linagliptin / Metformin XR Tablet range 5mg/2.5mg/1000mg, 10mg / 5mg / 1000mg, 12.5mg / 2.5mg / 1000mg,

25mg / 5mg / 1000mg which also have the same formulation as of Empagliflozin coating formulation in Empagliflozin Metformin XR Tablet Range.

- Therefore, stability batches of subjected product were proceeded for final film coating step without establishing the content for Empagliflozin at in process stage of active coating.
- **Clarification shall be submitted for the test applied to confirm that desired content for Empagliflozin has been achieved via active coating since submitted trial batch manufacturing record does not include any in process testing.**
- The firm has submitted results of trial batches at coated stage showing that desired content for Empagliflozin has been achieved
- **Minimum handling capacity of the equipment used in the manufacturing of trial batches shall be submitted.**
- The firm stated the manufacturing process is done in state of Art Nabiqasim R&D facility having R&D Solid Dosage Unity Dr. Pharm which is an integrated system having below processing units and also submitted brochure.

1. High Shear Mixer, three interchangeable bowls below:
   a. Capacity; 1.0kg-2.0kg
   b. Capacity; 2.0kg-5.0kg
   c. Capacity; 5.0kg-10.0kg
2. Fluid Bed dryer
3. Dry Mill
4. Cone Blender, three interchangeable blenders below:
   a. Capacity; 1.0kg-2.0kg
   b. Capacity; 2.0kg-5.0kg
   c. Capacity; 5.0kg-10.0kg
5. Tablet Coating Pan, three interchangeable coating pans as below:
   a. Capacity; 1.0kg-2.0kg
   b. Capacity; 2.0kg-5.0kg
   c. Capacity; 5.0kg-10.0kg

Decision: Approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

848.	Name, address of Applicant / Marketing Authorization Holder	M/s Nabiqasim Industries (Pvt.) Ltd., 17 / 24, Korangi Industrial Area, Karachi – Pakistan.
	Name, address of Manufacturing site.	M/s Nabiqasim Industries (Pvt.) Ltd., 17 / 24, Korangi Industrial Area, Karachi – Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate issued on 28-05-2022 based on inspection conducted on 27-05-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-20/85-Lic (Vol-V) dated 27-04-2020 which specifies Tablet (General) section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale

		☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy No. 3136 dated 02/02/2023
	Details of fee submitted	PKR 30,000/-: dated 13/12/2022 (Deposit silp#797900248997)
	The proposed proprietary name / brand name	GLEMPA-M XR Tablet 10mg/1000mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Empagliflozin ……..…….10mg Metformin HCl USP (extended release)….1000mg
	Pharmaceutical form of applied drug	Film coated tablet for oral use
	Pharmacotherapeutic Group of (API)	Type 2 Diabetes Mellitus, antidiabetic agent
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SYNJARDY XR Tablet (5mg/1000mg, 10mg/1000mg, 12.5mg/1000mg, 25mg/1000mg) USFDA Approved.
	For generic drugs (me-too status)	Xenglu-Met XR Tablet 10mg/1000mg by M/s Hilton Pharma, (Reg#105269)
	Name and address of API manufacturer.	**Empagliflozin:** Zhejiang Hongyuan Pharmaceuticals Co., Ltd., Chem & API's Industrial Zone, Linhai, Zhejiang Province, China. **Metformin Hydrochloride:** Aarti Drugs Limited., Plot No. 211-213, Road No. 2, G.I.D.C., Sarigam, Dist; Valsad Gujarat , India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	**Empagliflozin:** The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Metformin:** The firm as submitted details of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing

		process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (Z1215-170601, Z1215-170602, Z1215-170603) **Metformin HCl:** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (MEF/1410027, MEF/1410028, MEF/1410029)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted Pharmaceutical Equivalence studies against XENGLU-MET XR Tablet 10mg/1000mg by M/s Hilton Pharma, by performing quality tests (Description, Identification, Dissolution and Assay). CDP has been performed against the same brand that is XENGLU-MET XR Tablet 10mg/1000mg by M/s Hilton Pharma, in Acid media (0.1N) (pH 1.2), Acetate Buffer (4.5) & Phosphate Buffer (6.8). The values f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted method validation studies including linearity, range, accuracy, precision, specificity, LOD, LOQ, system suitability, robustness and forced degradation studies.

STABILITY STUDY DATA	
Manufacturer of API	**Empagliflozin:** Zhejiang Hongyuan Pharmaceuticals Co., Ltd., Chem & API's Industrial Zone, Linhai, Zhejiang Province, China. **Metformin Hydrochloride:** Aarti Drugs Limited., Plot No. 211-213, Road No. 2, G.I.D.C., Sarigam, Dist; Valsad Gujarat , India
API Lot No.	**Empagliflozin:** EPG20211101 **Metformin HCl:** MEF/11113625
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	584DS01	583DS02	
Batch Size	5000 tablets	5000 tablets	
Manufacturing Date	07-2022	07-2022	
Date of Initiation	08-08-2022	08-08-2022	
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** The firm has submitted copy of GMP certificate of M/s Zhejiang Hongyuan Pharmaceuticals Co., Ltd., Chem & API's Industrial Zone, Linhai, Zhejiang P.R. China issued by Linhai Medical and Chemical Industry Administration valid upto 29th December 2023. Firm has submitted copy of DML (Zhe20090508) in name of Zhejiang Hongyuan Pharmaceuticals Co., Ltd., Chem & API's Industrial Zone, Linhai, Zhejiang, China issued by Zhejiang Food and Drug Administration valid upto 13th January 2024 **Metformin HCl:** Firm has submitted Copy of GMP certificate in name of Aarti Drugs Limited (Unit-II)., Plot No. 211-213, Road No. 2, G.I.D.C., at & post Sarigam, Dist; Valsad, Gujarat state , India issued by Commissioner Food & Drugs control Administration, Gandhinagar India valid upto 19-03-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of invoice for import of 30kg Empagliflozin attested by AD (I&E) DRAP Karachi office dated 24-12-2021 Firm has submitted copy of form 6 for import of Empagliflozin attested by AD (I&E) DRAP Karachi office dated 17-12-2021 **Metformin HCl:** Firm has submitted copy of invoice EXP/2810/21/22 Dated: 10-12-2021 for import of 3000kg Metformin HCL USP attested by AD (I&E) DRAP Karachi office dated 03-11-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of	Submitted

	stability chambers (real time and accelerated)	

Remarks of Evaluator [XI]:

Section	Observations	Response
1.6.5	• Valid GMP certificate of drug substance manufacturer (empagliflozin & metformin) issued by relevant regulatory authority of country of origin is required	• The firm submitted that at the time of dossier submission previously submitted GMP certificate of Metformin HCl API, manufacturer: AARTI Drugs Limited was valid till 19-03-2023. *However, renewal application of GMP certificate dated 27-01-2023 received from manufacturer is submitted.*
	• The address mentioned in submitted GMP certificate of M/s Zhejiang Hongyuan Pharmaceuticals Co., Ltd is different than that available on NMPA website, clarify	• Firm has not submitted copy of GMP certificate of drug substance manufacturer for empagliflozin issued by relevant regulatory authority of country of origin • The firm submitted that address mentioned on Manufacturing License is same as mentioned on NMPA website (Chem & API's Industrial Zone, Linhai, Zhejiang, China), whereas on NMPA website the complete and detailed address has been given, furthermore, the office name, city and province are exactly same on both credentials. However, the addresses are different. **Name and address mentioned on DML:** Zhejiang Hongyuan Pharmaceuticals Co., Ltd., Chem & API's Industrial Zone, Linhai, Zhejiang, China **Name and address mentioned on NMPA website:** Zhejiang Hongyuan Pharmaceutical Co., Ltd., No. 6, Donghai Fourth Avenue, Toumen Port Economic Development Zone, Zhejiang Province, Linhai City, Taizhou City. Later the firm has submitted a Notice of change from the drug substance manufacturer declaring that description of the company's address has been changed from "Chem & API's Industrial Zone, Linhai, Zhejiang, China" to "No. 6, Donghai Fourth Avenue, Zheijiang Toumengang Economic Development Zone, Linhai City, Taizhou, Zhejiang, P.R of China." The notice further states that location of manufacturing site has not been changed and remains same with before. The GMP certificate and DML of the drug substance manufacturer verified from the NMPA website reveals that the description of the address has been changed.
3.2.S.4	Drug substance specifications for Empagliflozin shall be submitted from drug substance, manufacturer.	Drug substance specifications for Empagliflozin from drug substance manufacturer is submitted
3.2.P.2	Justification shall be submitted for not performing Pharmaceutical equivalence and CDP studies against the innovator product.	The firm submitted that Reference to CTD guidance document pharmaceutical equivalence and CDP studies can be performed against reference / comparator samples
3.2.P.5	• Justification shall be submitted that how the "specificity" of the applied method has been inferred	• Specificity of the applied method was conducted on PDA detector to establish analyte peaks are not attributable. Chromatograms representing peak

	without the performance of "Peak Purity Test (e.g., using diode array detector) to establish that analyte chromatographic peak is not attributable to more than one component". • Submitted analytical method validation report declares the details for "Empagliflozin/Linagliptin/Metformin tablet.	purity of Metformin and Empagliflozin are submitted • We acknowledge that previously submitted analytical method validation report is of "Empagliflozin/Metformin extended release tablet". • As mentioned by you that report declares the details of "Empagliflozin / Linagliptin / Metformin HCl". It is due to the typographical error, while compiling report, mention in system suitability parameter of Metformin HCl on pahe No. 15. Corrected method validation report is submitted.
3.2.P.6	COA of primary / secondary reference standard including source and lot number used for the analysis for trial batches shall be submitted shall be provided.	• COA of reference standards used in testing are submitted **Metformin Certified Reference Material** Source: Supelco LOT No: LRAC3162 **Empagliflozin** **Till 3rd month stability studies:** Source: Zhejiang Hongyuan Pharmaceutical Co., Ltd., China Batch No. EPG211202WS **For Onward Studies** Batch No. EPG220703WS
3.2.P.8	• The commercial invoice for Metformin HCl submitted by firm has been attested by AD I&E Karachi, dated 03-11-2022, whereas trial batches have been manufactured in July 2022. Justification shall be submitted for manufacturing of trial batches prior to the release of drug substance by AD I&E. • Stability studies data for 6th month time point shall be submitted.	• The firm has submitted copy of commercial invoice of Metformin HCl attested by AD *I&E mentioning comments that previously signed date by AD I&E (03-11-2022) was a writing error, Month is mentioned as November instead of January 2022.* • The firm has also submitted copy of goods declaration • Firm has submitted 6th month time point stability study data of applied product
2.3.R	• **Justification shall be submitted for dispensed quantity of Empagliflozin & alongwith 20% overage for formulation of trial batches alongwith the performance based evidence for the referred process loss.** The firm submitted that 20% excess quantity is taken to cover for process losses as mentioned below: 3. Coating process done in R&D having R&D solid dosage unity Dr. Pharm that is equipped with three interchangeable perforated coating pans that are suitable for coating 0.8kg-10kg tablets e. Process loss occurs during spray volume setting f. Process losses occur from exhaust as also the coating pan is perforated g. Process losses occur as some of the coating material stick to the coating pan during coating process h. Process losses occur as some of the coating material remains in the hoses and pipes of spray equipment and vessel after completion of coating process 4. Due to above losses it is a general practice to include 20% excess at coating stage. Weight gain is monitored during the process and coating process is stopped when the desired weight gain is achieved • **Justification shall be submitted for proceeding for the Seal coating upon the Metformin HCl core tablet without establishing the extended release dissolution profile of Metformin HCl core tablet at in process stage.**	

- The firm submitted that we have manufactured trial batches of the Empagliflozin/Metformin HCl XR tablet range. Trial batch testing was conducted at each stage and results were found satisfactory.
- On the basis of above reason testing of stability batches were conducted on final product only.
- Justification letter is enclose in Annexure-I along with test results of trial batches of Empagliflozin/Metformin HCl XR Tablet range for dissolution profile of Metformin HCl.
- The firm submitted justification stating that dissolution testing on Metformin HCl core tablet was done on below mentioned trial batches before proceeding to seal coating stage.
  5. Empagliflozin/Metformin HCl XR Tablet 5mg/1000mg Tablet, Batch No.:583DT01, Batch Size: 1.420kg
  6. Empagliflozin/Metformin HCl XR Tablet 10mg/1000mg Tablet, Batch No.:584DT01, Batch Size: 1.420kg
  7. Empagliflozin/Metformin HCl XR Tablet 12.5mg/1000mg Tablet, Batch No.:585DT01, Batch Size: 1.420kg
  8. Empagliflozin/Metformin HCl XR Tablet 25mg/1000mg Tablet, Batch No.:586DT01, Batch Size: 1.420kg
- Based on the satisfactory dissolution testing results of Metformin HCl core tablets of above mentioned trial batches (report submitted) and the experience with our recently registered product Empagliflozin/Linagliptin/Metformin XR Tablet range 5mg/2.5mg/1000mg, 10mg / 5mg / 1000mg, 12.5mg / 2.5mg / 1000mg, 25mg / 5mg / 1000mg which also have the same formulation as of Metformin HCl core tablet as of Metformin HCl core tablet formulation in Empagliflozin Metformin XR Tablet Range.
- Therefore, stability batches of subjected product were proceeded to seal coating stage without dissolution testing on Metformin core tablet
- **Justification shall be submitted for proceeding for the final film coating step without establishing the content of Empagliflozin at in process stage of active coating.**
- Empagliflozin API content testing was done after API coating on trial batches of Empagliflozin/Metformin HCl XR tablets range.(Justification letter and results of content of Empagliflozin are enclose in Annexure-J)
- Satisfactory results of trial batches obtained give us confidence to test the stability batches directly on finished product.
- However we commit to conduct testing the product at each stage for QC release batches.
- The firm submitted justification stating Empagliflozin content testing on Empagliflozin coated Metformin HCl XR tablet was done on below mentioned trial batches before proceeding to final coating stage.
  5. Empagliflozin/Metformin HCl XR Tablet 5mg/1000mg Tablet, Batch No.:583DT01, Batch Size: 1.420kg
  6. Empagliflozin/Metformin HCl XR Tablet 10mg/1000mg Tablet, Batch No.:584DT01, Batch Size: 1.420kg
  7. Empagliflozin/Metformin HCl XR Tablet 12.5mg/1000mg Tablet, Batch No.:585DT01, Batch Size: 1.420kg
  8. Empagliflozin/Metformin HCl XR Tablet 25mg/1000mg Tablet, Batch No.:586DT01, Batch Size: 1.420kg
- Based on the satisfactory Empagliflozin content testing results of Empagliflozin coated Metformin HCl XR tablet of above mentioned trial batches (report submitted) and on the experience with our recently registered product Empagliflozin / Linagliptin / Metformin XR Tablet range 5mg/2.5mg/1000mg, 10mg / 5mg / 1000mg, 12.5mg / 2.5mg / 1000mg, 25mg / 5mg / 1000mg which also have the same formulation as of Empagliflozin coating formulation in Empagliflozin Metformin XR Tablet Range.
- Therefore, stability batches of subjected product were proceeded for final film coating step without establishing the content for Empagliflozin at in process stage of active coating.
- **Clarification shall be submitted for the test applied to confirm that desired content for Empagliflozin has been achieved via active coating since submitted trial batch manufacturing record does not include any in process testing.**

	• The firm has submitted results of trial batches at coated stage showing that desired content for Empagliflozin has been achieved • **Minimum handling capacity of the equipment used in the manufacturing of trial batches shall be submitted.** • The firm stated the manufacturing process is done in state of Art Nabiqasim R&D facility having R&D Solid Dosage Unity Dr. Pharm which is an integrated system having below processing units and also submitted brochure. 1. High Shear Mixer, three interchangeable bowls below: a. Capacity; 1.0kg-2.0kg b. Capacity; 2.0kg-5.0kg c. Capacity; 5.0kg-10.0kg 2. Fluid Bed dryer 3. Dry Mill 4. Cone Blender, three interchangeable blenders below: a. Capacity; 1.0kg-2.0kg b. Capacity; 2.0kg-5.0kg c. Capacity; 5.0kg-10.0kg 5. Tablet Coating Pan, three interchangeable coating pans as below: a. Capacity; 1.0kg-2.0kg b. Capacity; 2.0kg-5.0kg c. Capacity; 5.0kg-10.0kg	
Decision: Approved with innovator's specifications. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
849.	Name, address of Applicant / Marketing Authorization Holder	M/s Nabiqasim Industries (Pvt.) Ltd., 17 / 24, Korangi Industrial Area, Karachi – Pakistan.
	Name, address of Manufacturing site.	M/s Nabiqasim Industries (Pvt.) Ltd., 17 / 24, Korangi Industrial Area, Karachi – Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate issued on 28-05-2022 based on inspection conducted on 27-05-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-20/85-Lic (Vol-V) dated 27-04-2020 which specifies Tablet (General) section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy No. 3137 dated 02/02/2023
	Details of fee submitted	PKR 30,000/-: dated 13/12/2022 (Deposit silp#476276141644)

	The proposed proprietary name / brand name	GLEMPA-M XR Tablet 12.5mg/1000mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Empagliflozin ……..12.5mg Metformin HCl USP (extended release)….1000mg
	Pharmaceutical form of applied drug	Film coated tablet for oral use
	Pharmacotherapeutic Group of (API)	Type 2 Diabetes Mellitus, antidiabetic agent
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SYNJARDY XR Tablet (5mg/1000mg, 10mg/1000mg, 12.5mg/1000mg, 25mg/1000mg) USFDA Approved.
	For generic drugs (me-too status)	Xenglu-Met XR Tablet 12.5mg/1000mg by M/s Hilton Pharma, (Reg#105270)
	Name and address of API manufacturer.	**Empagliflozin:** Zhejiang Hongyuan Pharmaceuticals Co., Ltd., Chem & API's Industrial Zone, Linhai, Zhejiang Province, China. **Metformin Hydrochloride:** Aarti Drugs Limited., Plot No. 211-213, Road No. 2, G.I.D.C., Sarigam, Dist; Valsad Gujarat , India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	**Empagliflozin:** The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Metformin:** The firm as submitted details of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance	**Empagliflozin:** Stability study conditions:

	(Conditions & duration of Stability studies)	Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (Z1215-170601, Z1215-170602, Z1215-170603) **Metformin HCl:** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (MEF/1410027, MEF/1410028, MEF/1410029)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted Pharmaceutical Equivalence studies against XENGLU-MET XR Tablet 12.5mg/1000mg by M/s Hilton Pharma, by performing quality tests (Description, Identification, Dissolution and Assay). CDP has been performed against the same brand that is XENGLU-MET XR Tablet 12.5mg/1000mg by M/s Hilton Pharma, in Acid media (0.1N) (pH 1.2), Acetate Buffer (4.5) & Phosphate Buffer (6.8). The values f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted method validation studies including linearity, range, accuracy, precision, specificity, LOD, LOQ, system suitability, robustness and forced degradation studies.

STABILITY STUDY DATA			
Manufacturer of API	**Empagliflozin:** Zhejiang Hongyuan Pharmaceuticals Co., Ltd., Chem & API's Industrial Zone, Linhai, Zhejiang Province, China. **Metformin Hydrochloride:** Aarti Drugs Limited., Plot No. 211-213, Road No. 2, G.I.D.C., Sarigam, Dist; Valsad Gujarat , India		
API Lot No.	**Empagliflozin:** EPG20211101 **Metformin HCl:** MEF/11113625		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	585DS01	585DS02	
Batch Size	5000 tablets	5000 tablets	

Manufacturing Date	07-2022	07-2022	
Date of Initiation	12-08-2022	12-08-2022	
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** The firm has submitted copy of GMP certificate of M/s Zhejiang Hongyuan Pharmaceuticals Co., Ltd., Chem & API's Industrial Zone, Linhai, Zhejiang P.R. China issued by Linhai Medical and Chemical Industry Administration valid upto 29th December 2023. Firm has submitted copy of DML (Zhe20090508) in name of Zhejiang Hongyuan Pharmaceuticals Co., Ltd., Chem & API's Industrial Zone, Linhai, Zhejiang, China issued by Zhejiang Food and Drug Administration valid upto 13th January 2024 **Metformin HCl:** Firm has submitted Copy of GMP certificate in name of Aarti Drugs Limited (Unit-II)., Plot No. 211-213, Road No. 2, G.I.D.C., at & post Sarigam, Dist; Valsad, Gujarat state , India issued by Commissioner Food & Drugs control Administration, Gandhinagar India valid upto 19-03-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of invoice for import of 30kg Empagliflozin attested by AD (I&E) DRAP Karachi office dated 24-12-2021 Firm has submitted copy of form 6 for import of Empagliflozin attested by AD (I&E) DRAP Karachi office dated 17-12-2021 **Metformin HCl:** Firm has submitted copy of invoice EXP/2810/21/22 Dated: 10-12-2021 for import of 3000kg Metformin HCL USP attested by AD (I&E) DRAP Karachi office dated 03-11-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.6.5	• Valid GMP certificate of drug substance manufacturer (empagliflozin & metformin) issued by relevant regulatory	• The firm submitted that at the time of dossier submission previously submitted GMP certificate of Metformin HCl API, manufacturer: AARTI Drugs Limited was valid till 19-03-2023. *However,*

	authority of country of origin is required • The address mentioned in submitted GMP certificate of M/s Zhejiang Hongyuan Pharmaceuticals Co., Ltd is different than that available on NMPA website, clarify	*renewal application of GMP certificate dated 27-01-2023 received from manufacturer is submitted.* • Firm has not submitted copy of GMP certificate of drug substance manufacturer for empagliflozin issued by relevant regulatory authority of country of origin • The firm submitted that address mentioned on Manufacturing License is same as mentioned on NMPA website (Chem & API's Industrial Zone, Linhai, Zhejiang, China), whereas on NMPA website the complete and detailed address has been given, furthermore, the office name, city and province are exactly same on both credentials. However, the addresses are different. **Name and address mentioned on DML:** Zhejiang Hongyuan Pharmaceuticals Co., Ltd., Chem & API's Industrial Zone, Linhai, Zhejiang, China **Name and address mentioned on NMPA website:** Zhejiang Hongyuan Pharmaceutical Co., Ltd., No. 6, Donghai Fourth Avenue, Toumen Port Economic Development Zone, Zhejiang Province, Linhai City, Taizhou City. Later the firm has submitted a Notice of change from the drug substance manufacturer declaring that description of the company's address has been changed from "Chem & API's Industrial Zone, Linhai, Zhejiang, China" to "No. 6, Donghai Fourth Avenue, Zheijiang Toumengang Economic Development Zone, Linhai City, Taizhou, Zhejiang, P.R of China." The notice further states that location of manufacturing site has not been changed and remains same with before. The GMP certificate and DML of the drug substance manufacturer verified from the NMPA website reveals that the description of the address has been changed.
3.2.S.4	Drug substance specifications for Empagliflozin shall be submitted from drug substance, manufacturer.	Drug substance specifications for Empagliflozin from drug substance manufacturer is submitted
3.2.P.2	Justification shall be submitted for not performing Pharmaceutical equivalence and CDP studies against the innovator product.	The firm submitted that Reference to CTD guidance document pharmaceutical equivalence and CDP studies can be performed against reference / comparator samples
3.2.P.5	• Justification shall be submitted that how the "specificity" of the applied method has been inferred without the performance of "Peak Purity Test (e.g., using diode array detector) to establish that analyte chromatographic peak is not attributable to more than one component". • Submitted analytical method validation report declares the	• Specificity of the applied method was conducted on PDA detector to establish analyte peaks are not attributable. Chromatograms representing peak purity of Metformin and Empagliflozin are submitted • We acknowledge that previously submitted analytical method validation report is of "Empagliflozin/Metformin extended release tablet". • As mentioned by you that report declares the details of "Empagliflozin / Linagliptin / Metformin

	details for "Empagliflozin/Linagliptin/Metformin tablet.	HCl". It is due to the typographical error, while compiling report, mention in system suitability parameter of Metformin HCl on pahe No. 15. Corrected method validation report is submitted.
3.2.P.6	COA of primary / secondary reference standard including source and lot number used for the analysis for trial batches shall be submitted shall be provided.	• COA of reference standards used in testing are submitted **Metformin Certified Reference Material** Source: Supelco LOT No: LRAC3162 **Empagliflozin** **Till 3rd month stability studies:** Source: Zhejiang Hongyuan Pharmaceutical Co., Ltd., China Batch No. EPG211202WS **For Onward Studies** Batch No. EPG220703WS
3.2.P.8	• The commercial invoice for Metformin HCl submitted by firm has been attested by AD I&E Karachi, dated 03-11-2022, whereas trial batches have been manufactured in July 2022. Justification shall be submitted for manufacturing of trial batches prior to the release of drug substance by AD I&E. • Stability studies data for 6th month time point shall be submitted.	• The firm has submitted copy of commercial invoice of Metformin HCl attested by AD *I&E mentioning comments that previously signed date by AD I&E (03-11-2022) was a writing error, Month is mentioned as November instead of January 2022.* • The firm has also submitted copy of goods declaration • Firm has submitted 6th month time point stability study data of applied product
2.3.R	• **Justification shall be submitted for dispensed quantity of Empagliflozin & alongwith 20% overage for formulation of trial batches alongwith the performance based evidence for the referred process loss.** The firm submitted that 20% excess quantity is taken to cover for process losses as mentioned below: 5. Coating process done in R&D having R&D solid dosage unity Dr. Pharm that is equipped with three interchangeable perforated coating pans that are suitable for coating 0.8kg-10kg tablets i. Process loss occurs during spray volume setting j. Process losses occur from exhaust as also the coating pan is perforated k. Process losses occur as some of the coating material stick to the coating pan during coating process l. Process losses occur as some of the coating material remains in the hoses and pipes of spray equipment and vessel after completion of coating process 6. Due to above losses it is a general practice to include 20% excess at coating stage. Weight gain is monitored during the process and coating process is stopped when the desired weight gain is achieved • **Justification shall be submitted for proceeding for the Seal coating upon the Metformin HCl core tablet without establishing the extended release dissolution profile of Metformin HCl core tablet at in process stage.** • The firm submitted that we have manufactured trial batches of the Empagliflozin/Metformin HCl XR tablet range. Trial batch testing was conducted at each stage and results were found satisfactory. • On the basis of above reason testing of stability batches were conducted on final product only. • Justification letter is enclose in Annexure-I along with test results of trial batches of Empagliflozin/Metformin HCl XR Tablet range for dissolution profile of Metformin HCl. • The firm submitted justification stating that dissolution testing on Metformin HCl core tablet was done on below mentioned trial batches before proceeding to seal coating stage.	

9. Empagliflozin/Metformin HCl XR Tablet 5mg/1000mg Tablet, Batch No.:583DT01, Batch Size: 1.420kg
10. Empagliflozin/Metformin HCl XR Tablet 10mg/1000mg Tablet, Batch No.:584DT01, Batch Size: 1.420kg
11. Empagliflozin/Metformin HCl XR Tablet 12.5mg/1000mg Tablet, Batch No.:585DT01, Batch Size: 1.420kg
12. Empagliflozin/Metformin HCl XR Tablet 25mg/1000mg Tablet, Batch No.:586DT01, Batch Size: 1.420kg

- Based on the satisfactory dissolution testing results of Metformin HCl core tablets of above mentioned trial batches (report submitted) and the experience with our recently registered product Empagliflozin/Linagliptin/Metformin XR Tablet range 5mg/2.5mg/1000mg, 10mg / 5mg / 1000mg, 12.5mg / 2.5mg / 1000mg, 25mg / 5mg / 1000mg which also have the same formulation as of Metformin HCl core tablet as of Metformin HCl core tablet formulation in Empagliflozin Metformin XR Tablet Range.
- Therefore, stability batches of subjected product were proceeded to seal coating stage without dissolution testing on Metformin core tablet
- **Justification shall be submitted for proceeding for the final film coating step without establishing the content of Empagliflozin at in process stage of active coating.**
- Empagliflozin API content testing was done after API coating on trial batches of Empagliflozin/Metformin HCl XR tablets range.(Justification letter and results of content of Empagliflozin are enclose in Annexure-J)
- Satisfactory results of trial batches obtained give us confidence to test the stability batches directly on finished product.
- However we commit to conduct testing the product at each stage for QC release batches.
- The firm submitted justification stating Empagliflozin content testing on Empagliflozin coated Metformin HCl XR tablet was done on below mentioned trial batches before proceeding to final coating stage.

9. Empagliflozin/Metformin HCl XR Tablet 5mg/1000mg Tablet, Batch No.:583DT01, Batch Size: 1.420kg
10. Empagliflozin/Metformin HCl XR Tablet 10mg/1000mg Tablet, Batch No.:584DT01, Batch Size: 1.420kg
11. Empagliflozin/Metformin HCl XR Tablet 12.5mg/1000mg Tablet, Batch No.:585DT01, Batch Size: 1.420kg
12. Empagliflozin/Metformin HCl XR Tablet 25mg/1000mg Tablet, Batch No.:586DT01, Batch Size: 1.420kg

- Based on the satisfactory Empagliflozin content testing results of Empagliflozin coated Metformin HCl XR tablet of above mentioned trial batches (report submitted) and on the experience with our recently registered product Empagliflozin / Linagliptin / Metformin XR Tablet range 5mg/2.5mg/1000mg, 10mg / 5mg / 1000mg, 12.5mg / 2.5mg / 1000mg, 25mg / 5mg / 1000mg which also have the same formulation as of Empagliflozin coating formulation in Empagliflozin Metformin XR Tablet Range.
- Therefore, stability batches of subjected product were proceeded for final film coating step without establishing the content for Empagliflozin at in process stage of active coating.
- **Clarification shall be submitted for the test applied to confirm that desired content for Empagliflozin has been achieved via active coating since submitted trial batch manufacturing record does not include any in process testing.**
- The firm has submitted results of trial batches at coated stage showing that desired content for Empagliflozin has been achieved
- **Minimum handling capacity of the equipment used in the manufacturing of trial batches shall be submitted.**
- The firm stated the manufacturing process is done in state of Art Nabiqasim R&D facility having R&D Solid Dosage Unity Dr. Pharm which is an integrated system having below processing units and also submitted brochure.

1. High Shear Mixer, three interchangeable bowls below:

	a. Capacity; 1.0kg-2.0kg b. Capacity; 2.0kg-5.0kg c. Capacity; 5.0kg-10.0kg 2. Fluid Bed dryer 3. Dry Mill 4. Cone Blender, three interchangeable blenders below: a. Capacity; 1.0kg-2.0kg b. Capacity; 2.0kg-5.0kg c. Capacity; 5.0kg-10.0kg 5. Tablet Coating Pan, three interchangeable coating pans as below: a. Capacity; 1.0kg-2.0kg b. Capacity; 2.0kg-5.0kg c. Capacity; 5.0kg-10.0kg	
Decision: Approved with innovator's specifications. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
850.	Name, address of Applicant / Marketing Authorization Holder	M/s Nabiqasim Industries (Pvt.) Ltd., 17 / 24, Korangi Industrial Area, Karachi – Pakistan.
	Name, address of Manufacturing site.	M/s Nabiqasim Industries (Pvt.) Ltd., 17 / 24, Korangi Industrial Area, Karachi – Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted copy of cGMP certificate issued on 28-05-2022 based on inspection conducted on 27-05-2022.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-20/85-Lic (Vol-V) dated 27-04-2020 which specifies Tablet (General) section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy No. 4041 dated 13/02/2023
	Details of fee submitted	PKR 30,000/-: dated 13/12/2022 (Deposit silp#7016823815)
	The proposed proprietary name / brand name	GLEMPA-M XR Tablet 25mg/1000mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Empagliflozin ……25mg Metformin HCl USP (extended release)….1000mg
	Pharmaceutical form of applied drug	Film coated tablet for oral use
	Pharmacotherapeutic Group of (API)	Type 2 Diabetes Mellitus, antidiabetic agent

	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SYNJARDY XR Tablet (5mg/1000mg, 10mg/1000mg, 12.5mg/1000mg, 25mg/1000mg) USFDA Approved.
	For generic drugs (me-too status)	Xenglu-Met XR Tablet 25mg/1000mg by M/s Hilton Pharma, (Reg#105271)
	Name and address of API manufacturer.	**Empagliflozin:** Zhejiang Hongyuan Pharmaceuticals Co., Ltd., Chem & API's Industrial Zone, Linhai, Zhejiang Province, China. **Metformin Hydrochloride:** Aarti Drugs Limited., Plot No. 211-213, Road No. 2, G.I.D.C., Sarigam, Dist; Valsad Gujarat , India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	**Empagliflozin:** The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Metformin:** The firm as submitted details of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	**Empagliflozin:** Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (Z1215-170601, Z1215-170602, Z1215-170603) **Metformin HCl:** Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months

		Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (MEF/1410027, MEF/1410028, MEF/1410029)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted Pharmaceutical Equivalence studies against XENGLU-MET XR Tablet 25mg/1000mg by M/s Hilton Pharma, by performing quality tests (Description, Identification, Dissolution and Assay). CDP has been performed against the same brand that is XENGLU-MET XR Tablet 25mg/1000mg by M/s Hilton Pharma, in Acid media (0.1N) (pH 1.2), Acetate Buffer (4.5) & Phosphate Buffer (6.8). The values f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted method validation studies including linearity, range, accuracy, precision, specificity, LOD, LOQ, system suitability, robustness and forced degradation studies.

STABILITY STUDY DATA			
Manufacturer of API	**Empagliflozin:** Zhejiang Hongyuan Pharmaceuticals Co., Ltd., Chem & API's Industrial Zone, Linhai, Zhejiang Province, China. **Metformin Hydrochloride:** Aarti Drugs Limited., Plot No. 211-213, Road No. 2, G.I.D.C., Sarigam, Dist; Valsad Gujarat , India		
API Lot No.	**Empagliflozin:** EPG20211101 **Metformin HCl:** MEF/11113625		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	586DS01	586DS02	
Batch Size	5000 tablets	5000 tablets	
Manufacturing Date	07-2022	07-2022	
Date of Initiation	15-08-2022	15-08-2022	
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** The firm has submitted copy of GMP certificate of M/s Zhejiang Hongyuan Pharmaceuticals Co., Ltd., Chem & API's Industrial Zone, Linhai, Zhejiang P.R. China issued by Linhai Medical and Chemical Industry Administration valid upto 29th December 2023. Firm has submitted copy of DML (Zhe20090508) in name of Zhejiang Hongyuan Pharmaceuticals Co., Ltd., Chem & API's Industrial Zone, Linhai, Zhejiang, China issued by Zhejiang Food and Drug Administration valid upto 13th January 2024 **Metformin HCl:** Firm has submitted Copy of GMP certificate in name of Aarti Drugs Limited (Unit-II)., Plot No. 211-213, Road No. 2, G.I.D.C., at & post Sarigam, Dist; Valsad, Gujarat state , India issued by Commissioner Food & Drugs control Administration, Gandhinagar India valid upto 19-03-2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of invoice for import of 30kg Empagliflozin attested by AD (I&E) DRAP Karachi office dated 24-12-2021 Firm has submitted copy of form 6 for import of Empagliflozin attested by AD (I&E) DRAP Karachi office dated 17-12-2021 **Metformin HCl:** Firm has submitted copy of invoice EXP/2810/21-22 Dated: 10-12-2021 for import of 3000kg Metformin HCL USP attested by AD (I&E) DRAP Karachi office dated 03-11-2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.6.5	• Valid GMP certificate of drug substance manufacturer (empagliflozin & metformin) issued by relevant regulatory authority of country of origin is required • The address mentioned in submitted GMP certificate of M/s Zhejiang Hongyuan	• The firm submitted that at the time of dossier submission previously submitted GMP certificate of Metformin HCl API, manufacturer: AARTI Drugs Limited was valid till 19-03-2023. *However, renewal application of GMP certificate dated 27-01-2023 received from manufacturer is submitted.* • Firm has not submitted copy of GMP certificate of drug substance manufacturer for empagliflozin

	Pharmaceuticals Co., Ltd is different than that available on NMPA website, clarify	issued by relevant regulatory authority of country of origin • The firm submitted that address mentioned on Manufacturing License is same as mentioned on NMPA website (Chem & API's Industrial Zone, Linhai, Zhejiang, China), whereas on NMPA website the complete and detailed address has been given, furthermore, the office name, city and province are exactly same on both credentials. However, the addresses are different. **Name and address mentioned on DML:** Zhejiang Hongyuan Pharmaceuticals Co., Ltd., Chem & API's Industrial Zone, Linhai, Zhejiang, China **Name and address mentioned on NMPA website:** Zhejiang Hongyuan Pharmaceutical Co., Ltd., No. 6, Donghai Fourth Avenue, Toumen Port Economic Development Zone, Zhejiang Province, Linhai City, Taizhou City. Later the firm has submitted a Notice of change from the drug substance manufacturer declaring that description of the company's address has been changed from "Chem & API's Industrial Zone, Linhai, Zhejiang, China" to "No. 6, Donghai Fourth Avenue, Zheijiang Toumengang Economic Development Zone, Linhai City, Taizhou, Zhejiang, P.R of China." The notice further states that location of manufacturing site has not been changed and remains same with before. The GMP certificate and DML of the drug substance manufacturer verified from the NMPA website reveals that the description of the address has been changed.
3.2.S.4	Drug substance specifications for Empagliflozin shall be submitted from drug substance, manufacturer.	Drug substance specifications for Empagliflozin from drug substance manufacturer is submitted
3.2.P.2	Justification shall be submitted for not performing Pharmaceutical equivalence and CDP studies against the innovator product.	The firm submitted that Reference to CTD guidance document pharmaceutical equivalence and CDP studies can be performed against reference / comparator samples
3.2.P.5	• Justification shall be submitted that how the "specificity" of the applied method has been inferred without the performance of "Peak Purity Test (e.g., using diode array detector) to establish that analyte chromatographic peak is not attributable to more than one component". • Submitted analytical method validation report declares the details for "Empagliflozin/Linagliptin/Metformin tablet.	• Specificity of the applied method was conducted on PDA detector to establish analyte peaks are not attributable. Chromatograms representing peak purity of Metformin and Empagliflozin are submitted • We acknowledge that previously submitted analytical method validation report is of "Empagliflozin/Metformin extended release tablet". • As mentioned by you that report declares the details of "Empagliflozin / Linagliptin / Metformin HCl". It is due to the typographical error, while compiling report, mention in system suitability parameter of Metformin HCl on pahe

		No. 15. Corrected method validation report is submitted.
3.2.P.6	COA of primary / secondary reference standard including source and lot number used for the analysis for trial batches shall be submitted shall be provided.	• COA of reference standards used in testing are submitted **Metformin Certified Reference Material** Source: Supelco LOT No: LRAC3162 **Empagliflozin** **Till 3rd month stability studies:** Source: Zhejiang Hongyuan Pharmaceutical Co., Ltd., China Batch No. EPG211202WS **For Onward Studies** Batch No. EPG220703WS
3.2.P.8	• The commercial invoice for Metformin HCl submitted by firm has been attested by AD I&E Karachi, dated 03-11-2022, whereas trial batches have been manufactured in July 2022. Justification shall be submitted for manufacturing of trial batches prior to the release of drug substance by AD I&E. • Stability studies data for 6th month time point shall be submitted.	• The firm has submitted copy of commercial invoice of Metformin HCl attested by AD *I&E mentioning comments that previously signed date by AD I&E (03-11-2022) was a writing error, Month is mentioned as November instead of January 2022.* • The firm has also submitted copy of goods declaration • Firm has submitted 6th month time point stability study data of applied product
2.3.R	• **Justification shall be submitted for dispensed quantity of Empagliflozin & alongwith 20% overage for formulation of trial batches alongwith the performance based evidence for the referred process loss.** The firm submitted that 20% excess quantity is taken to cover for process losses as mentioned below: 7. Coating process done in R&D having R&D solid dosage unity Dr. Pharm that is equipped with three interchangeable perforated coating pans that are suitable for coating 0.8kg-10kg tablets m. Process loss occurs during spray volume setting n. Process losses occur from exhaust as also the coating pan is perforated o. Process losses occur as some of the coating material stick to the coating pan during coating process p. Process losses occur as some of the coating material remains in the hoses and pipes of spray equipment and vessel after completion of coating process 8. Due to above losses it is a general practice to include 20% excess at coating stage. Weight gain is monitored during the process and coating process is stopped when the desired weight gain is achieved • **Justification shall be submitted for proceeding for the Seal coating upon the Metformin HCl core tablet without establishing the extended release dissolution profile of Metformin HCl core tablet at in process stage.** • The firm submitted that we have manufactured trial batches of the Empagliflozin/Metformin HCl XR tablet range. Trial batch testing was conducted at each stage and results were found satisfactory. • On the basis of above reason testing of stability batches were conducted on final product only. • Justification letter is enclose in Annexure-I along with test results of trial batches of Empagliflozin/Metformin HCl XR Tablet range for dissolution profile of Metformin HCl. • The firm submitted justification stating that dissolution testing on Metformin HCl core tablet was done on below mentioned trial batches before proceeding to seal coating stage. 13. Empagliflozin/Metformin HCl XR Tablet 5mg/1000mg Tablet, Batch No.:583DT01, Batch Size: 1.420kg	

14. Empagliflozin/Metformin HCl XR Tablet 10mg/1000mg Tablet, Batch No.:584DT01, Batch Size: 1.420kg
15. Empagliflozin/Metformin HCl XR Tablet 12.5mg/1000mg Tablet, Batch No.:585DT01, Batch Size: 1.420kg
16. Empagliflozin/Metformin HCl XR Tablet 25mg/1000mg Tablet, Batch No.:586DT01, Batch Size: 1.420kg

- Based on the satisfactory dissolution testing results of Metformin HCl core tablets of above mentioned trial batches (report submitted) and the experience with our recently registered product Empagliflozin/Linagliptin/Metformin XR Tablet range 5mg/2.5mg/1000mg, 10mg / 5mg / 1000mg, 12.5mg / 2.5mg / 1000mg, 25mg / 5mg / 1000mg which also have the same formulation as of Metformin HCl core tablet as of Metformin HCl core tablet formulation in Empagliflozin Metformin XR Tablet Range.
- Therefore, stability batches of subjected product were proceeded to seal coating stage without dissolution testing on Metformin core tablet
- **Justification shall be submitted for proceeding for the final film coating step without establishing the content of Empagliflozin at in process stage of active coating.**
- Empagliflozin API content testing was done after API coating on trial batches of Empagliflozin/Metformin HCl XR tablets range.(Justification letter and results of content of Empagliflozin are enclose in Annexure-J)
- Satisfactory results of trial batches obtained give us confidence to test the stability batches directly on finished product.
- However we commit to conduct testing the product at each stage for QC release batches.
- The firm submitted justification stating Empagliflozin content testing on Empagliflozin coated Metformin HCl XR tablet was done on below mentioned trial batches before proceeding to final coating stage.

13. Empagliflozin/Metformin HCl XR Tablet 5mg/1000mg Tablet, Batch No.:583DT01, Batch Size: 1.420kg
14. Empagliflozin/Metformin HCl XR Tablet 10mg/1000mg Tablet, Batch No.:584DT01, Batch Size: 1.420kg
15. Empagliflozin/Metformin HCl XR Tablet 12.5mg/1000mg Tablet, Batch No.:585DT01, Batch Size: 1.420kg
16. Empagliflozin/Metformin HCl XR Tablet 25mg/1000mg Tablet, Batch No.:586DT01, Batch Size: 1.420kg

- Based on the satisfactory Empagliflozin content testing results of Empagliflozin coated Metformin HCl XR tablet of above mentioned trial batches (report submitted) and on the experience with our recently registered product Empagliflozin / Linagliptin / Metformin XR Tablet range 5mg/2.5mg/1000mg, 10mg / 5mg / 1000mg, 12.5mg / 2.5mg / 1000mg, 25mg / 5mg / 1000mg which also have the same formulation as of Empagliflozin coating formulation in Empagliflozin Metformin XR Tablet Range.
- Therefore, stability batches of subjected product were proceeded for final film coating step without establishing the content for Empagliflozin at in process stage of active coating.
- **Clarification shall be submitted for the test applied to confirm that desired content for Empagliflozin has been achieved via active coating since submitted trial batch manufacturing record does not include any in process testing.**
- The firm has submitted results of trial batches at coated stage showing that desired content for Empagliflozin has been achieved
- **Minimum handling capacity of the equipment used in the manufacturing of trial batches shall be submitted.**
- The firm stated the manufacturing process is done in state of Art Nabiqasim R&D facility having R&D Solid Dosage Unity Dr. Pharm which is an integrated system having below processing units and also submitted brochure.

1. High Shear Mixer, three interchangeable bowls below:
   a. Capacity; 1.0kg-2.0kg
   b. Capacity; 2.0kg-5.0kg

c. Capacity; 5.0kg-10.0kg 2. Fluid Bed dryer 3. Dry Mill 4. Cone Blender, three interchangeable blenders below: a. Capacity; 1.0kg-2.0kg b. Capacity; 2.0kg-5.0kg c. Capacity; 5.0kg-10.0kg 5. Tablet Coating Pan, three interchangeable coating pans as below: a. Capacity; 1.0kg-2.0kg b. Capacity; 2.0kg-5.0kg c. Capacity; 5.0kg-10.0kg
Decision: Approved with innovator's specifications. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Case No. 03; Deferred registration application of Human drugs on Form 5-F on export facilitation
Assistant director PR-I/EFD vide letter No.F.1-6/2019-PR-I (EFD) dated 29-12-2022 has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the *pharmaceutical* i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm have achieved the benchmark of more than **100,000 USD** during the **fiscal Year 2021-2022** and submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.,

851.	Name, address of Applicant / Marketing Authorization Holder	Highnoon Laboratories Limited., 17.5km, Multan Road, Lahore
	Name, address of Manufacturing site.	Highnoon Laboratories Limited., 17.5km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-30/92-Lic (Vol-VII) dated 04-01-2022 which specifies Tablet (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20199 dated: 15/07/2022
	Details of fee submitted	Copy of fee challan of another strength is submitted
	The proposed proprietary name / brand name	Daplozmet XR 5/500mg Tablet

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Dapagliflozin (as propanediol monohydrate) (immediate release) …….5mg Metformin hydrochloride (Extended release) ….……500mg
	Pharmaceutical form of applied drug	Film coated tablet.
	Pharmacotherapeutic Group of (API)	Drugs used in type 2 diabetes mellitus as an adjunct to diet and exercise.
	Reference to Finished product specifications	Manufacturer's Specs/ Innovator
	Proposed Pack size	5's, 7's, 10's, 14's, 20's, 28's, 30's, 50's, 60's, 100's, 120's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	XIGDUO XR 5/500mg film coated Tablets, USFDA Approved.
	For generic drugs (me-too status)	Xiga-Met 5/500 XR Tablet by M/s CCL Pharmaceuticals (Reg#110985)
	Name and address of API manufacturer.	**Dapagliflozin:** Fuxin Long Rui Pharmaceutical CO., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China. **Metformin HCl:** Ipca Laboratories Limited., H-4, M.I.D.C., Waluj Aurangabad (Maharashtra) Pin: 431136, India
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	**Dapagliflozin:** Firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Metformin:** The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: **Dapagliflozin:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (160108, 160124, 160220)

		Metformin HCl: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (9002ML2RMI, 9003ML2RMI, 9004ML2RMI)
	Module-III (Drug Product):	The firm has submitted detail of composition, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the innovator brand that is XIGDUO XR 5/500mg Tablets by M/s Astra Zeneca USA by performing quality test (Identification, average weight, dissolution, assay) CDP has been performed against the same brand that is XIGDUO XR 5/500mg Tablets by M/s Astra Zeneca USA in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor are in acceptable range
	Analytical method validation/verification of product	Firm has submitted method validation studies including Specificity, Linearity, range, accuracy, precision, LOD, LOQ, Robustness, solution stability, System Suitability.

STABILITY STUDY DATA			
Manufacturer of API	**Dapagliflozin:** Fuxin Long Rui Pharmaceutical CO., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China. **Metformin HCl:** Ipca Laboratories Limited., H-4, M.I.D.C., Waluj Aurangabad (Maharashtra) Pin: 431136, India		
API Lot No.	**Dapagliflozin:** L-DG-20210805-D02-DG06-01 **Metformin HCl:** 21023ML2AJMI		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	RD-21320	RD-21321	RD-21305
Batch Size	4000 Tablets	4000 Tablets	4000 Tablets
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	08-01-2022	08-01-2022	08-01-2022
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Dapagliflozin:** Firm has submitted copy of GMP certificate in the name of M/s Fuxin Long Rui Pharmaceutical CO., Ltd., issued by Fuxin Food and Drug administration, valid upto 16-11-2024 Firm has submitted copy of DML (Certificate# Liao20150233) in the name of M/s Fuxin Long Rui Pharmaceutical CO., Ltd., issued by Liaoning Medical Products Administration, valid upto 20-12-2022 **Metformin HCl:** Firm has submitted copy of GMP certificate in the name of M/s Ipca Laboratories Limited., India., issued by Food and Drug administration, Maharashtra State India, valid upto 27-04-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dapagliflozin:** The firm has submitted a copy of invoice # HN210922-D) Dated 22-10-2021 for import of 15Kg of Dapagliflozin propanediol monohydrate (Batch# L-DG-20210805-D02-DG06-01) in name of M/s Highnoon Laboratories Ltd attested by AD (I&E) DRAP Lahore dated 12/11/2021. **Metformin HCl:** Firm has submitted copy of invoice# MEG2122/1630495 Dated 10-05-2021 for import of 6000Kg of Metformin HCl (Batch# 21023ML2AJMI, 21027ML2AJMI, 21116ML2AJMI, 21117ML2AJMI) in name of M/s Highnoon Laboratories Ltd attested by AD (I&E) DRAP Lahore 21-05-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing upto 03 months is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations
1.1	• Fee challan for applied product is not submitted. Submit original fee challan submitted for applied product
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted
1.5.2 / 3.2.P.1	• Label claim of the applied formulation with reference to the innovator product shall be submitted along with submission of applicable fee
1.5.6	• Clarification is required as you have applied for Manufacturer's Specifications / Innovator specifications?

3.2.S.4	• Justification is required for not including the test for propylene glycol content in drug substance specifications (dapagliflozin) by drug substance manufacturer and drug product manufacturer as recommended by innovator product review document
3.2.P.2	• Justification is required for using 5% (0.307mg) overage in case of dapagliflozin propanediol monohydrated in applied formulation
3.2.P.5	• Justification is required for not performing the identification test in batch analysis as recommended by innovator product review document • Specify the mesh size used with USP type-I apparatus used in dissolution studies
3.2.P.8	• Submit stability study data of applied product at 6th month time point • Compliance Record of HPLC software 21CFR & audit trail reports on product testing upto 06 months is not submitted

Previous Decision (M-326DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Firm's response:

Section	Observations	Response
1.1	• Fee challan for applied product is not submitted. Submit original fee challan submitted for applied product	• Firm has submitted copy of fee challan No#4026653104 dated 20-04-2023 for Daplozmet XR 5/500mg Tablet. The firm submitted that previously submitted fee challan have typographical error in strength.
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted	• Firm has submitted cGMP certificate issued on 19-01-2022 based on inspection conducted on 11-11-2021.
1.5.2 / 3.2.P.1	• Label claim of the applied formulation with reference to the innovator product shall be submitted along with submission of applicable fee	• The firm submitted that our formulation is same as the reference product formulation and requested to consider the below label claim without submission of fee. Each bi-layered film coated tablet contains: Dapagliflozin (as propanediol monohydrate) (immediate release) …….5mg Metformin HCl (Extended release) …..…500mg
1.5.6	• Clarification is required as you have applied for Manufacturer's Specifications / Innovator specifications?	• The firm submitted that as the applied product is not available in any Pharmacopoeia, so it is Innovator's Specification.
3.2.S.4	• Justification is required for not including the test for propylene glycol content in drug substance specifications (dapagliflozin) by drug substance manufacturer and drug product manufacturer as recommended by innovator product review document	• The firm submitted that Propylene Glycol is also named as 1,2-Propane diol. 1,2-Propane diol is used as a reactant in the drug substance manufacturing, and it has been identified as impurity in DMF of drug substance i.e. section 3.2.S.3.2.1 of the submitted DMF. • This impurity along with other impurities is controlled collectively under the test of "Related substances" which has been reported in the COA of drug substance manufacturer as well as drug product manufacturer. Limits for both "individual impurity" and "Total impurity" are also mentioned in CoA. Extract of the DMF and COA are submitted
3.2.P.2	• Justification is required for using 5% (0.307mg) overage in case of dapagliflozin propanediol monohydrated in applied formulation	• The firm submitted that overage is used to compensate the process loss. We will ensure to not use the overage in commercial batches.

3.2.P.5	• Justification is required for not performing the identification test in batch analysis as recommended by innovator product review document • Specify the mesh size used with USP type-I apparatus used in dissolution studies	• The firm submitted that Identification test for drug product is performed and submitted revised COA's • The firm submitted that USP Type 1 basket of 40 mesh screens with wire openings of 0.36 - 0.44 mm as per USP Dissolution chapter <711> is used in dissolution studies. *However innovator product review document recommends use of USP Type 1 basket with 20 mesh.*
3.2.P.8	• Submit stability study data of applied product at 6th month time point • Compliance Record of HPLC software 21CFR & audit trail reports on product testing upto 06 months is not submitted	• The firm has submitted 6th month time point stability data • Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted

Decision: Deferred for submission of following:

- **Scientific justification for using overage in case of Dapagliflozin propanediol monohydrated in applied formulation**
- **Fee of Rs. 7,500/- for correction/pre-approval change in label claim, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

852.	Name, address of Applicant / Marketing Authorization Holder	Highnoon Laboratories Limited., 17.5km, Multan Road, Lahore
	Name, address of Manufacturing site.	Highnoon Laboratories Limited., 17.5km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Not submitted
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-30/92-Lic (Vol-VII) dated 04-01-2022 which specifies Tablet (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20201 dated: 15/07/2022
	Details of fee submitted	Copy of fee challan of another strength is submitted
	The proposed proprietary name / brand name	Daplozmet XR 5/1000mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Dapagliflozin (as propanediol monohydrate) (immediate release) …….5mg Metformin hydrochloride (Extended release) ……1000mg
	Pharmaceutical form of applied drug	Film coated tablet.
	Pharmacotherapeutic Group of (API)	Drugs used in type 2 diabetes mellitus as an adjunct to diet and exercise.
	Reference to Finished product specifications	Manufacturer's Specs/ Innovator

	Proposed Pack size	5's, 7's, 10's, 14's, 20's, 28's, 30's, 50's, 60's, 100's, 120's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	XIGDUO XR 5/1000mg film coated Tablets, USFDA Approved.
	For generic drugs (me-too status)	Xiga-Met 5/1000 XR Tablet by M/s CCL Pharmaceuticals (Reg# 110626)
	Name and address of API manufacturer.	**Dapagliflozin:** Fuxin Long Rui Pharmaceutical CO., Ltd., Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China. **Metformin HCl:** Ipca Laboratories Limited., H-4, M.I.D.C., Waluj Aurangabad (Maharashtra) Pin: 431136, India
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	**Dapagliflozin:** Firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Metformin:** The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: **Dapagliflozin:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (160108, 160124, 160220) **Metformin HCl:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (9002ML2RMI, 9003ML2RMI, 9004ML2RMI)
	Module-III (Drug Product):	The firm has submitted detail of composition, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification,

		reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the innovator brand that is XIGDUO XR 5/1000mg Tablets by M/s Astra Zeneca USA by performing quality test (Identification, average weight, dissolution, assay) CDP has been performed against the brand that is XIGDUO XR 5/1000mg Tablets by M/s Astra Zeneca USA in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor are in acceptable range
	Analytical method validation/verification of product	Firm has submitted method validation studies including Specificity, Linearity, range, accuracy, precision, LOD, LOQ, Robustness, solution stability, System Suitability.

STABILITY STUDY DATA			
Manufacturer of API	**Dapagliflozin:** Fuxin Long Rui Pharmaceutical CO., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China. **Metformin HCl:** Ipca Laboratories Limited., H-4, M.I.D.C., Waluj Aurangabad (Maharashtra) Pin: 431136, India		
API Lot No.	**Dapagliflozin:** L-DG-20210805-D02-DG06-01 **Metformin HCl:** 21023ML2AJMI		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD-21281	RD-21226	RD-21168
Batch Size	4000 Tablets	4000 Tablets	4000 Tablets
Manufacturing Date	10-2021	09-2021	08-2021
Date of Initiation	06-11-2022	06-11-2022	06-11-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Dapagliflozin:** Firm has submitted copy of GMP certificate in the name of M/s Fuxin Long Rui Pharmaceutical CO., Ltd., issued by Fuxin Food and Drug administration, valid upto 16-11-2024 Firm has submitted copy of DML (Certificate# Liao20150233) in the name of M/s Fuxin Long Rui

		Pharmaceutical CO., Ltd., issued by Liaoning Medical Products Administration, valid upto 20-12-2022 **Metformin HCl:** Firm has submitted copy of GMP certificate in the name of M/s Ipca Laboratories Limited., India., issued by Food and Drug administration, Maharashtra State India, valid upto 27-04-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dapagliflozin:** The firm has submitted a copy of invoice # HN210922-D Dated 22-10-2021 for import of 15Kg of Dapagliflozin propanediol monohydrate (Batch# L-DG-20210805-D02-DG06-01) in name of M/s Highnoon Laboratories Ltd attested by AD (I&E) DRAP Lahore dated 12/11/2021. **Metformin HCl:** Firm has submitted copy of invoice# MEG2122/1630495 Dated 10-05-2021 for import of 6000Kg of Metformin HCl (Batch# 21023ML2AJMI, 21027ML2AJMI, 21116ML2AJMI, 21117ML2AJMI) in name of M/s Highnoon Laboratories Ltd attested by AD (I&E) DRAP Lahore 21-05-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations
1.1	• Fee challan for applied product is not submitted. Submit original fee challan submitted for applied product
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted
1.5.2 / 3.2.P.1	• Label claim of the applied formulation with reference to the innovator product shall be submitted along with submission of applicable fee
1.5.6	• Clarification is required as you have claimed Manufacturer's Specifications / Innovator specifications?
3.2.S.4	• Justification is required for not including the test for propylene glycol content in drug substance specifications (dapagliflozin) by drug substance manufacturer and drug product manufacturer as recommended by innovator product review document
3.2.P.2	• Justification is required for using 5% (0.307mg) overage in case of dapagliflozin propanediol monohydrated in applied formulation
3.2.P.5	• Justification is required for not performing the identification test in batch analysis as recommended by innovator product review document • Specify the mesh size used with USP type-I apparatus used in dissolution studies
3.2.P.8	• Justification is required since submitted chromatograms show that content uniformity test for dapagliflozin and weight variation test for metformin is performed (22-11-2021) subsequent to the initiation of stability study (6-11-2021) for all batches

Previous Decision (M-326DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Firm's response:

Section	Observations	Response
1.1	• Fee challan for applied product is not submitted. Submit original fee challan submitted for applied product	• Firm has submitted copy of fee challan No#570830147709 dated 23/06/2022 submitted for Daplozmet XR 5/1000mg Tablet
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted	• Firm has submitted cGMP certificate issued on 19-01-2022 based on inspection conducted on 11-11-2021.
1.5.2 / 3.2.P.1	• Label claim of the applied formulation with reference to the innovator product shall be submitted along with submission of applicable fee	• The firm submitted that our formulation is same as the reference product formulation and requested to consider the below label claim without submission of fee. Each bi-layered film coated tablet contains: Dapagliflozin (as propanediol monohydrate) (immediate release) …….5mg Metformin HCl (Extended release) ….1000mg
1.5.6	• Clarification is required as you have applied for Manufacturer's Specifications / Innovator specifications?	• The firm submitted that as the applied product is not available in any Pharmacopoeia, so it is Innovator's Specification.
3.2.S.4	• Justification is required for not including the test for propylene glycol content in drug substance specifications (dapagliflozin) by drug substance manufacturer and drug product manufacturer as recommended by innovator product review document	• The firm submitted that Propylene Glycol is also named as 1,2-Propane diol. 1,2-Propane diol is used as a reactant in the drug substance manufacturing, and it has been identified as impurity in DMF of drug substance i.e. section 3.2.S.3.2.1 of the submitted DMF. • This impurity along with other impurities is controlled collectively under the test of "Related substances" which has been reported in the COA of drug substance manufacturer as well as drug product manufacturer. Limits for both "individual impurity" and "Total impurity" are also mentioned in CoA. Extract of the DMF and COA are submitted
3.2.P.2	• Justification is required for using 5% (0.307mg) overage in case of dapagliflozin propanediol monohydrated in applied formulation	• The firm submitted that overage is used to compensate the process loss. We will ensure to not use the overage in commercial batches.
3.2.P.5	• Justification is required for not performing the identification test in batch analysis as recommended by innovator product review document • Specify the mesh size used with USP type-I apparatus used in dissolution studies	• The firm submitted that Identification test for drug product is performed and submitted revised COA's • The firm submitted that USP Type 1 basket of 40 mesh screens with wire openings of 0.36 - 0.44 mm as per USP Dissolution chapter <711> is used in dissolution studies. *However innovator product review document recommends use of USP Type 1 basket with 20 mesh.*
3.2.P.8	• Justification is required since submitted chromatograms show that content uniformity test for dapagliflozin and weight variation test	• The firm submitted that content uniformity test is performed at the time of release batches that's why it is included at the initial time point. While content uniformity test is not stability

	for metformin is performed (22-11-2021) subsequent to the initiation of stability study (6-11-2021) for all batches	indicating that's why it is not included in the latter's time point of stability studies.

Decision: Deferred for submission of following:

- **Scientific justification for using overage in case of Dapagliflozin propanediol monohydrated in applied formulation**
- **Justification as submitted chromatograms show that content uniformity test for dapagliflozin and weight variation test for metformin is performed subsequent to the initiation of stability study for all batches**
- **Fee of Rs. 7,500/- for correction/pre-approval change in label claim, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

853.	Name, address of Applicant / Marketing Authorization Holder	Highnoon Laboratories Limited., 17.5km, Multan Road, Lahore
	Name, address of Manufacturing site.	Highnoon Laboratories Limited., 17.5km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted cGMP certificate issued on 19-01-2022 based on inspection conducted on 11-11-2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-30/92-Lic (Vol-VII) dated 04-01-2022 which specifies Tablet (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20200 dated: 15/06/2022
	Details of fee submitted	Rs. 30,000/- dated 23-06-2022 (Deposit silp#41842899)
	The proposed proprietary name / brand name	Daplozmet XR 10/500mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Dapagliflozin (as propanediol monohydrate) (immediate release) …….10mg Metformin hydrochloride (Extended release) ….……500mg
	Pharmaceutical form of applied drug	Film coated tablet.
	Pharmacotherapeutic Group of (API)	Drugs used in type 2 diabetes mellitus as an adjunct to diet and exercise.
	Reference to Finished product specifications	Manufacturer's Specs/ Innovator
	Proposed Pack size	5's, 7's, 10's, 14's, 20's, 28's, 30's, 50's, 60's, 100's, 120's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	XIGDUO XR 10/500mg film coated Tablets, USFDA Approved.
	For generic drugs (me-too status)	Xiga-Met 10/500mg XR Tablet by M/s CCL Pharmaceuticals (Reg#112049)
	Name and address of API manufacturer.	**Dapagliflozin:** Fuxin Long Rui Pharmaceutical CO., Ltd., Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China. **Metformin HCl:** Ipca Laboratories Limited., H-4, M.I.D.C., Waluj Aurangabad (Maharashtra) Pin: 431136, India
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	**Dapagliflozin:** Firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Metformin:** The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: **Dapagliflozin:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (160108, 160124, 160220) **Metformin HCl:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (9002ML2RMI, 9003ML2RMI, 9004ML2RMI)
	Module-III (Drug Product):	The firm has submitted detail of composition, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the innovator brand that is XIGDUO XR

		10/500mg Tablets by M/s Astra Zeneca USA by performing quality test (Identification, average weight, dissolution, assay) CDP has been performed against the same brand that is XIGDUO XR 10/500mg Tablets by M/s Astra Zeneca USA in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor are in acceptable range	
	Analytical method validation/verification of product	Firm has submitted method validation studies including Specificity, Linearity, range, accuracy, precision, LOD, LOQ, Robustness, solution stability, System Suitability.	
STABILITY STUDY DATA			
Manufacturer of API	**Dapagliflozin:** Fuxin Long Rui Pharmaceutical CO., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China. **Metformin HCl:** Ipca Laboratories Limited., H-4, M.I.D.C., Waluj Aurangabad (Maharashtra) Pin: 431136, India		
API Lot No.	**Dapagliflozin:** L-DG-20210805-D02-DG06-01 **Metformin HCl:** 21023ML2AJMI		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	RD-21313	RD-21327	RD-21326
Batch Size	4000 Tablets	4000 Tablets	4000 Tablets
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	08-01-2022	08-01-2022	08-01-2022
No. of Batches	03		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Dapagliflozin:** Firm has submitted copy of GMP certificate in the name of M/s Fuxin Long Rui Pharmaceutical CO., Ltd., issued by Fuxin Food and Drug administration, valid upto 16-11-2024 Firm has submitted copy of DML (Certificate# Liao20150233) in the name of M/s Fuxin Long Rui Pharmaceutical CO., Ltd., issued by Liaoning Medical Products Administration, valid upto 20-12-2022 **Metformin HCl:** Firm has submitted copy of GMP certificate in the name of M/s Ipca Laboratories Limited., India., issued by	

		Food and Drug administration, Maharashtra State India, valid upto 27-04-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dapagliflozin:** The firm has submitted a copy of invoice # HN210922-D) Dated 20-10-2021 for import of 15Kg of Dapagliflozin propanediol monohydrate (Batch# L-DG-20210805-D02-DG06-01) in name of M/s Highnoon Laboratories Ltd attested by AD (I&E) DRAP Lahore dated 12/11/2021. **Metformin HCl:** Firm has submitted copy of invoice# MEG2122/1630495 Dated 10-05-2021 for import of 6000Kg of Metformin HCl (Batch# 21023ML2AJMI, 21027ML2AJMI, 21116ML2AJMI, 21117ML2AJMI) in name of M/s Highnoon Laboratories Ltd attested by AD (I&E) DRAP Lahore 21-05-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing upto 03 months is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations
1.5.2 / 3.2.P.1	• Label claim of the applied formulation with reference to the innovator product shall be submitted along with submission of applicable fee
1.5.6	• Clarification is required as you have applied for Manufacturer's Specifications / Innovator specifications?
3.2.S.4	• Justification is required for not including the test for propylene glycol content in drug substance specifications (dapagliflozin) by drug substance manufacturer and drug product manufacturer as recommended by innovator product review document
3.2.P.2	• Justification is required for using 5% (0.615mg) overage in case of dapagliflozin propanediol monohydrated in applied formulation
3.2.P.5	• Justification is required for not performing the identification test in batch analysis as recommended by innovator product review document • Specify the mesh size used with USP type-I apparatus used in dissolution studies
3.2.P.8	• Submit stability study data of applied product at 6th month time point • Compliance Record of HPLC software 21CFR & audit trail reports on product testing upto 06 months is not submitted

Previous Decision (M-326DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Firm's response:

Section	Observations	Response
1.5.2 / 3.2.P.1	• Label claim of the applied formulation with reference to the innovator product shall be submitted along with submission of applicable fee	• The firm submitted that our formulation is same as the reference product formulation and requested to consider the below label claim without submission of fee. Each bi-layered film coated tablet contains:

		Dapagliflozin (as propanediol monohydrate) (immediate release) …….10mg Metformin HCl (Extended release) ……500mg
1.5.6	• Clarification is required as you have applied for Manufacturer's Specifications / Innovator specifications?	• The firm submitted that as the applied product is not available in any Pharmacopoeia, so it is Innovator's Specification.
3.2.S.4	• Justification is required for not including the test for propylene glycol content in drug substance specifications (dapagliflozin) by drug substance manufacturer and drug product manufacturer as recommended by innovator product review document	• The firm submitted that Propylene Glycol is also named as 1,2-Propane diol. 1,2-Propane diol is used as a reactant in the drug substance manufacturing, and it has been identified as impurity in DMF of drug substance i.e. section 3.2.S.3.2.1 of the submitted DMF. • This impurity along with other impurities is controlled collectively under the test of "Related substances" which has been reported in the COA of drug substance manufacturer as well as drug product manufacturer. Limits for both "individual impurity" and "Total impurity" are also mentioned in CoA. Extract of the DMF and COA are submitted
3.2.P.2	• Justification is required for using 5% (0.615mg) overage in case of dapagliflozin propanediol monohydrated in applied formulation	• The firm submitted that overage is used to compensate the process loss. We will ensure to not use the overage in commercial batches.
3.2.P.5	• Justification is required for not performing the identification test in batch analysis as recommended by innovator product review document • Specify the mesh size used with USP type-I apparatus used in dissolution studies	• The firm submitted that Identification test for drug product is performed and submitted revised COA's • The firm submitted that USP Type 1 basket of 40 mesh screens with wire openings of 0.36 - 0.44 mm as per USP Dissolution chapter <711> is used in dissolution studies. *However innovator product review document recommends use of USP Type 1 basket with 20 mesh.*
3.2.P.8	• Submit stability study data of applied product at 6th month time point • Compliance Record of HPLC software 21CFR & audit trail reports on product testing upto 06 months is not submitted	• The firm has submitted 6th month time point stability data • Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted
Decision: Deferred for submission of following: • **Scientific justification for using overage in case of Dapagliflozin propanediol monohydrated in applied formulation** • **Fee of Rs. 7,500/- for correction/pre-approval change in label claim, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**		
854.	Name, address of Applicant / Marketing Authorization Holder	Highnoon Laboratories Limited., 17.5km, Multan Road, Lahore
	Name, address of Manufacturing site.	Highnoon Laboratories Limited., 17.5km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted cGMP certificate issued on 19-01-2022 based on inspection conducted on 11-11-2021.

	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 1-30/92-Lic (Vol-VII) dated 04-01-2022 which specifies Tablet (General) Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 20202 dated: 15/06/2022
	Details of fee submitted	Rs. 30,000/- dated 23-06-2022 (Deposit silp#8069049838)
	The proposed proprietary name / brand name	Daplozmet XR 10/1000mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Dapagliflozin (as propanediol monohydrate) (immediate release) …….10mg Metformin hydrochloride (Extended release) ……1000mg
	Pharmaceutical form of applied drug	Film coated tablet.
	Pharmacotherapeutic Group of (API)	Drugs used in type 2 diabetes mellitus as an adjunct to diet and exercise.
	Reference to Finished product specifications	Manufacturer's Specs/ Innovator
	Proposed Pack size	5's, 7's, 10's, 14's, 20's, 28's, 30's, 50's, 60's, 100's, 120's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	XIGDUO XR 10/1000mg film coated Tablets, USFDA Approved.
	For generic drugs (me-too status)	Xiga-Met 10/1000mg XR Tablet by M/s CCL Pharmaceuticals (Reg#110627)
	Name and address of API manufacturer.	**Dapagliflozin:** Fuxin Long Rui Pharmaceutical CO., Ltd., Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China. **Metformin HCl:** Ipca Laboratories Limited., H-4, M.I.D.C., Waluj Aurangabad (Maharashtra) Pin: 431136, India
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	**Dapagliflozin:** Firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process

		and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. **Metformin:** The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: **Dapagliflozin:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (160108, 160124, 160220) **Metformin HCl:** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (9002ML2RMI, 9003ML2RMI, 9004ML2RMI)
	Module-III (Drug Product):	The firm has submitted detail of composition, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the innovator brand that is XIGDUO XR 10/1000mg Tablets by M/s Astra Zeneca USA by performing quality test (Identification, average weight, dissolution, assay) CDP has been performed against the same brand that is XIGDUO XR 10/1000mg Tablets by M/s Astra Zeneca USA in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values of f2 factor are in acceptable range
	Analytical method validation/verification of product	Firm has submitted method validation studies including Specificity, Linearity, range, accuracy, precision, LOD, LOQ, Robustness, solution stability, System Suitability.

STABILITY STUDY DATA	
Manufacturer of API	**Dapagliflozin:** Fuxin Long Rui Pharmaceutical CO., Ltd. Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China. **Metformin HCl:** Ipca Laboratories Limited., H-4, M.I.D.C., Waluj Aurangabad (Maharashtra) Pin: 431136, India
API Lot No.	**Dapagliflozin:** L-DG-20210805-D02-DG06-01 **Metformin HCl:** 21023ML2AJMI
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton

Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD-21166	RD-21225	RD-21282
Batch Size	4000 Tablets	4000 Tablets	4000 Tablets
Manufacturing Date	08-2021	09-2021	10-2021
Date of Initiation	06-11-2021	06-11-2021	06-11-2021
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Dapagliflozin:** Firm has submitted copy of GMP certificate in the name of M/s Fuxin Long Rui Pharmaceutical CO., Ltd., issued by Fuxin Food and Drug administration, valid upto 16-11-2024 Firm has submitted copy of DML (Certificate# Liao20150233) in the name of M/s Fuxin Long Rui Pharmaceutical CO., Ltd., issued by Liaoning Medical Products Administration, valid upto 20-12-2022 **Metformin HCl:** Firm has submitted copy of GMP certificate in the name of M/s Ipca Laboratories Limited., India., issued by Food and Drug administration, Maharashtra State India, valid upto 27-04-2024
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dapagliflozin:** The firm has submitted a copy of invoice # HN210922-D) Dated 20-10-2021 for import of 15Kg of Dapagliflozin propanediol monohydrate (Batch# L-DG-20210805-D02-DG06-01) in name of M/s Highnoon Laboratories Ltd attested by AD (I&E) DRAP Lahore dated 12/11/2021. **Metformin HCl:** Firm has submitted copy of invoice# MEG2122/1630495 Dated 10-05-2021 for import of 6000Kg of Metformin HCl (Batch# 21023ML2AJMI, 21027ML2AJMI, 21116ML2AJMI, 21117ML2AJMI) in name of M/s Highnoon Laboratories Ltd attested by AD (I&E) DRAP Lahore 21-05-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Remarks of Evaluator [XI]:

Section	Observations
1.5.2 / 3.2.P.1	• Label claim of the applied formulation with reference to the innovator product shall be submitted along with submission of applicable fee
1.5.6	• Clarification is required as you have applied for Manufacturer's Specifications / Innovator specifications?
3.2.S.4	• Justification is required for not including the test for propylene glycol content in drug substance specifications (dapagliflozin) by drug substance manufacturer and drug product manufacturer as recommended by innovator product review document
3.2.P.2	• Justification is required for using 5% (0.615mg) overage in case of dapagliflozin propanediol monohydrated in applied formulation
3.2.P.5	• Justification is required for not performing the identification test in batch analysis as recommended by innovator product review document • Specify the mesh size used with USP type-I apparatus used in dissolution studies
3.2.P.8	• Justification is required since submitted chromatograms show that content uniformity test for dapagliflozin and weight variation test for metformin is performed (22-11-2021) subsequent to the initiation of stability study (6-11-2021) for all batches

Previous Decision (M-326DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Firms' s response:

Section	Observations	Response
1.5.2 / 3.2.P.1	• Label claim of the applied formulation with reference to the innovator product shall be submitted along with submission of applicable fee	• The firm submitted that our formulation is same as the reference product formulation and requested to consider the below label claim without submission of fee. Each bi-layered film coated tablet contains: Dapagliflozin (as propanediol monohydrate) (immediate release) …….10mg Metformin HCl (Extended release)…….1000mg
1.5.6	• Clarification is required as you have applied for Manufacturer's Specifications / Innovator specifications?	• The firm submitted that as the applied product is not available in any Pharmacopoeia, so it is Innovator's Specification.
3.2.S.4	• Justification is required for not including the test for propylene glycol content in drug substance specifications (dapagliflozin) by drug substance manufacturer and drug product manufacturer as recommended by innovator product review document	• The firm submitted that Propylene Glycol is also named as 1,2-Propane diol. 1,2-Propane diol is used as a reactant in the drug substance manufacturing, and it has been identified as impurity in DMF of drug substance i.e. section 3.2.S.3.2.1 of the submitted DMF. • This impurity along with other impurities is controlled collectively under the test of "Related substances" which has been reported in the COA of drug substance manufacturer as well as drug product manufacturer. Limits for both "individual impurity" and "Total impurity" are also mentioned in CoA. Extract of the DMF and COA are submitted
3.2.P.2	• Justification is required for using 5% (0.615mg) overage in case of dapagliflozin propanediol monohydrated in applied formulation	• The firm submitted that overage is used to compensate the process loss. We will ensure to not use the overage in commercial batches.

3.2.P.5	• Justification is required for not performing the identification test in batch analysis as recommended by innovator product review document • Specify the mesh size used with USP type-I apparatus used in dissolution studies	• The firm submitted that Identification test for drug product is performed and submitted revised COA's • The firm submitted that USP Type 1 basket of 40 mesh screens with wire openings of 0.36 - 0.44 mm as per USP Dissolution chapter <711> is used in dissolution studies. *However innovator product review document recommends use of USP Type 1 basket with 20 mesh.*
3.2.P.8	• Justification is required since submitted chromatograms show that content uniformity test for dapagliflozin and weight variation test for metformin is performed (22-11-2021) subsequent to the initiation of stability study (6-11-2021) for all batches	• The firm submitted that content uniformity test is performed at the time of release batches that's why it is included at the initial time point. While content uniformity test is not stability indicating that's why it is not included in the latter's time point of stability studies.
Decision: Deferred for submission of following: • **Scientific justification for using overage in case of Dapagliflozin propanediol monohydrated in applied formulation** • **Justification as submitted chromatograms show that content uniformity test for dapagliflozin and weight variation test for metformin is performed subsequent to the initiation of stability study for all batches** • **Fee of Rs. 7,500/- for correction/pre-approval change in label claim, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**		

Case No. 04: Deferred Routine Registration applications of Human Drugs on Form 5F (Local)

855.	Name, address of Applicant / Marketing Authorization Holder	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy. No 16112 dated 10-06-2021
	Details of fee submitted	Rs.20,000/- dated 03-05-2021
	Proposed proprietary name/brand name	Gludap 5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin as Propanediol Monohydrate…5mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Reference to Finished product specifications	In house

	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	FARXIGA (5mg, 10mg) film coated tablets USFDA Approved
	For generic drugs (me-too status)	Xiga 5mg Tablets by M/s CCL Pharmaceuticals (Reg#090504)
	GMP status of the Finished product manufacturer	GMP certificate issued to firm on 21st May 2019, based on inspection conducted on 23-04-2019 & valid upto 22-4-20222
	Name and address of API manufacturer.	Jiangsu yongan Pharmaceutical Co. Ltd., No. 18, 237 provincial road economic development zone, huaian Jiangsu China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has submitted summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, control of excipients, control of drug product, specifications, analytical procedures, validation/verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability study is conducted at $40^{O} \pm 2^{O}C$ /75% ± 5% RH for 6 months. The real time stability study is conducted at $30^{O}C \pm 2^{O}$ C / 65% ± 5% RH for 36 months. (Batch No. 130401, 130402 & 130501)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures and its verification studies, batch analysis, justification of specifications, reference standard or materials, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been performed against innovator product Forxiga 5mg tablet.

		CDP has been performed against innovator product Forxiga 5mg tablet in Acid media (pH 1.2), acetate buffer pH 4.5 & Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies is submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	Jiangsu yongan Pharmaceutical Co. Ltd., No. 18, 237 provincial road economic development zone, huaian Jiangsu China.		
API Lot No.	DGF-201902001		
Description of Pack (Container closure system)	Alu/Alu Blister Packing		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	DPT-001	DPT-002	DPT-003
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	08-01-2020	08-01-2020	08-01-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm submitted copy of minutes of 296th meeting of registration board dated 8th, 9th & 10th September, 2020 in which their product Empaglif 10mg and 25mg applied on form 5F has been approved based on the inspection conducted by the panel for authenticity of stability data
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm submitted copy of GMP certificate of Jiangsu Yongan Pharmaceutical Co., Ltd China valid up to 03-03-2021
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted clearance certificate and form 6 attested by Assistant Director (I&E) DRAP Islamabad dated 01-04-2019 for the import of 200gm Dapagliflozin Propanediol Monohydrate and 5mg impurity A and 5mg Impurity B. However, the firm has not submitted invoice for import of said materials.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports on product testing
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.4	Submit Valid copy of Drug Manufacturing License	The firm have submitted valid Drug Manufacturing License
1.6.5	Submit valid GMP certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	The firm submitted valid GMP certificate
3.2.S.4.1. - 3.2.S.4.2	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Firm have submitted Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer. However, the chromatographic test conditions were different as compared with drug substance manufacturer. For example, the chromatographic conditions used by the **drug substance manufacturer are:** **Related substances:** Mobile phase; Water R (0.01M NaH2PO4); Acetonitrile R (50;50v/v) DetectIion; 225nm Injection; 20ul Flow rate; 1ml/min **Drug product manufacturer;** **Related substances:** Mobile phase; Methanol:Water (70;30 v/v) Detectio; 223nm Injection; 20ul Flow rate; 1.5ml/min Temperature; 40ºC **Drug substance manufacturer:** **Assay:** Mobile phase; Water R (0.01M NaH2PO4); Acetonitrile R (50;5 v/v) Detection; 225nm Injection; 20ul Flow rate; 1ml/min Temperature: 25ºC **Drug product manufacturer;** **Assay:** Mobile phase; Methanol:Water (70;30 v/v) Detection; 223nm Injection; 20ul Flow rate; 1.5ml/min Temperature; 40ºC
3.2.S.4.3	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	The firm have submitted Analytical Method validation studies performed by the Drug Product manufacturer for drug substance(s)
3.2.S.4.4	• In batch analysis of drug substance performed by drug product manufacturer, in test for	• The firm submitted that during analysis Dapagliflozin was identified. *However due to typo-graphical error Empagliflozin was written*

	identification you have submitted that it is positive for empagliflozin while the applied product is dapagliflozin, clarify? • Justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer (propanediol, residue on ignition, heavy metals, related substances, residual solvents, particle size)	*instead of dapagliflozin in COA. The rectified COA with supportive documents is submitted*. • No justification provided for incomplete analysis
3.2.P.1	• You have used lactose monohydrate in your formulation while innovator product has used lactose anhydrous. Justify that the applied product is equivalent to innovator product.	The firm submitted that we designed formulation qualitatively similar to innovator (Forxiga tablet). *We actually used lactose anhydrous and was mistakenly written as lactose monohydrate. The firm have submitted revised BMR.*
3.2.P.4	• In control of excipients you have given specifications for croscarmellose while you have not used croscarmellose in formulation, clarify? Moreover, you have used lactose monohydrate while you have not provided specifications of lactose monohydrate?	The firm submitted that it was mistakenly written, specifications for lactose anhydrous is submitted
3.2.P.8.1	• Stability data of drug product at initial time point is not submitted • You have mentioned in house specifications in module I section 1.5.6 while innovators specifications in stability summary sheets, clarify?	• Stability data of drug product at initial time point is submitted • The firm submitted that they have designed their product on innovator's specifications and updated the specifications at section 1.5.6. as innovator's specifications without submission of applicable fee. The firm also submitted revised form 5F
	• Submit invoice for the imported raw materials. • Submit Compliance Record of HPLC software 21CFR • Provide complete calculation for determining the quantity of dispensed drug substance keeping in view water content	• The firm have not submitted invoice for the imported raw material • The firm submitted A General Compliance certificate of HPLC software 21CFR • The firm have submitted calculation for determining the quantity of dispensed drug substance on theoretical basis. *The water content was not kept in mind while making calculation for dispensing drug substance*

Previous Decision (M-316-DRB) : Deferred for following:

- Justification for incomplete analyses of the drug substance / API by Drug Product manufacturer
- Justification for using different chromatographic conditions for analysis of related substances and assay test by the drug product manufacturer than those applied by drug substance manufacturer.
- Clarification for not considering the water content while making calculation for dispensing of drug substance
- Submission of the fee of Rs. 7,500 for correction/pre-approval change in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

Evaluation by PEC:

Deferment reasons	**Response**

• Justification for incomplete analyses of the drug substance / API by Drug Product manufacturer	The firm submitted that testing of propanediol contents were not performed due to unavailability of GC. In future testing will be done through 3rd party i.e. M/s Rotex Pharmaceuticals and submitted copy of agreement for contract testing of raw materials
• Justification for using different chromatographic conditions for analysis of related substances and assay test by the drug product manufacturer than those applied by drug substance manufacturer.	The firm has submitted revised DMF of drug substance manufacturer from drug substance manufacturer and chromatographic conditions of drug substance manufacturer and drug product manufacturer are same. The firm further stated that this source of API have been used for the manufacturing of product for stability batches. The previous DMF has been mistakenly submitted in the dossier
• Clarification for not considering the water content while making calculation for dispensing of drug substance	The firm submitted that Water contents are already calculated in factor calculation
• Submission of the fee of Rs. 7,500 for correction/pre-approval change in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	Firm has submitted fee Rs. 7500/- on deposit slip# 09840920132 for correction/pre-approval change in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

Decision: Deferred for submission of following:

- **Clarification regarding legal provision of outsourcing testing of drug substance from M/s Rotex Pharmaceuticals since applied application is of self-manufacturing.**
- **Clarification from the drug substance manufacturer regarding revised DMF along with trail of revision of drug substance analytical procedure.**

856.	Name, address of Applicant / Marketing Authorization Holder	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Name, address of Manufacturing site.	M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Form-5F Dy. No 16113 dated 10-06-2021
	Details of fee submitted	Rs.20,000/- dated 03-05-2021
	The proposed proprietary name / brand name	Gludap 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin as Propanediol Monohydrate…10mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Reference to Finished product specifications	In house

	Proposed Pack size	14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	FARXIGA (5mg, 10mg) film coated tablets USFDA Approved
	For generic drugs (me-too status)	Dapa 10mg Tablet by M/s Hilton Pharma (Reg#089368)
	GMP status of the Finished product manufacturer	GMP certificate issued to firm on 21st May 2019, based on inspection conducted on 23-04-2019 and valid upto 22-04-20222
	Name and address of API manufacturer.	Jiangsu yongan Pharmaceutical Co. Ltd., No. 18, 237 provincial road economic development zone, huaian Jiangsu China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. The firm has submitted summarized information of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, control of excipients, control of drug product, specifications, analytical procedures, validation/verification of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability study is conducted at $40^{O} \pm 2^{O}C$ /75% ± 5% RH for 6 months. The real time stability study is conducted at $30^{O}C \pm 2^{O}$ C / 65% ± 5% RH for 36 months. (Batch No. 130401, 130402 & 130501)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures and its verification studies, batch analysis, justification of specifications, reference

		standard or materials, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been performed against innovator product Forxiga 10mg tablet. CDP has been performed against innovator product Forxiga 10mg tablet in Acid media (pH 1.2), acetate buffer pH 4.5 & Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies is submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA				
Manufacturer of API		Jiangsu yongan Pharmaceutical Co. Ltd., No. 18, 237 provincial road economic development zone, huaian Jiangsu China.		
API Lot No.		DGF-201902001		
Description of Pack (Container closure system)		Alu/Alu Blister Packing		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 24 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.		DPT-004	DPT-005	DPT-006
Batch Size		1500 tab	1500 tab	1500 tab
Manufacturing Date		01-2020	01-2020	01-2020
Date of Initiation		13-01-2020	13-01-2020	13-01-2020
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm submitted copy of minutes of 296th meeting of registration board dated 8th, 9th & 10th September, 2020 in which their product Empaglif 10mg and 25mg applied on form 5F has been approved based on the inspection conducted by the panel for authenticity of stability data		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm submitted copy of GMP certificate of Jiangsu Yongan Pharmaceutical Co., Ltd China valid up to 03-03-2021		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted clearance certificate and form 6 attested by Assistant Director (I&E) DRAP Islamabad dated 01-04-2019 for the import of 200gm Dapagliflozin Propanediol Monohydrate and 5mg impurity A and 5mg Impurity B. However, the firm has not submitted invoice for import of said materials.		

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail reports on product testing
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.4	Submit Valid copy of Drug Manufacturing License	The firm have submitted valid Drug Manufacturing License
1.6.5	Submit valid GMP certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	The firm submitted valid GMP certificate
3.2.S.4.1 . - 3.2.S.4.2	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Firm have submitted Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer. However, the chromatographic test conditions were different as compared with drug substance manufacturer. For example, the chromatographic conditions used by the **drug substance manufacturer are:** **Related substances:** Mobile phase; Water R (0.01M NaH2PO4); Acetonitrile R (50;5 v/v) Detector 225nm Injection; 20ul Flow rate; 1ml/min **Drug product manufacturer;** **Related substances:** Mobile phase; Methanol:Water (70;30 v/v) Detector 223nm Injection; 20ul Flow rate; 1.5ml/min Temperature; 40ºC **Drug substance manufacturer:** **Assay:** Mobile phase; Water R (0.01M NaH2PO4); Acetonitrile R (50;5 v/v) Detector 225nm Injection; 20ul Flow rate; 1ml/min Temperature: 25ºC **Drug product manufacturer;** **Assay:** Mobile phase; Methanol:Water (70;30 v/v) Detector 223nm Injection; 20ul Flow rate; 1.5ml/min Temperature; 40ºC

3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	The firm have submitted Analytical Method validation studies performed by the Drug Product manufacturer for drug substance(s)
3.2.S.4.4	• In batch analysis of drug substance performed by drug product manufacturer, in test for identification you have submitted that it is positive for empagliflozin while the applied product is dapagliflozin, clarify? • Justification shall be provided for any incomplete analyses of the drug substance/API by Drug Product manufacturer (propanediol, residue on ignition, heavy metals, related substances, residual solvents, particle size)	• The firm submitted that during analysis Dapagliflozin was identified. *However due to typo-graphical error Empagliflozin was written instead of dapagliflozin in COA. The rectified COA with supportive documents is submitted*. • No justification provided for incomplete analysis
3.2.P.1	• You have used lactose monohydrate in your formulation while innovator product has used lactose anhydrous. Justify that the applied product is equivalent to innovator product.	The firm submitted that we designed formulation qualitatively similar to innovator (Forxiga tablet). *We actually used lactose anhydrous and was mistakenly written as lactose monohydrate. The firm have submitted revised BMR.*
3.2.P.2.2.1	The batch number of innovator product Forxiga 10mg tablet mentioned in Pharmaceutical equivalence report is 132642 while the batch number mentioned in comparative dissolution report is NX101. Clarify that which batch number product was used in both the studies	The batch No. of innovator product Forxiga 10mg tablet taken in Pharmaceutical equivalence report is NX101. Submitted chromatogram too is written with batch No. NX101. *It was a typo error in report. Corrected repot is submitted.*
3.2.P.4	• In control of excipients you have given specifications for croscarmellose while you have not used croscarmellose in formulation, clarify? Moreover, you have used lactose monohydrate while you have not provided specifications of lactose monohydrate?	It was mistakenly written, specifications for lactose anhydrous is submitted
3.2.P.5.2	• The Mobile phase composition in assay test is not mentioned in analytical procedure?	Method for analysis of drug product is submitted along with chromatographic conditions / mobile phase composition in assay analysis
3.2.P.8.1	• Stability data of drug product at initial time point is not submitted • Stability summary sheet for accelerated and real time stability data at 6th month time point is not submitted	• Stability data of drug product at initial time point is submitted • Stability summary sheet for accelerated and real time stability data at 6th month time point is submitted

	• You have mentioned in house specifications in module I section 1.5.6 while innovators specifications in stability summary sheets, clarify?	• The firm submitted that they have designed their product on innovator's specifications and updated the specifications at section 1.5.6. as innovator's specifications without submission of applicable fee. The firm also submitted revised form 5F
	• Submit invoice for the imported raw materials. • Submit Compliance Record of HPLC software 21CFR • Provide complete calculation for determining the quantity of dispensed drug substance keeping in view water content	• The firm have not submitted invoice for the imported raw material • The firm submitted A General Compliance certificate of HPLC software 21CFR • The firm have submitted calculation for determining the quantity of dispensed drug substance on theoretical basis. *The water content was not kept in consideration while making calculation for dispensing drug substance*

Previous Decision (M-316-DRB) : Deferred for following:

- Justification for using different chromatographic conditions for analysis of related substances and assay test by the drug product manufacturer than drug substance manufacturer.
- Justification for incomplete analyses of the drug substance / API by Drug Product manufacturer
- Clarification for not considering the water content while making calculation for dispensing of drug substance
- Submission of the fee of Rs. 7,500 for correction/pre-approval change in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

Evaluation by PEC:

Deferment reasons	**Response**
• Justification for incomplete analyses of the drug substance / API by Drug Product manufacturer	The firm submitted that testing of propanediol contents were not performed due to unavailability of GC. In future testing will be done through 3rd party i.e. M/s Rotex Pharmaceuticals and submitted copy of agreement for contract testing of raw materials
• Justification for using different chromatographic conditions for analysis of related substances and assay test by the drug product manufacturer than those applied by drug substance manufacturer.	The firm has submitted revised DMF of drug substance manufacturer from drug substance manufacturer and chromatographic conditions of drug substance manufacturer and drug product manufacturer are same. The firm further stated that this source of API have been used for the manufacturing of product for stability batches. The previous DMF has been mistakenly submitted in the dossier
• Clarification for not considering the water content while making calculation for dispensing of drug substance	The firm submitted that Water contents are already calculated in factor calculation
• Submission of the fee of Rs. 7,500 for correction/pre-approval change in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.	Firm has submitted fee Rs. 7500/- on deposit slip# 433726858656 for correction/pre-approval change in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.

Decision: Deferred for submission of following:

- **Clarification regarding legal provision of outsourcing testing of drug substance from M/s Rotex Pharmaceuticals since applied application is of self-manufacturing.**
- **Clarification from the drug substance manufacturer regarding revised DMF along with trail of revision of drug substance analytical procedure.**

857.	Name, address of Applicant / Marketing Authorization Holder	ATCO Laboratories Limited., B-18, S.I.T.E., Karachi -7500, Pakistan

	Name, address of Manufacturing site.	ATCO Laboratories Limited., B-18, S.I.T.E., Karachi -7500, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 28456 Dated 15/ 10/ 2021
	Details of fee submitted	PKR 30,000/-: Dated 04/10/2021 (Deposit Slip#489820062060)
	The proposed proprietary name / brand name	Ondansetron Tablet 4mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ondansetron…….4mg (as Ondansetron Hydrochloride Dihydrate BP)
	Pharmaceutical form of applied drug	Film coated Tablet
	Pharmacotherapeutic Group of (API)	Antiemetics and antinauseants, Serotonin (5-HT3) antagonists.
	Reference to Finished product specifications	USP
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Zofran 4mg film coated tablet MHRA approved
	For generic drugs (me-too status)	Ongene 4mg Tablet by M/s High-Q Pharmaceuticals (Reg#091206)
	GMP status of the Finished product manufacturer	The firm was inspected on 22-03-2022 & 05-04-2022 by the panel for renewal of DML, regularization of section as per layout plan and additional sections and decision of panel is: Keeping in view the good facilities provided for manufacturing and quality control of pharmaceutical products registered in the name of firm being produced at the site and overall good maintenance of plan and the required documentation and SOPs, the panel recommended the grand of DML of the firm as well as regularization of sections as per layout plan and approval of additional sections
	Name and address of API manufacturer.	M/s Anugraha Chemicals, No D-47 to D-50, C-62 and C-63, KSSIDC, Industrial Estate, Doddaballapur, Bengaluru Rural District-561203 India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls,

		specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Stability studies	Stability study conditions: Real time:30°C±2°C/75% ± 5%RH Accelerated:40°C±2°C/75%±5%RH Stability of all three batches at accelerated conditions (AOND-17002, AOND-17003, AOND-17004) conducted for 06 months Real time stability study of two batches AOND-17002, AOND-17003, conducted for 36 months while real time stability study of one batch AOND-17004 conducted for 24 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand that is Zofran 8mg Tablet by **GlaxoSmithKline Research Triangle Park, NC 27709** **Marketed by: Novartis Pharmaceuticals UK Limited** performing quality tests (Identification, Assay, Dissolution, disintegration). CDP of ondansetron 8mg tablets has been performed against the zofran 8mg tablets in Acid media (pH 1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f2 are in the acceptable range.
	Analytical method validation/verification of product	Firm has submitted method verification studies including range, accuracy, precision, specificity and robustness.

STABILITY STUDY DATA	
Manufacturer of API	M/s Anugraha Chemicals, No D-47 to D-50, C-62 and C-63, KSSIDC, Industrial Estate, Doddaballapur, Bangaluru Rural District-561203 India
API Lot No.	AOND-20013
Description of Pack (Container closure system)	ALU-ALU Blister pack packed in unit carton
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months

	Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	MA096C	MA097C	MA098C
Batch Size	4200 Tablets	4220 Tablets	4490 Tablets
Manufacturing Date	03/2021	03/2021	03/2021
Date of Initiation	25/03/2021	25/03/2021	25/03/2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection for authenticity of stability data of Rofl 500mcg tablet on the basis of which Registration Board in its 277th meeting dated 27-29 December, 2017 decided to approve registration of Rofl 500mcg tablet. Inspection date: 10-10-2017 The report shows that: The HPLC software is 21 CFR compliant. Adequate monitoring and control are available for stability chambers
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted copy of GMP certificate #DCD/SPL.CL-1/CR-1510/2020-21 dated 06-02-2021 of M/s Anugraha Chemicals, No D-47 to D-50, C-62 and C-63, KSSIDC, Industrial Estate, Doddaballapur, Bangaluru Rural District-561203 India valid upto one year from the date of issue. The firm has submitted copy of DML #DCD/MFG/Applicant Id-240 dated 26/06/2020 of M/s Anugraha Chemicals, No D-47 to D-50, C-62 and C-63, KSSIDC, Industrial Estate, Doddaballapur, Bangaluru Rural District-561203 India valid upto 13/02/2025
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice # OND1200 dated 10-11-2020 for import on 300gm of Ondansetron HCl Dihydrate Batch #AOND-20014, AOND-20012 and AOND-20013 in the name of M/s Atco Laboratories Ltd Karachi form M/s Agraha Chemical India. *However, the invoice is not attested by AD (I&E) DRAP field office*
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Remarks of Evaluator [XI]:

Section	Observations	Response
1.6.5	Submit valid GMP certificate of drug substance manufacturer	

<table>
<tr><td>3.2.S.4</td><td>• Copies of the analytical procedures used for routine testing of the Drug substance / Active Pharmaceutical ingredient by Drug Product manufacturer is required.
• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.</td><td>•</td></tr>
<tr><td>3.2.S.5</td><td>Firm has submitted COA of primary reference standard which follows usp specifications and secondary reference standard which has followed Ph. Eu specifications while applied product manufacturer follows bp specifications</td><td></td></tr>
<tr><td>3.2.P.2</td><td>• Submit compatibility study as the qualitative composition of the applied formulation is not similar to innovator / reference product.
<table>
<tr><td>Applied product</td><td>Zofran 4mg tab</td></tr>
<tr><td>Lactose anhydrous</td><td>Lactose</td></tr>
<tr><td>Sodium starch glycolate</td><td>Microcrystalline Cellulose</td></tr>
<tr><td>Crospovidone</td><td>Pregelatinized maize starch</td></tr>
<tr><td>Magnesium stearate</td><td>Magnesium Stearate,</td></tr>
<tr><td>Opadry white</td><td>Methyl hydroxypropyl cellulose</td></tr>
<tr><td>Purified water</td><td>Titanium dioxide (E171)</td></tr>
<tr><td></td><td>Iron oxide (E172)</td></tr>
</table>
• Justification is required as the pharmaceutical equivalence and CDP of higher strength has been submitted
• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the innovator product including the tests recommended by USP monograph (dissolution, identification, assay, uniformity of dosage unit).
• Provide details of innovator product used during pharmaceutical equivalence study (batch #, mfg, exp)</td><td>•</td></tr>
<tr><td>3.2.P.5.1</td><td>Justification for finished product specifications of USP is required as the drug substance has been analysed as per BP specifications by M/s Atco.</td><td></td></tr>
<tr><td>3.2.P.6</td><td>Firm has submitted COA of secondary reference standard which has followed Ph. Eu specifications while the applied product follows USP specifications</td><td></td></tr>
<tr><td>3.2.P.8</td><td>Submit documents for the procurement of API with approval from DRAP.</td><td></td></tr>
</table>

Previous Decision (M-322-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Evaluation by PEC:

Section	Observations	Response
1.6.5	Submit valid GMP certificate of drug substance manufacturer	The firm has submitted valid copy of GMP certificate #DCD/SPL-1/CR-13/2023-24 dated 10-04-2023 of M/s Anugraha Chemicals, D-47, TO D-50 C-62 AND C-63, KSSIDC, Industrial Estate, Doddaballapur, India valid upto one year from the date of issue.
3.2.S.4	• Copies of the analytical procedures used for routine testing of the Drug substance / Active	• Firm has submitted copy of the analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer

<table>
<tr><td></td><td>Pharmaceutical ingredient by Drug Product manufacturer is required.
• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.</td><td>• Firm has submitted analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance.</td></tr>
<tr><td>3.2.S.5</td><td>Firm has submitted COA of primary reference standard which follows usp specifications and secondary reference standard which has followed Ph. Eu specifications while applied product manufacturer follows bp specifications</td><td>M/s. Anugraha Chemicals is manufacturing and supplying Ondansetron Hydrochloride Dihydrate worldwide and complies with both USP specifications and Ph. Eur. specifications depending on the requirements of their customers. They have also provided COA of reference standard which follows Ph. Eur. Specifications.</td></tr>
<tr><td>3.2.P.2</td><td>• Submit compatibility study as the qualitative composition of the applied formulation is not similar to innovator / reference product.
<table><tr><td>Applied product</td><td>Zofran 4mg tab</td></tr><tr><td>Lactose anhydrous</td><td>Lactose</td></tr><tr><td>Sodium starch glycolate</td><td>Microcrystalline Cellulose</td></tr><tr><td>Crospovidone</td><td>Pregelatinized starch</td></tr><tr><td>Magnesium stearate</td><td>Magnesium Stearate</td></tr><tr><td>Opadry white</td><td>Methyl hydroxypropyl cellulose</td></tr><tr><td>Purified water</td><td>Titanium dioxide (E171)</td></tr><tr><td></td><td>Iron oxide (E172)</td></tr></table>• Justification is required as the pharmaceutical equivalence and CDP of higher strength has been submitted
• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the innovator product including the tests recommended by USP monograph (dissolution, identification, assay, uniformity of dosage unit).
• Provide details of innovator product used during pharmaceutical equivalence study (batch #, mfg, exp)</td><td>• Firm has submitted protocol for drug excipient compatibility study and the report of drug excipient compatibility study. The results show that insignificant variation occurs during compatibility studies. Hence it is concluded that drug is compatible with excipients
• Pharmaceutical Equivalence report of Ondansetron Tablets 4mg and comparative dissolution profile studies (CDP) report for our product Ondansetron Tablets 4mg is being attached.
• Critical tests recommended by USP monograph e.g. Physical Description, Identification, Disintegration, Assay, Dissolution and Impurities was included in the pharmaceutical equivalence study of Ondansetron Tablets 4mg. Furthermore, Uniformity of dosage units (content uniformity) is an in-process control test and should meet the requirements of Acceptance value at the time of release which is well controlled during release of drug product. The firm has submitted pharmaceutical equivalence report
• Firm has provided details of innovator product. Zofran 4mg tablets, Batch Number B83122A, Manufactured by M/s Aspen Bad Oldesloe GmbH, Bad Oldesloe, Germany for Novartis Pharma AG, Basle, Switzerland Mfg date;01-2022, Exp date; 12-2024.</td></tr>
<tr><td>3.2.P.5.1</td><td>Justification for finished product specifications of USP is required as the drug substance has been analysed as per BP specifications by M/s Atco.</td><td>The firm submitted that initially at the time of development, we have started the material and product development according to British pharmacopeia monograph. During the development of product, we found that the drug release of both</td></tr>
</table>

		test and reference sample is greater than 85% within 15 minutes in comparison studies while the time limit mentioned in BP was 45 minutes. We switched to more stringent specification for our products and complies with USP specifications which states that "NLT 80% (Q) of the labeled amount of ondansetron is dissolved in 15 minutes".
3.2.P.6	Firm has submitted COA of secondary reference standard which has followed Ph. Eu specifications while the applied product follows USP specifications	The firm submitted that initially, at the time of development, we have started the material and product development according to British pharmacopeia monograph which is sync with Ph. Eur. Monograph. Afterwards, we switched to more stringent specification for our products and complies with USP specifications.
3.2.P.8	**Submit documents for the procurement of API with approval from DRAP.** The firm submitted that for product development purpose, initially ATCO has arranged Ondansetron drug substance form M/s Anugrha Chemicals, India via our UAE based indenter Pan Golf Sourcing and Trading International on 10-11-2020. This sample was imported by our indenter in Sharja, UAE and then supplied us complementary through courier service. Due to direct courier of material on ATCO premises from Sharja, material was not hold at port for clearance and we forgot to attest the invoice with DRAP ADC. We have used this material for product development and further put the 03 development batches for stability studies up to 6 months on accelerated and real time conditions as per requirement of Zone IV-B. Same stability data as well as material arrangement documents with non-attested invoice were initially submitted with dossier in DRAP. After pre-screening, dossiers were accepted by DRAP and log for further evaluation. At the time of dossier compilation before the submission in DRAP, we have already gauged that non-attested ADC invoice issue can be identified during dossier evaluation. Therefore, we have immediately arranged another lot of Ondansetron drug substance from the same manufacturer i.e. M/s Anugrha Chemicals, India with attested ADC invoice. We have manufactured another 03 development batches with this material and also conducted the stability studies up to 6 months on accelerated and real time conditions as per Zone (IV-B) requirement. At the time of dossier evaluation, Evaluator has advised us to submit the attested ADC invoice and we have submitted the ADC attested invoice of second supply mentioned Ondansetron Batch#AOND-21007. But the BMR and Stability report which was produced with first supply of Ondansetron Batch# AOND-20013 were not replaced in dossier. This is the reason for difference in Batch No. of API between the material invoice and product development documents. Now all tracking record for import of first material (API) dated 10-11-2020 which was imported by our UAE based indenter Pan Golf Sourcing and Trading International form M/s Anugrha Chemicals, India has been arranged from indenter and attached along with CoA and un-attested sale invoice for your kind perusal. Above clarification related to submitted API invoice via letter number 197/Reg/11-2022 dated 3rd November, 2022 (copy with supporting documents enclosed) which was accepted by the Drug Registration Board in its 322nd meeting and we have been granted the drug registration certificate of Ondansetron Tablet 8mg and Ondansetron Syrup 4mg/5ml with brand name Ubkino (copy of meeting minutes and drug registration certificate, enclosed). We would like to state that kindly consider the same justification/explanation regarding procurement of API for Ondansetron Tablet 4mg.	

	Keeping in view the above facts, the firm has requested to consider that we have tried our level best to meet all quality requirements for the development and stability studies of ondansetron tablet. And executed more development work to meet the compliance requirement. We are expecting your favorable response regarding the approval of subject products by ignoring our reluctance regarding the ADC attestation of material invoice and consider the development record and stability studies produced with ondansetron first supply. We assure you that we will be more vigilant in future to meet the compliance as per requirement.

Decision: Deferred for submission of transportation details of API from supplier including courier details

858.	Name, address of Applicant / Marketing Authorization Holder	Magns Pharmaceuticals Plot No. 7 B Value Addition City Sahianwala Road Khurrianwala Faisalabad.
	Name, address of Manufacturing site.	Magns Pharmaceuticals Plot No. 7 B Value Addition City Sahianwala Road Khurrianwala Faisalabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26524 dated 24/09/2021
	Details of fee submitted	PKR 20,000/-: dated 28/12/2020 PKR 10,000/-: dated 09/06/2021
	The proposed proprietary name / brand name	Dexopra Capsule 30mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Dexlansoprazole (as dual delayed release pellets) ……. 30 mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors
	Reference to Finished product specifications	**Innovator's Specifications"**
	Proposed Pack size	3x10, s capsules
	Proposed unit price	MRP Rs. 540/-
	The status in reference regulatory authorities	DEXILANT (30mg, 60mg) delayed-release capsules USFDA Approved
	For generic drugs (me-too status)	Dextop Capsule 30 mg by M/s The Searle Company Ltd. (Reg#086978)
	GMP status of the Finished product manufacturer	The firm have submitted cGMP certificate issued on 22-03-2019 based on inspection conducted on 01-03-2019
	Name and address of API manufacturer.	**Source of Pellets:** Vision Pharmaceuticals Pvt. Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. Tel : + 92-51-4493587-90

		Fax : + 92-51-4493591 E-mail: contact@visionpharmapk.com
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (DLP125T, DLP124T, DLP123T)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Dextop 30mg capsule by M/s The Searle Company Ltd Karachi by performing quality tests (Assay, Dissolution).
	Analytical method validation/verification of product	Firm have submitted method validation studies including linearity, range, accuracy, precision, LOD, LOQ and solution stability.

STABILITY STUDY DATA

Manufacturer of API	Source of Pellets: Vision Pharmaceuticals Pvt. Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. Tel : + 92-51-4493587-90 Fax : + 92-51-4493591 E-mail: contact@visionpharmapk.com
API Lot No.	DLP 420
Description of Pack (Container closure system)	Alu-alu Blisters, packed in unit carton
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 24 months

	Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6,9,12,18,24 (Months)		
Batch No.	T-003	***T-004***	***T-005***
Batch Size	5000 caps	***3000 caps***	***3000 caps***
Manufacturing Date	06-2019	***12/10/2021***	***15/10/2021***
Date of Initiation	27-06-2019		
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted cGMP certificate of Vision Pharmaceuticals issued on 31-07-2019 based on inspection conducted on 11-02-2019
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice #502094 dated 19-02-2019 for 1.2kg of Dexlansoprazole DDR Pellets 22.5% batch # DLP420 from Vision Pharmaceuticals Islamabad.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of one batch only along with chromatograms, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time.

Remarks of Evaluator [XI]:

Section	Observations	Response
	• Submit valid DML as the submitted DML has been expired on 24-11-2021 • Submit latest GMP inspection report conducted with in last three years • Submit valid GMP certificate of drug substance manufacturer	• The firm have submitted valid copy of DML issued in name of M/s Magns Pharmaceuticals on 06/06/2022 • The firm have submitted GMP certificate issued on 13-04-2022 based on inspection conducted on 11-03-2022. • The firm have submitted cGMP certificate of Vision Pharmaceuticals issued on 25-03-2022 based on inspection conducted on 11-02-2019 and further extended till 09-05-2022.
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	Firm has submitted Batch Manufacturing Record (BMR) for all the batches (T-003, T-004, T-005) of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>. ***Two more batches, Batch T-004 and T-005 was manufactured on 12/10/2021 and 15/10/2021 respectively while batch T-003 was manufactured on23/06/2019. The details of these two batches are incorporated in above table.***
3.2.S.4	• Copies of the Drug substance specifications and analytical	• ***Copies of the Drug substance specifications and analytical procedures used for routine testing of***

	procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	***the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is not submitted.*** • ***Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) is not submitted.***
3.2.P.2.2.1	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by innovator product. • Comparative dissolution profile against the innovator product shall be submitted	• ***No clarification is submitted. However pharmaceutical equivalence is again submitted. Test like content uniformity, loss on drying and identification are not performed.*** • ***The firm submitted that we have performed comparative study for assay and dissolution hence Comparative dissolution profile is not required***
3.2.P.4	• Justify the use of gelatine capsule shell in dexlansoprazole capsule since innovator product has specified hypromellose capsule shells. • For excipients of human or animal origin, a certificate shall be provided, confirming that the excipient(s) are free from BSE and TSE. • Halal certificate for gelatin shall be provided	• The firm submitted that hard gelatine capsules are easily available and having same dissolving time and behaviour and other competitors are also using gelatine capsule shell. • ***No clarification submitted*** • The firm have submitted Halal certificate for gelatin shall
3.2.P.5	• You have mentioned innovator specifications under section 1.5.6 while you have followed manufacturer specifications for applied product, justify? • The tests of content uniformity and loss on drying were not included in the submitted specifications as recommended by literature of innovator product, justify? • Results of specificity test in method validation is not submitted • The copies of complete analysis of at least two batches shall be provided while you have provided batch analysis of only one batch, justify?	• The firm submitted that we have followed innovator's specifications. • ***The firm submitted that content uniformity test is recommended for dosage form which have API 25mg or less than 25mg in all pharmacopeia reference, so we have not performed.*** • ***Results of specificity test in method validation is not submitted*** • Firm have submitted copies of complete analysis of two batches
3.2.P.8	• Submit latest inspection report for exemption conducted by the	• ***Inspection report for exemption conducted by the panel for authenticity of stability data (PSI) is not submitted***

	panel for authenticity of stability data (PSI) • Submit Raw data sheets & analytical record of stability studies containing calculation formula for both assay & dissolution test • Justify why you have submitted stability study data of only one batch while it is required to submit stability study data of three batches as per zone IV-A conditions • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions)	• ***Firm has not submitted stability study data including summary data sheets, COA, raw data sheet and attested respective chromatogram as per requirement.*** • ***Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) is not submitted***

Previous Decision (321-DRB): Deferred for following:

- Submission of Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer
- Submission of Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s)
- Submission of Comparative dissolution profile against the innovator product
- Submission of results of specificity test in method validation studies of drug product
- Submission of stability study data including summary data sheets, COA, raw data sheet and attested respective chromatogram as per requirement.
- Submission of Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions)

Response of Firm:

- Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is submitted
- Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer *for drug substance(s) is not submitted instead Analytical Method validation studies for drug product is submitted*
- Comparative dissolution profile against the innovator product *is not submitted instead pharmaceutical equivalence report is again submitted.*
- *The firm submitted that in as in specificity test placebo product is required but we are using ready to fill pellets and we have no placebo pellets and specificity test of API manufacturer is attached.*
- *Stability study data including summary data sheets, COA, raw data sheet and attested respective chromatogram is not submitted as per requirement*
- Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) *for time in which Batch T-004 and T-005 is manufactured is submitted*
- The firm further submitted that our product Cetamol tablet has been approved in 321st meeting and we have submitted audit trial and CFR 21 compliance already but if required PEC can conduct inspection for stability data

Previous Decision (323-DRB):

- Submission of Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s)
- Submission of Comparative dissolution profile against the innovator product
- Submission of results of specificity test in method validation studies of drug product
- Submission of stability study data including summary data sheets, COA, raw data sheet and attested respective chromatogram as per requirement.

- Submission of Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions)

Response of Firm:

Section	Observations	Response
3.2.S.4	• Submission of Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s)	• Firm has submitted Analytical Method Verification studies including specificity, accuracy and repeatability (method precision), linearity and range performed by the Drug Product manufacturer for drug substance
3.2.P.2.2.1	• Submission of Comparative dissolution profile against the innovator product	• Firm has submitted Comparative dissolution profile of their product against Dextop capsule 30mg by M/s The Searle Company Ltd in acid media pH 1.2, phosphate Buffer pH 5.5 and Phosphate Buffer pH 7. The values of f2 factor are in acceptable range.
3.2.P.5	• Submission of results of specificity test in method validation studies of drug product	• Firm has submitted results of specificity test in method validation studies of drug product
3.2.P.8	• Submission of stability study data including summary data sheets, COA, raw data sheet and attested respective chromatogram as per requirement. • Submission of Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions)	• Firm has submitted stability study data including summary data sheets, COA, raw data sheet and attested respective chromatogram as per requirement. • Firm has submitted of Record of Digital data logger for temperature and humidity monitoring of stability chambers at accelerated conditions

Decision: Approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Registration letter will be issued after submission of:

- **Fee of Rs. 7,500/- for correction/pre-approval changes in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

859.	Name, address of Applicant / Marketing Authorization Holder	Magns Pharmaceuticals Plot No. 7 B Value Addition City Sahianwala Road Khurrianwala Faisalabad.
	Name, address of Manufacturing site.	Magns Pharmaceuticals Plot No. 7 B Value Addition City Sahianwala Road Khurrianwala Faisalabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 26525 dated 24/09/2021

	Details of fee submitted	PKR 20,000/-: dated 28/12/2020 PKR 10,000/-: dated 09/06/2021
	The proposed proprietary name / brand name	Dexopra Capsule 60mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Dexlansoprazole (as dual delayed release pellets) ……..……. 60 mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors
	Reference to Finished product specifications	**Innovator's Specifications"**
	Proposed Pack size	3x10, s capsules
	Proposed unit price	MRP Rs. 840/-
	The status in reference regulatory authorities	DEXILANT (30mg, 60mg) delayed-release capsules USFDA Approved
	For generic drugs (me-too status)	Dextop Capsule 60 mg by M/s The Searle Company Ltd. (Reg#086979)
	GMP status of the Finished product manufacturer	The firm have submitted cGMP certificate issued on 22-03-2019 based on inspection conducted on 01-03-2019
	Name and address of API manufacturer.	**Source of Pellets:** Vision Pharmaceuticals Pvt. Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. Tel : + 92-51-4493587-90 Fax : + 92-51-4493591 E-mail: contact@visionpharmapk.com
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (DLP125T, DLP124T, DLP123T)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical

		procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.	
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Dextop 60mg capsule by M/s The Searle Company Ltd Karachi by performing quality tests (Assay, Dissolution).	
	Analytical method validation/verification of product	Firm have submitted method validation studies including linearity, range, accuracy, precision, LOD, LOQ and solution stability.	
STABILITY STUDY DATA			
Manufacturer of API	Source of Pellets: Vision Pharmaceuticals Pvt. Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad Pakistan. Tel : + 92-51-4493587-90 Fax : + 92-51-4493591 E-mail: contact@visionpharmapk.com		
API Lot No.	DLP 420		
Description of Pack (Container closure system)	Alu-alu Blisters, packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3,6,9,12,18,24 (Months)		
Batch No.	T-003	***T-004***	***T-005***
Batch Size	3000 caps	***3000 caps***	***3000 caps***
Manufacturing Date	06-2019	***12/10/2021***	***15/10/2021***
Date of Initiation	27-06-2019		
No. of Batches	03		
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The firm have submitted cGMP certificate of Vision Pharmaceuticals issued on 31-07-2019 based on inspection conducted on 11-02-2019	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of one batch only along with chromatograms, COA and summary data sheets.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted Compliance Record of HPLC software 21CFR & audit trail reports on product testing	

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time.

Remarks of Evaluator [XI]:

Section	Observations	Response
	• Submit valid DML as the submitted DML has been expired on 24-11-2021 • Submit latest GMP inspection report conducted with in last three years • Submit valid GMP certificate of drug substance manufacturer	• The firm have submitted valid copy of DML issued in name of M/s Magns Pharmaceuticals on 06/06/2022 • The firm have submitted GMP certificate issued on 13-04-2022 based on inspection conducted on 11-03-2022. • The firm have submitted cGMP certificate of Vision Pharmaceuticals issued on 25-03-2022 based on inspection conducted on 11-02-2019 and further extended till 09-05-2022.
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	Firm has submitted Batch Manufacturing Record (BMR) for all the batches (T-003, T-004, T-005) of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>. ***Two more batches, Batch T-004 and T-005 was manufactured on 12/10/2021 and 15/10/2021 respectively while batch T-003 was manufactured on23/06/2019. The details of these two batches are incorporated in above table.***
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	• ***Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is not submitted.*** • ***Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) is not submitted.***
3.2.P.2.2.1	• Justify why the pharmaceutical equivalence study does not include complete testing of the drug product and the comparator product including the tests recommended by innovator product. • Comparative dissolution profile against the innovator product shall be submitted	• ***No clarification is submitted. However pharmaceutical equivalence is again submitted. Test like content uniformity, loss on drying and identification are not performed.*** • ***The firm submitted that we have performed comparative study for assay and dissolution hence Comparative dissolution profile is not required***

3.2.P.4	• Justify the use of gelatine capsule shell in dexlansoprazole capsule since innovator product has specified hypromellose capsule shells. • For excipients of human or animal origin, a certificate shall be provided, confirming that the excipient(s) are free from BSE and TSE. • Halal certificate for gelatin shall be provided	• The firm submitted that hard gelatine capsules are easily available and having same dissolving time and behaviour and other competitors are also using gelatine capsule shell. • ***No clarification submitted*** • The firm have submitted Halal certificate for gelatin shall
3.2.P.5	• You have mentioned innovator specifications under section 1.5.6 while you have followed manufacturer specifications for applied product, justify? • The tests of content uniformity and loss on drying were not included in the submitted specifications as recommended by literature of innovator product, justify? • Results of specificity test in method validation is not submitted • The copies of complete analysis of at least two batches shall be provided while you have provided batch analysis of only one batch, justify?	• The firm submitted that we have followed innovator's specifications. • ***The firm submitted that content uniformity test is recommended for dosage form which have API 25mg or less than 25mg in all pharmacopeia reference, so we have not performed.*** • ***Results of specificity test in method validation is not submitted*** • Firm have submitted copies of complete analysis of two batches
3.2.P.8	• Submit latest inspection report for exemption conducted by the panel for authenticity of stability data (PSI) • Submit Raw data sheets & analytical record of stability studies containing calculation formula for both assay & dissolution test • Justify why you have submitted stability study data of only one batch while it is required to submit stability study data of three batches as per zone IV-A conditions • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) • Submit documents for the procurement of API	• ***Inspection report for exemption conducted by the panel for authenticity of stability data (PSI) is not submitted*** • ***Firm has not submitted stability study data including summary data sheets, COA, raw data sheet and attested respective chromatogram as per requirement.*** • ***Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) is not submitted*** • The firm has submitted copy of invoice #800742 dated 23-09-2021 for 2.5kg of Dexlansoprazole DDR Pellets 22.5% batch # DLP775 from Vision Pharmaceuticals Islamabad.

Previous Decision (321-DRB): Deferred for following:

- Submission of Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer
- Submission of Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s)
- Submission of Comparative dissolution profile against the innovator product
- Submission of results of specificity test in method validation studies of drug product
- Submission of stability study data including summary data sheets, COA, raw data sheet and attested respective chromatogram as per requirement.
- Submission of Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions)

Response of the firm:

- Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is submitted
- Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer *for drug substance(s) is not submitted instead Analytical Method validation studies for drug product is submitted*
- Comparative dissolution profile against the innovator product *is not submitted instead pharmaceutical equivalence report is again submitted.*
- *The firm submitted that in as in specificity test placebo product is required but we are using ready to fill pellets and we have no placebo pellets and specificity test of API manufacturer is attached.*
- *Stability study data including summary data sheets, COA, raw data sheet and attested respective chromatogram is not submitted as per requirement*
- Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions) *for time in which Batch T-004 and T-005 is manufactured is submitted*
- The firm further submitted that our product Cetamol tablet has been approved in 321st meeting and we have submitted audit trial and CFR 21 compliance already but if required PEC can conduct inspection for stability data

Previous Decision (323-DRB):

- Submission of Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s)
- Submission of Comparative dissolution profile against the innovator product
- Submission of results of specificity test in method validation studies of drug product
- Submission of stability study data including summary data sheets, COA, raw data sheet and attested respective chromatogram as per requirement.
- Submission of Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions)

Response of the firm:

Section	Observations	Response
3.2.S.4	• Submission of Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s)	• Firm has submitted Analytical Method Verification studies including specificity, accuracy, repeatability (method precision), linearity and range performed by the Drug Product manufacturer for drug substance
3.2.P.2.2.1	• Submission of Comparative dissolution profile against the innovator product	• Firm has submitted Comparative dissolution profile of their product against Dextop capsule 60mg by M/s The Searle Company Ltd in acid media pH 1.2, phosphate Buffer pH 5.5 and Phosphate Buffer pH 7. The values of f2 factor are in acceptable range.
3.2.P.5	• Submission of results of specificity test in method validation studies of drug product	• Firm has submitted results of specificity test in method validation studies of drug product
3.2.P.8	• Submission of stability study data including summary data sheets, COA, raw data sheet and attested respective chromatogram as per requirement.	• Firm has submitted stability study data including summary data sheets, COA, raw data sheet and attested respective chromatogram as per requirement.

	• Submission of Record of Digital data logger for temperature and humidity monitoring of stability chambers (accelerated conditions)	• Firm has submitted of Record of Digital data logger for temperature and humidity monitoring of stability chambers at accelerated conditions

Decision: Approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Registration letter will be issued after submission of:

- **Fee of Rs. 7,500/- for correction/pre-approval changes in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

860.	Name, address of Applicant / Marketing Authorization Holder	M/s Welwrd Pharmaceuticals., Plot No#3, Block A, Phase I-II, Industrial Estate, Hattar, Haripur
	Name, address of Manufacturing site.	M/s Welwrd Pharmaceuticals., Plot No#3, Block A, Phase I-II, Industrial Estate, Hattar, Haripur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the Finished product manufacturer	Firm has submitted GMP certificate dated 08-07-2019 based on inspection conducted on 12-11-2018
	Evidence of approval of manufacturing facility	Firm has submitted copy of GMP certificate dated 08-07-2019 based on inspection conducted on 12-11-2018 which specifies Tablet section (General/Antibiotic)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 2367 dated 25/01/2022
	Details of fee submitted	PKR 30,000/-: dated 15/09/2021 (Deposit Slip# 87660456)
	The proposed proprietary name / brand name	**Empawrd-M 12. 5/500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin (In-House)……..……12.5mg Metformin HCl (USP)……...500mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Antidiabetics
	Reference to Finished product specifications	Manufacturer specifications
	Proposed Pack size	3x10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	SYNJARDY (5mg/500mg, 5mg/1000mg, 12.5mg/500mg, 12.5 mg/1000 mg) film-coated tablet USFDA approved
	For generic drugs (me-too status)	Xenglu-Met 12.5/500mg Tablets by M/s Hilton Pharma (Reg#093067)

	Name and address of API manufacturer.	**<u>Empagliflozin:</u>** M/s Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial park, Fumeng County, Fuxin city, Liaoning province, 123000, China. **<u>Metformin HCl</u>:** M/s Aarti Drugs Limited., Plot No. 109-D, Mahendra Industrial Estate Road No.29 Sion (East), Mumbai – 400022, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Stability study conditions: **<u>Metformin HCl:</u>** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (MEF/1410029, MEF/1410028, MEF/1410027) **Empagliflozin:** ***Real time: 30˚C ± 2˚C / 65% ± 5%RH for 12 months*** Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (20160606, 20161017, 20161219)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand that is Empaa-M 12.5/500mg tablet by M/s Weatherfolds Pharma by performing quality tests (Identification, Assay, Dissolution, weight variation). CDP has been performed against the same brand that is Empaa M 12.5/500 mg Tablet by M/s Weatherfolds Pharma in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8).

	Analytical method validation/verification of product	Firm has submitted method validation studies including linearity, range, accuracy, precision, LOD, LOQ.

STABILITY STUDY DATA

Manufacturer of API	**Empagliflozin:** Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial park, Fuxin city, Liaoning province, 123000, China. **Metformin HCl:** M/s Aarti Drugs Limited., Plot No. 109-D, Mahendra Industrial Estate Road No.29 Sion (East), Mumbai – 400022, India		
API Lot No.	**Metformin HCl:** MEF/18091912 **Empagliflozin:** E-20181027-D02-E06-01		
Description of Pack (Container closure system)	Not submitted		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-004	T-005	T-006
Batch Size	900 tab	900 tab	900 tab
Manufacturing Date	08-2020	08-2020	08-2020
Date of Initiation	28/08/2020	28/08/2020	28/08/2020
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	N/A
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Empagliflozin:** Firm has submitted copy of GMP certificate in the name of M/s Fuxin Long Rui Pharmaceutical Co., Ltd, Fluoride Industrial Park, Fuxin City, Liaoning Province - 123000, China issued by Fuxin Food and Drug Administration China valid upto 27-09-2020. Firm has submitted copy of DML (Certificate# Liao20150233) in the name of M/s Fuxin Long Rui Pharmaceutical CO., Ltd., China valid upto 20-12-2022. **Metformin HCl:** The firm has submitted GMP certificate for M/s Aarti Drugs Limited., (Unit-II) Plot No. 211 & 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat State India issued by Food & Drug Control Administration Gandhinagar India. The certificate is valid till 09-01-2020
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of invoice No. HN190108-C dated 08-01-2019 for import of

		0.41Kg of Empagliflozin (Batch No# E-20181027-D02-E06-01) in name of M/s Welwrd Pharmaceuticals attested by AD (I&E) DRAP Peshawar dated 23-01-2019. Firm has also submitted copy of form 6 dated 23-01-2019 for import of 0.41Kg of Empagliflozin in name of M/s Welwrd Pharmaceuticals attested by AD (I&E) DRAP Peshawar dated 23-01-2019. **Metformin HCl:** Firm has submitted copy of invoice No. EXP/1678/18-19 dated 21-11-2018 for import of 500Kg of Metformin HCl (Batch No# MEF/18091912) in name of M/s Welwrd Pharmaceuticals attested by AD (I&E) DRAP Peshawar dated 05-12-2018.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Fir has submitted data of stability batches supported by attested respective documents like chromatograms, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations
1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted
1.4.1.	• The applied drug product is a generic drug product while you have applied for a new drug product, clarify
1.6.5	• Valid GMP certificate / DML of drug substance manufacturer for Empagliflozin and Metformin issued by relevant regulatory authority of country of origin is required • Address of M/s Aarti drugs Limited in submitted application is different than that mentioned in GMP certificate, clarify
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.3	• Details of Elucidation of Structure and other Characteristics for metformin HCl shall be submitted • List of Drug Substance / API-related impurities and process-related impurities metformin HCl shall be submitted along with acceptance limits
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug Substance Metformin HCl by both drug substance manufacturer and Drug Product manufacturer is required. • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug Substance Empagliflozin by Drug Product manufacturer is required.

	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance Metformin HCl and Empagliflozin shall be submitted. • Clarification is required as the drug substance manufacturer has performed assay of drug substance Metformin HCl in batch analysis by potentiometric method instead of HPLC method as recommended by USP. • Justification is required for not performing test for identification (IR & Reaction of Chloride) and residue on ignition for drug substance metformin HCl in batch analysis by drug product manufacturer as recommended by USP • Justification is required for not performing test for identification and residue on ignition for drug substance empagliflozin by drug product manufacturer as recommended by drug substance manufacturer. • Unsigned copy of batch analysis of drug substance empagliflozin by drug product manufacturer is submitted
3.2.P.2	• Justify why Pharmaceutical equivalence of the applied product has not been performed against the innovator product? • Submit detailed CDP studies including details of dissolution parameters, dissolution media, sampling time point and details of analytical parameters used and f2 factor calculation
3.2.P.5	• Justification is required for not including test for content uniformity for empagliflozin in finished product specifications as recommended by innovator product review document • Justification is required for not including the test for assay in finished product specifications • Justification is required for not mentioning the time for dissolution studies in finished product specifications as recommended by innovator product review document • Detailed analytical procedures used for testing the drug product shall be provided. • Results for specificity test is not submitted in method validation studies • Justification is required for not performing test for content uniformity in batch analysis as recommended by innovator product review document
3.2.P.6	• Detail of the container closure systems of drug substance is submitted instead of drug product
3.2.P.8	• Submit complete analytical record of stability study including summary data sheets, COA, Raw data sheets, and chromatograms • Compliance Record of HPLC software 21CFR & audit trail reports on product testing is not submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted

Previous Decision (M-326-DRB): Board deferred the case for submission of reply to the above cited shortcomings within six months as the board was apprised that the letter of shortcoming has been initially shared with the firm and waiting firm reply.

Evaluation by PEC:

Section	**Observations**	

1.3.5	• GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted	• Firm has submitted copy of GMP certificate issued on 10-06-2022 based on inspection conducted on 30-03-2022
1.4.1.	• The applied drug product is a generic drug product while you have applied for a new drug product, clarify	• *No response submitted*
1.6.5	• Valid GMP certificate / DML of drug substance manufacturer for Empagliflozin and Metformin issued by relevant regulatory authority of country of origin is required • Address of M/s Aarti drugs Limited in submitted application is different than that mentioned in GMP certificate, clarify	**Empagliflozin:** The firm has submitted written confirmation for active substance exported to EU to M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China for Active substance Empagliflozin confirming that the manufacturing plant complies with requirement of Chinese Good Manufacturing practices. This certificate is valid till 25-05-2024 **Metformin HCl:** The firm has submitted GMP certificate for M/s Aarti Drugs Limited., (Unit-II) Plot No. 211 & 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat State India issued by Food & Drug Control Administration Gandhinagar India. *The certificate is valid till 19-03-2023*
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	• Firm has submitted copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.3	• Details of Elucidation of Structure and other Characteristics for metformin HCl shall be submitted • List of Drug Substance / API-related impurities and process-related impurities metformin HCl shall be submitted along with acceptance limits	• Details in this section are submitted as per guidance document
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug Substance Metformin HCl by both drug substance manufacturer and Drug Product manufacturer is required. • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug Substance Empagliflozin by Drug Product manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug Substance Metformin HCl by drug substance manufacturer is submitted. *However, Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug Substance Metformin HCl by drug product manufacturer is not submitted* • *Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug*

	substance Metformin HCl and Empagliflozin shall be submitted. • Clarification is required as the drug substance manufacturer has performed assay of drug substance Metformin HCl in batch analysis by potentiometric method instead of HPLC method as recommended by USP. • Justification is required for not performing test for identification (IR & Reaction of Chloride) and residue on ignition for drug substance metformin HCl in batch analysis by drug product manufacturer as recommended by USP • Justification is required for not performing test for identification and residue on ignition for drug substance empagliflozin by drug product manufacturer as recommended by drug substance manufacturer. • Unsigned copy of batch analysis of drug substance empagliflozin by drug product manufacturer is submitted	*substance Metformin HCl and Empagliflozin is not submitted* • The firm submitted that drug substance manufacturer has performed assay of drug substance Metformin HCl in batch analysis by potentiometric titration method and HPLC method. *However, no evidence of HPLC method or performance is submitted* • *No response submitted* • *No response submitted* • *No response submitted*
3.2.P.2	• Justify why Pharmaceutical equivalence of the applied product has not been performed against the innovator product? • Submit detailed CDP studies including details of dissolution parameters, dissolution media, sampling time point and details of analytical parameters used and f2 factor calculation	Firm has again submitted Pharmaceutical Equivalence of applied product against the brand that is Empaa-M 12.5/500mg tablet by M/s Weatherfolds Pharma by performing quality tests (Identification, Assay, Dissolution, weight variation). • Firm has submitted details of CDP studies including details of dissolution parameters, dissolution media, sampling time point and details of analytical parameters. *However CDP has been performed against the comparator product Empaa-M 12.5/500mg tablet by M/s Weatherfolds Pharmaceuticals.*
3.2.P.5	• Justification is required for not including test for content uniformity for empagliflozin in finished product specifications as recommended by innovator product review document • Justification is required for not mentioning the time for dissolution studies in finished product specifications as recommended by innovator product review document • Justification is required for not including the test for assay in finished product specifications	• Firm has submitted revised finished product specifications containing content uniformity test for empagliflozin, time point for dissolution studies and details of assay test. • Firm has submitted analytical procedures for assay and dissolution tests. *Complete Analytical procedure is not submitted* • Results for specificity test is submitted in method validation studies

	• Detailed analytical procedures used for testing the drug product shall be provided. • Results for specificity test is not submitted in method validation studies • Justification is required for not performing test for content uniformity in batch analysis as recommended by innovator product review document	• *Firm has submitted unsigned copy of revised batch analysis report containing results of content uniformity test*
3.2.P.6	• Detail of the container closure systems of drug substance is submitted instead of drug product	• Firm has submitted details of the container closure systems of drug product. Alu-alu blister packed in bleach card box
3.2.P.8	• Submit complete analytical record of stability study including summary data sheets, COA, Raw data sheets, and chromatograms • Compliance Record of HPLC software 21CFR & audit trail reports on product testing is not submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is not submitted	• Firm has submitted analytical record of stability study including summary data sheets, COA and chromatograms. *However detailed Raw data sheets are not submitted* • Compliance Record of HPLC software 21CFR & audit trail reports on product testing is submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Decision: Deferred for submission of following:

- **Clarification as the applied drug product is a generic drug product while you have applied for a new drug product.**
- **Valid GMP certificate / DML of drug substance manufacturer for Metformin issued by relevant regulatory authority of country of origin**
- **Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug Substance Metformin HCl by drug product manufacturer**
- **Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance Metformin HCl and Empagliflozin**
- **Clarification as the drug substance manufacturer has performed assay of drug substance Metformin HCl in batch analysis by potentiometric method instead of HPLC method as recommended by USP.**
- **Justification for not performing test for identification (IR & Reaction of Chloride) and residue on ignition for drug substance metformin HCl in batch analysis by drug product manufacturer as recommended by USP**
- **Justification for not performing test for identification and residue on ignition for drug substance empagliflozin by drug product manufacturer as recommended by drug substance manufacturer.**
- **Justification for submission of unsigned copy of batch analysis of drug substance empagliflozin by drug product manufacturer**
- **Justification as Pharmaceutical equivalence and CDP studies of the applied product has not been performed against the innovator**

- **Detailed analytical procedures used for testing the finished drug product.**
- **Justification for submission of unsigned copy of revised batch analysis report of finished product**
- **Detailed Raw data sheets**

Case No. 05: Deferred Registration applications of New Section of Human drugs on Form 5-F (Local)

861.	Name, address of Applicant / Marketing Authorization Holder	M/s Titlis Pharma (Pvt.) Limited., 528-A, Sunder Industrial Estate, Raiwind Road, Lahore.
	Name, address of Manufacturing site.	M/s Titlis Pharma (Pvt) Limited., 528-A, Sunder Industrial Estate, Raiwind Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17526 dated 15/06/2022
	Details of fee submitted	PKR 30,000/-: dated 31/05/2022 (Slip#23068996766)
	The proposed proprietary name / brand name	Linet 2.5mg/500mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Linagliptin ……. 2.5mg Metformin Hydrochloride ……. 500mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Dipeptidyl peptidase-4 (DPP-4) inhibitor & Biguanide (antidiabetic)
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	2x7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	JENTADUETO 2.5mg/500mg, 2.5mg/850mg, 2.5mg/1000mg (linagliptin/metformin hydrochloride) film coated Tablets USFDA Approved Trajentamet (linagliptin/metformin hydrochloride) 2.5mg/500mg, 2.5mg/850mg, 2.5mg/1000mg film coated Tablets TGA Approved JENTADUETO (linagliptin/metformin hydrochloride) 2.5 mg/500 mg, 2.5 mg/850 mg, 2.5 mg/1000mg film coated tablets Health Canada Approved

	For generic drugs (me-too status)	N/A
	GMP status of the Finished product manufacturer	New section granted on 17th & 18th March, 2022 and letter issued on 10th May, 2022
	Name and address of API manufacturer.	**Linagliptin:** Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial park, Fuxin city, Liaoning province, 123000, China. **Metformin HCl:** Aarti Drugs Limited (Unit-II)., Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. INDIA.396155
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**Linagliptin:** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (L-20170429-D01-L9-01, L-20170604-D01-L9-02, L-20170604-D01-L9-03) **Metformin Hydrochloride:** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (MEF/1510145, MEF/1510146, MEF/1510147)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Not submitted

	Analytical method validation/verification of product	Firm has submitted method validation studies including linearity, range, accuracy, precision, specificity, LOD, LOQ, solution stability and robustness.		
STABILITY STUDY DATA				
Manufacturer of API		**<u>Linagliptin:</u>** Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial park, Fuxin city, Liaoning province, 123000, China. **<u>Metformin HCl</u>:** Aarti Drugs Limited (Unit-II)., Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. INDIA.396155		
API Lot No.		<u>Linagliptin</u> L-20210123-D01-L09-02 <u>Metformin Hydrochloride</u> MEF/10041416		
Description of Pack (Container closure system)		ALU-ALU blister packed in cardboard unit carton.		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		LP-04	LP-05	LP-06
Batch Size		700 Tablets	700 Tablets	700 Tablets
Manufacturing Date		Nov-2021	Nov-2021	Nov-2021
Date of Initiation		20-12-2021	20-12-2021	20-12-2021
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**<u>Linagliptin:</u>** The firm have submitted written confirmation for active substance exported to EU to M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China for Active substance Linagliptin by Deputy General Director confirming that the manufacturing plant complies with requirement of Chinese Good Manufacturing practices. This certificate is valid till 25-05-2024 Metformin HCl: The firm has submitted GMP certificate for M/s Aarti Drugs Limited (Unit-II) India issued by Food & Drug Control Administration Gandhinagar India. The certificate is valid till 19-03-2023		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted		

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.1	• Submit differential fee as the applied product is new drug molecule	
1.3.2	• The name of applicant as per form 5F is M/s Titlis Pharma (Pvt.) Limited., while name mentioned on DML is M/s Titlis Pharma., Clarification is required	
1.4	• Clarification is required as the applied drug product is a New Drug Product while you have applied for generic drug product	
1.6.5	• Submit valid GMP certificate / Drug Manufacturing License of the Drug Substance manufacturer for Linagliptin issued by relevant regulatory authority of country of origin	
3.2.S.4	• Justification is required for not including the test for sulphated ash in drug substance specification of drug substance metformin by drug product manufacturer as recommended by BP. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) linagliptin and Metformin HCl shall be submitted. • Clarification is required as the drug substance manufacturer has performed assay of drug substance Metformin HCl in batch analysis by potentiometric method as per BP while drug product manufacturer has performed assay of drug substance Metformin HCl by titrimetric method. • Justification is required for not performing test for appearance of solution and sulphated ash test in batch analysis of drug substance metformin by drug product manufacturer as recommended by BP.	
3.2.S.7	• Stability study of Linagliptin drug substance batch No. L-20170604-D01-L9-03 at accelerated conditions is not submitted	
3.2.P.2	• Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.	

Applied product	**JENTADUETO tablet**
Linagliptin	Linagliptin
Metformin HCl	Metformin HCl
Lactose	Arginine
Avecil PH 102	Corn Starch
Starch	Copovidone
PVP K30	Colloidal Silicon Dioxide
Aerosil 200	Magnesium Stearate
Ac-di-sol	

	Magnesium stearate Purified water
	• Pharmaceutical equivalence and CDP of the applied product has not been submitted. • Only protocol for CDP is submitted
3.2.P.4	• The specifications, Analytical procedures and Validation of analytical procedures for excipients shall be provided as the firm have stated that excipient specifications follow in-house or manufacturer specifications
3.2.P.5	• Justification is required for setting dissolution specification of NLT 75% in 45 minutes while innovator product review document recommends NLT Q in 30 minutes • Justification is required for not including test for identification test active substances and uniformity of dosage units in finished product specification as recommended by innovator product review document. • Justification is required since composition of dissolution media and rotation (0.03M Potassium dihydrogen phosphate and 75rpm) mentioned in dissolution method for applied drug product is different than that recommended by innovator product review document (0.1N HCl and 50 rpm)
3.2.P.8	• Justification is required since composition of dissolution media (0.03M Potassium dihydrogen phosphate) mentioned in dissolution test for applied drug product in stability summary sheets is different than that recommended by innovator product review document (0.1N HCl) • Justification is required for setting dissolution specification NLT 75% in 45minutes in stability study summary sheets instead of NLT 75% in 30minutes as recommended by innovator product review document. • Submit documents for procurement of API with approval from DRAP • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) • Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing

INDICATIONS AND USAGE

JENTADUETO is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use

JENTADUETO should not be used in patients with type 1 diabetes.

JENTADUETO has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using JENTADUETO

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosing

The dosage of JENTADUETO should be individualized on the basis of both effectiveness and tolerability, while not exceeding the maximum recommended dose of 2.5 mg linagliptin/1000 mg metformin hydrochloride (HCl) twice daily. JENTADUETO should be given twice daily with meals. Dose escalation should be gradual to reduce the gastrointestinal (GI) side effects associated with metformin use.

Recommended starting dose:

- In patients currently not treated with metformin HCl, initiate treatment with 2.5 mg linagliptin/500 mg metformin HCl twice daily.
- In patients already treated with metformin HCl, start with 2.5 mg linagliptin and the current dose of metformin HCl taken at each of the two daily meals (e.g., a patient on metformin HCl 1000 mg twice daily would be started on 2.5 mg linagliptin/1000 mg metformin HCl twice daily with meals).
- Patients already treated with linagliptin and metformin HCl individual components may be switched to JENTADUETO containing the same doses of each component.

Previous Decision (M-323-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Evaluation by PEC:

The submitted COA from Drug substance manufacturer and finished product manufacturer does not depict the enantiomeric form of Linagliptin

Section	Observations	Response
1.1	• Submit differential fee as the applied product is new drug molecule	Differential fee Rs 7500/- for the applied product is submitted vide deposit slip No. (3132785169) by the firm. Firm has submitted differential fee Rs. 37500/- for applied product vide deposit slip No. 0869445288.
1.3.2	• The name of applicant as per form 5F is M/s Titlis Pharma (Pvt.) Limited., while name mentioned on DML is M/s Titlis Pharma., Clarification is required	The firm submitted that the title of our company has been changed in 279th meeting of Central Licensing Board held on 18th February 2021, and the new approved title is "Titlis Pharma (Private) Limited". The change of title approval letter No. F. 1-11/2009-Lic (Vol-I) from Central Licensing Board in the name of "Titlis Pharma (Private) Limited" is submitted.
1.4	• Clarification is required as the applied drug product is a New Drug Product while you have applied for generic drug product	The firm submitted that we have applied for New Drug Product but Generic Drug Product was mentioned by typographic error.
1.6.5	• Submit valid GMP certificate / Drug Manufacturing License of the Drug Substance manufacturer for Linagliptin issued by relevant regulatory authority of country of origin	The firm have submitted written confirmation for active substances exported to EU to M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China for Active substance Linagliptin by Deputy General Director confirming that the manufacturing plant complies with requirement of Chinese Good Manufacturing practices. This certificate is valid till 25-05-2024
3.2.S.4	• Justification is required for not including the test for sulphated ash in drug substance specification of drug substance metformin by drug product manufacturer as recommended by BP. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) linagliptin and Metformin HCl shall be submitted. • Clarification is required as the drug substance manufacturer has performed assay of drug substance Metformin HCl in batch analysis by potentiometric method as per BP while drug product manufacturer has performed assay of drug substance Metformin HCl by titrimetric method. • Justification is required for not performing test for appearance of solution and sulphated ash test in batch analysis of drug	• The firm submitted that we have revised our testing method and now performing testing of Metformin HCL by HPLC method as per USP43 monograph and test for sulphated ash is not mentioned in USP monograph. • The testing and COA of most recent batch of metformin HCL (Batch no; MEF/12051645) as per USP Method is submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) linagliptin and Metformin HCl is submitted. • The firm submitted that previously, we were performing the assay of Metformin HCL on titrimetric method. However, we have revised our testing method and now performing testing of

	substance metformin by drug product manufacturer as recommended by BP.	Metformin HCl by HPLC method as per USP43 monograph. The testing and COA of most recent batch of metformin HCL (Batch no; MEF/12051645) as per USP Method is submitted. • The firm submitted that previously, we were performing the analysis of Metformin HCl on titrimetric method. However, we have revised our testing method and now performing testing of Metformin HCL by HPLC method as per USP43 monograph and test for appearance of solution and sulphated ash is not mentioned in USP monograph. • The testing and COA of most recent batch of metformin HCl (Batch no; MEF/12051645) as per USP Method is submitted.
3.2.S.7	• Stability study of Linagliptin drug substance batch No. L-20170604-D01-L9-03 at accelerated conditions is not submitted	Stability study of Linagliptin drug substance batch no. L-20170604-D01-L9-03 at accelerated condition is submitted.
3.2.P.2	• Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product. **Applied product** / **JENTADUETO tablet** Linagliptin / Linagliptin Metformin HCl / Metformin HCl Lactose / Arginine Avecil PH 102 / Corn Starch Starch / Copovidone PVP K30 / Colloidal Silicon Dioxide Aerosil 200 / Magnesium Stearate Ac-di-sol Magnesium stearate Purified water	• The firm submitted that as per literature review and study of Hand Book for Pharmaceutical Excipients, it is notable that all the excipients used in our formulation are inert, and are compatible with active pharmaceutical ingredient of Linet tablet 2.5mg/500mg. Moreover, their safety and compatibility have also been established as no harsh / adverse effect has been observed in our stability studies. • The firm further stated that we have also performed Drug Excipients Compatibility studies concluded that all the excipients are inert and has no harsh effect on product stability.
	• Pharmaceutical equivalence and CDP of the applied product has not been submitted. • Only protocol for CDP is submitted	• The firm submitted that the innovator product **Jentadueto 2.5/500mg Tablet Manufactured by Boehringer Ingelheim, Germany** is not registered/available in Pakistan and we also didn't found in UAE (Abroad). Therefore, we could not perform the Comparative dissolution Profile of Linet 2.5/500mg Tablet due to unavailability of original sample. • It is notable that we have performed Comparative dissolution Profile of Linet 2.5/850mg Tablet (Linagliptin + Metformin) and Linet 2.5/1000mg Tablet (Linagliptin + Metformin) against the Innovator Brand Jentadueto and found

		that both said products release more that 80% within 30 minutes in all three media (0.1 N HCl pH 1.2, Acetate buffer pH 4.5 and Phosphate buffer pH 6.8. o The results show that dissolution profile of test and reference products are almost similar. o F2 value comply with acceptance criteria (Evidence is submitted) • Moreover, composition of all the three products Linet 2.5/500mg, Linet 2.5/850mg and Linet 2.5/1000mg Tablets are same except the quantity of Metformin HCl (Evidence is submitted). • *As per DRAP Guidelines for Industry on Investigation of Bio-Equivalence (BE) /Bioavailability (BA) studies for Multisource Generic Drug Products (9.3.1/(ii)):* ➢ If the amounts of the different excipients or capsule contents are same for the strengths concerned and only the mount of the API has changed ➢ If the amount of filler is changed to account for the change in amount of API: the amounts of other core excipients or capsule content should be the same for the strength concerned. • *Therefore, as per DRAP guidelines, we have conducted and complied the Comparative Dissolution Profile of Major Strengths (Linet 2.5/850mg & Linet 2.5/1000mg). So it is requested to waive off the small strength (Linet 2.5/500mg).* • We further undertake to perform Comparative Dissolution Profile (CDP) of Linet 2.5/500mg Tablet once we get the Innovator brand **Jentadueto 2.5/500mg Tablet Manufactured by Boehringer Ingelheim, Germany**
3.2.P.4	• The specifications, Analytical procedures and Validation of analytical procedures for excipients shall be provided as the firm have stated that excipient specifications follow in-house or manufacturer specifications	The firm submitted that all the excipients used in our formulation, follow pharmacopoeial specifications and submitted pharmacopoeial monographs of all the excipients.
3.2.P.5	• Justification is required for setting dissolution specification of NLT 75% in 45 minutes while innovator product review document recommends NLT Q in 30 minutes • Justification is required for not including test for identification test active substances	• The firm submitted that initially we performed dissolution by using following parameters: Media: 0.03 M Potassium Dihydrogen phosphate RPM: 75 rpm Apparatus: II (Paddle)

	and uniformity of dosage units in finished product specification as recommended by innovator product review document. • Justification is required since composition of dissolution media and rotation (0.03M Potassium dihydrogen phosphate and 75rpm) mentioned in dissolution method for applied drug product is different than that recommended by innovator product review document (0.1N HCl and 50 rpm)	Time 45 min. • Stability batches were analyzed at 0 & 3 months on in house testing but after innovator's product literature review, we revised our testing method and performed 6th month stability studies (accelerated + long run) as per innovator's specifications with below parameters. **Media: 0.1M HCl** **RPM: 50 rpm** **Apparatus: II (Paddle)** **Time 30 min.** • Moreover, we manufactured 3 new batches (Batch numbers: LP-22, LP-23 and LP-24) for performance of accelerated and long run stability testing as per innovator's specifications / dissolution parameters and "0", 3rd & 6th month testing has been completed and results are complying with innovator specification. (Reports and chromatogram are attached for kind perusal).
		Batch No. / **LP-22** / **LP-23** / **LP-24** Batch Size / 700 tablets / 700 tablets / 700 tablets Manufacturing Date / 04-2022 / 04-2022 / 04-2022 Date of Initiation / 21-04-2022 / 21-04-2022 / 21-04-2022
		CONCLUSION: Therefore, we have performed 0, 3, & 6th month stability studies as per innovator's specifications / dissolution parameters and the results are complying with innovator's specifications. The firm submitted that we have revised the specification and included the test for identification test for active substance, uniformity of dosage units in finished product specification as recommended by innovator product review document and submitted revised specifications
3.2.P.8	• Justification is required since composition of dissolution media (0.03M Potassium dihydrogen phosphate) mentioned in dissolution test for applied drug product in stability summary sheets is different than that recommended by innovator product review document (0.1N HCl) • Justification is required for setting dissolution specification NLT 75% in 45minutes in stability study summary	• The firm submitted that initially we performed dissolution by using following parameters: Media: 0.03 M Potassium Dihydrogen phosphate RPM: 75 rpm Apparatus: II (Paddle) Time 45 min. • Stability batches were analyzed at 0 & 3 months on in house testing but after

sheets instead of NLT 75% in 30minutes as recommended by innovator product review document.

- Submit documents for procurement of API with approval from DRAP
- Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)
- Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing

innovator's product literature review, we revised our testing method and performed 6th month stability studies (accelerated + long run) as per innovator's specifications with below parameters. (Revised stability study summary sheets are attached)

Media: 0.1M HCl
RPM: 50 rpm
Apparatus: II (Paddle)
Time 30 min.

- Moreover, we manufactured 3 new batches (Batch numbers: LP-22, LP-23 and LP-24) for performance of accelerated and long run stability testing as per innovator's specifications / dissolution parameters and "0", & 3rd and 6th month testing has been completed and results are complying with innovator specification (Reports and chromatogram are submitted).

Batch No.	**LP-22**	**LP-23**	**LP-24**
Batch Size	700 tablets	700 tablets	700 tablets
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	21-04-2022	21-04-2022	21-04-2022

CONCLUSION:

Therefore, we have performed 0, 3 & 6th month stability studies as per innovator's specifications / dissolution parameters and the results are complying with innovator's specifications.

- The firm has submitted copy of invoice No. EXP/321/20-21 dated 18-05-2020 in name of M/s Titli Pharma for import of Metformin HCl (Batch No. MEF/10041416) 1000kg attested by AD (I&E) DRAP Lahore.
- Firm has submitted copy of Form 6 for import of 0.220kg of Linagliptin from M/s Fuxin Long Rui Pharmaceutical Co., Ltd., China attested by AD (I&E) DRAP Lahore dated 09-08-2021.
- Firm has also submitted copy invoice No. HN210713-J dated 13-07-2021 for import of 0.22kg Linagliptin in name of M/s Titlis Pharma attested AD (I&E) DRAP Lahore dated 09-08-2021.
- Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

		• Certificate for compliance Record of HPLC software 21CFR is submitted. *Audit trial report is not submitted.* The firm submitted that date and time of this HPLC (QC-HPLC-001) is locked and data alteration/editing is strictly restricted. Moreover this HPLC (QC-HPLC-001) has access control and only two authorized QC analysts have authorization to access and operate this HPLC (QC-HPLC-001).
Decision: Deferred for submission of following: • **Clarification for using the type of enantiomeric form of Linagliptin used in product development and stability studies and test performed for enantiomeric purity from drug substance manufacturer and drug product manufacturer** • **Pharmaceutical equivalence and CDP studies of the applied product against the innovator product.** • **Clarification for not using arginine in finished product as stabilizer as recommended by innovator product** • **Fee of Rs. 75,000/- for revision in stability data, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**		
862.	Name, address of Applicant / Marketing Authorization Holder	M/s Titlis Pharma (Pvt.) Limited., 528-A, Sunder Industrial Estate, Raiwind Road, Lahore.
	Name, address of Manufacturing site.	M/s Titlis Pharma (Pvt) Limited., 528-A, Sunder Industrial Estate, Raiwind Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 17527 dated 15/06/2022
	Details of fee submitted	PKR 30,000/-: dated 31/05/2022 (Slip#6268150924)
	The proposed proprietary name / brand name	Linet 2.5mg/850mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Linagliptin ……. 2.5mg Metformin Hydrochloride ……. 850mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Dipeptidyl peptidase-4 (DPP-4) inhibitor & Biguanide (antidiabetic)

	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	2x7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	JENTADUETO 2.5mg/500mg, 2.5mg/850mg, 2.5mg/1000mg (linagliptin/metformin hydrochloride) film coated Tablets USFDA Approved Trajentamet (linagliptin/metformin hydrochloride) 2.5mg/500mg, 2.5mg/850mg, 2.5mg/1000mg film coated Tablets TGA Approved JENTADUETO (linagliptin/metformin hydrochloride) 2.5 mg/500 mg, 2.5 mg/850 mg, 2.5 mg/1000mg film coated tablets Health Canada Approved
	For generic drugs (me-too status)	N/A
	GMP status of the Finished product manufacturer	New section granted on 17th & 18th March, 2022 and letter issued on 10th May, 2022
	Name and address of API manufacturer.	**Linagliptin:** Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial park, Fuxin city, Liaoning province, 123000, China. **Metformin HCl:** Aarti Drugs Limited (Unit-II)., Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. INDIA.396155
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**Linagliptin:** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (L-20170429-D01-L9-01, L-20170604-D01-L9-02, L-20170604-D01-L9-03) **Metformin Hydrochloride:** Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months

		Batches: (MEF/1510145, MEF/1510146, MEF/1510147)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against Jentadueto 2.5/850mg Tablet of M/s Boehringer Ingelheim Pharma Germany by performing quality tests (disintegration, weight variation, Dissolution and Assay).
	Analytical method validation/verification of product	Firm has submitted method validation studies including linearity, range, accuracy, precision, specificity, LOD, LOQ, solution stability and robustness.

STABILITY STUDY DATA			
Manufacturer of API	**<u>Linagliptin:</u>** Fuxin Long Rui Pharmaceutical Co. Ltd., Fluoride Industrial park, Fuxin city, Liaoning province, 123000, China. **<u>Metformin HCl</u>:** Aarti Drugs Limited (Unit-II)., Plot No. 211 - 213, Road No.2 G.I.D.C., Sarigam, Dist.: Valsad, Gujarat. INDIA.396155		
API Lot No.	<u>Linagliptin</u> L-20210123-D01-L09-02 <u>Metformin Hydrochloride</u> MEF/10041416		
Description of Pack (Container closure system)	ALU-ALU blister packed in cardboard unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	LP-07	LP-08	LP-09
Batch Size	700 Tablets	700 Tablets	700 Tablets
Manufacturing Date	Nov-2021	Nov-2021	Nov-2021
Date of Initiation	31-12-2021	31-12-2021	31-12-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted
2.	Approval of API/ DML/GMP certificate of API manufacturer issued	**<u>Linagliptin:</u>** The firm have submitted written confirmation for active substance exported to EU to M/s Fuxin Long Rui

	by concerned regulatory authority of country of origin.	Pharmaceutical Co., Ltd, China for Active substance Linagliptin by Deputy General Director confirming that the manufacturing plant complies with requirement of Chinese Good Manufacturing practices. This certificate is valid till 25-05-2024 Metformin HCl: The firm has submitted GMP certificate for M/s Aarti Drugs Limited (Unit-II) India issued by Food & Drug Control Administration Gandhinagar India. The certificate is valid till 19-03-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.1	• Submit differential fee as the applied product is new drug molecule	
1.3.2	• The name of applicant as per form 5F is M/s Titlis Pharma (Pvt.) Limited., while name mentioned on DML is M/s Titlis Pharma., Clarification is required	
1.4	• Clarification is required as the applied drug product is a New Drug Product while you have applied for generic drug product	
1.6.5	• Submit valid GMP certificate / Drug Manufacturing License of the Drug Substance manufacturer for Linagliptin issued by relevant regulatory authority of country of origin	
3.2.S.4	• Justification is required for not including the test for sulphated ash in drug substance specification of drug substance metformin by drug product manufacturer as recommended by BP. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) linagliptin and Metformin HCl shall be submitted. • Clarification is required as the drug substance manufacturer has performed assay of drug substance Metformin HCl in batch analysis by potentiometric method as per BP while drug product manufacturer has performed assay of drug substance Metformin HCl by titrimetric method.	

- Justification is required for not performing test for appearance of solution and sulphated ash test in batch analysis of drug substance metformin by drug product manufacturer as recommended by BP.

3.2.S.7
- Stability study of Linagliptin drug substance batch No. L-20170604-D01-L9-03 at accelerated conditions is not submitted

3.2.P.2
- Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product.

Applied product	**JENTADUETO tablet**
Linagliptin	Linagliptin
Metformin HCl	Metformin HCl
Lactose	Arginine
Avecil PH 102	Corn Starch
Starch	Copovidone
PVP K30	Colloidal Silicon Dioxide
Aerosil 200	Magnesium Stearate
Ac-di-sol	
Magnesium stearate	
Purified water	

- CDP of the applied product has not been submitted.
- Only protocol for CDP is submitted

3.2.P.4
- The specifications, Analytical procedures and Validation of analytical procedures for excipients shall be provided as the firm have stated that excipient specifications follow in-house or manufacturer specifications

3.2.P.5
- Justification is required for setting dissolution specification of NLT 75% in 45 minutes while innovator product review document recommends NLT Q in 30 minutes
- Justification is required for not including test for identification test active substances and uniformity of dosage units in finished product specification as recommended by innovator product review document.
- Justification is required since composition of dissolution media and rotation (0.03M Potassium dihydrogen phosphate and 75rpm) mentioned in dissolution method for applied drug product is different than that recommended by innovator product review document (0.1N HCl and 50 rpm)

3.2.P.8
- Justification is required since composition of dissolution media (0.03M Potassium dihydrogen phosphate) mentioned in dissolution test for applied drug product in stability summary sheets is different than that recommended by innovator product review document (0.1N HCl)
- Justification is required for setting dissolution specification NLT 75% in 45minutes in stability study summary sheets instead of NLT 75% in 30minutes as recommended by innovator product review document.
- Submit documents for procurement of API with approval from DRAP
- Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)
- Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing

INDICATIONS AND USAGE

JENTADUETO is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use

JENTADUETO should not be used in patients with type 1 diabetes.

JENTADUETO has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using JENTADUETO

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosing

The dosage of JENTADUETO should be individualized on the basis of both effectiveness and tolerability, while not exceeding the maximum recommended dose of 2.5 mg linagliptin/1000 mg metformin hydrochloride (HCl) twice daily. JENTADUETO should be given twice daily with meals. Dose escalation should be gradual to reduce the gastrointestinal (GI) side effects associated with metformin use.

Recommended starting dose:

- In patients currently not treated with metformin HCl, initiate treatment with 2.5 mg linagliptin/500 mg metformin HCl twice daily.
- In patients already treated with metformin HCl, start with 2.5 mg linagliptin and the current dose of metformin HCl taken at each of the two daily meals (e.g., a patient on metformin HCl 1000 mg twice daily would be started on 2.5 mg linagliptin/1000 mg metformin HCl twice daily with meals).
- Patients already treated with linagliptin and metformin HCl individual components may be switched to JENTADUETO containing the same doses of each component.

Previous Decision (M-323-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Evaluation by PEC:

The submitted COA from Drug substance manufacturer and finished product manufacturer does not depict the enantiomeric form of Linagliptin

Section	Observations	Response
1.1	• Submit differential fee as the applied product is new drug molecule	Differential fee Rs 7500/- for the applied product is submitted vide deposit slip No. (546145406) by the firm. Firm has submitted differential fee Rs. 37500/- for applied product vide deposit slip No. 7990568766.
1.3.2	• The name of applicant as per form 5F is M/s Titlis Pharma (Pvt.) Limited., while name mentioned on DML is M/s Titlis Pharma., Clarification is required	The firm submitted that the title of our company has been changed in 279th meeting of Central Licensing Board held on 18th February 2021, and the new approved title is "Titlis Pharma (Private) Limited". The change of title approval letter No. F. 1-11/2009-Lic (Vol-I) from Central Licensing Board in the name of "Titlis Pharma (Private) Limited" is submitted.
1.4	• Clarification is required as the applied drug product is a New Drug Product while you have applied for generic drug product	The firm submitted that we have applied for New Drug Product but Generic Drug Product was mentioned by typographic error.
1.6.5	• Submit valid GMP certificate / Drug Manufacturing License of the Drug Substance manufacturer for Linagliptin issued by relevant regulatory authority of country of origin	The firm have submitted written confirmation for active substances exported to EU to M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China for Active substance Linagliptin by Deputy General Director confirming that the manufacturing plant complies with requirement of Chinese Good Manufacturing practices. This certificate is valid till 25-05-2024
3.2.S.4	• Justification is required for not including the test for sulphated ash in drug substance specification of drug substance metformin by drug product manufacturer as recommended by BP. • Analytical Method Verification studies including specificity, accuracy and	• The firm submitted that we have revised our testing method and now performing testing of Metformin HCL by HPLC method as per USP43 monograph and test for sulphated ash is not mentioned in USP monograph.

	repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) linagliptin and Metformin HCl shall be submitted. • Clarification is required as the drug substance manufacturer has performed assay of drug substance Metformin HCl in batch analysis by potentiometric method as per BP while drug product manufacturer has performed assay of drug substance Metformin HCl by titrimetric method. • Justification is required for not performing test for appearance of solution and sulphated ash test in batch analysis of drug substance metformin by drug product manufacturer as recommended by BP.	• The testing and COA of most recent batch of metformin HCL (Batch no; MEF/12051645) as per USP Method is submitted. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) linagliptin and Metformin HCl is submitted. • The firm submitted that previously, we were performing the assay of Metformin HCL on titrimetric method. However, we have revised our testing method and now performing testing of Metformin HCl by HPLC method as per USP43 monograph. The testing and COA of most recent batch of metformin HCL (Batch no; MEF/12051645) as per USP Method is submitted. • The firm submitted that previously, we were performing the analysis of Metformin HCl on titrimetric method. However, we have revised our testing method and now performing testing of Metformin HCL by HPLC method as per USP43 monograph and test for appearance of solution and sulphated ash is not mentioned in USP monograph. • The testing and COA of most recent batch of metformin HCl (Batch no; MEF/12051645) as per USP Method is submitted.
3.2.S.7	• Stability study of Linagliptin drug substance batch No. L-20170604-D01-L9-03 at accelerated conditions is not submitted	Stability study of Linagliptin drug substance batch no. L-20170604-D01-L9-03 at accelerated condition is submitted.
3.2.P.2	• Compatibility studies of the Drug Substance(s) with excipients shall be provided as the qualitative composition of the formulation is not similar to innovator / reference product. **Applied product** / **JENTADUETO tablet** Linagliptin / Linagliptin Metformin HCl / Metformin HCl Lactose / Arginine Avecil PH 102 / Corn Starch Starch / Copovidone PVP K30 / Colloidal Silicon Dioxide Aerosil 200 / Magnesium Stearate Ac-di-sol Magnesium stearate Purified water	• The firm submitted that as per literature review and study of Hand Book for Pharmaceutical Excipients, it is notable that all the excipients used in our formulation are inert, and are compatible with active pharmaceutical ingredient of Linet tablet 2.5mg/850mg. Moreover, their safety and compatibility have also been established as no harsh / adverse effect has been observed in our stability studies. • The firm further stated that we have also performed Drug Excipients Compatibility studies and concluded that all the excipients are inert and has no harsh effect on product stability.

	• Pharmaceutical equivalence and CDP of the applied product has not been submitted. Only protocol for CDP is submitted	• CDP has been performed against the brand Jentadueto 2.5/850mg tablet by M/s Boehringer Ingelheim Pharma Germany in Acid media pH 1.2, acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The values for f2 are in the acceptable range. • Pharmaceutical Equivalence have been established against Jentadueto 2.5/850mg Tablet of M/s Boehringer Ingelheim Pharma Germany by performing quality tests (Identification, disintegration, weight variation, content uniformity, Dissolution and Assay).
3.2.P.4	• The specifications, Analytical procedures and Validation of analytical procedures for excipients shall be provided as the firm have stated that excipient specifications follow in-house or manufacturer specifications	The firm submitted that all the excipients used in our formulation, follow pharmacopoeial specifications and submitted pharmacopoeial monographs of all the excipients.
3.2.P.5	• Justification is required for setting dissolution specification of NLT 75% in 45 minutes while innovator product review document recommends NLT Q in 30 minutes • Justification is required for not including test for identification test active substances and uniformity of dosage units in finished product specification as recommended by innovator product review document. • Justification is required since composition of dissolution media and rotation (0.03M Potassium dihydrogen phosphate and 75rpm) mentioned in dissolution method for applied drug product is different than that recommended by innovator product review document (0.1N HCl and 50 rpm)	• The firm submitted that initially we performed dissolution by using following parameters: Media: 0.03 M Potassium Dihydrogen phosphate RPM: 75 rpm Apparatus: II (Paddle) Time 45 min. • It is notable that the data of comparative dissolution profile report for Linet 2.5mg/850mg tablet is remarkable and recognizes that the product is highly soluble and dissolves not less than 75% after 45 minutes in all three media (0.1 N HCl pH 1.2, Acetate buffer pH 4.5 and Phosphate buffer pH 6.8) at all seven sampling points. Therefore, it is ascertained that dissolution studies of test and reference products are almost similar in all three prescribed dissolution mediums including Acetate buffer pH 4.5. Moreover, f2 values comply with the acceptance criteria. • Stability batches were analyzed at 0 & 3 months on in house testing but after innovator's product literature review, we revised our testing method and performed 6th month stability studies (accelerated + long run) as per innovator's specifications with below parameters. **Media: 0.1M HCl** **RPM: 50 rpm** **Apparatus: II (Paddle)** **Time 30 min.** • Moreover, we manufactured 3 new batches (Batch numbers: LP-25, LP-26 and LP-27) for performance of accelerated

		and long run stability testing as per innovator's specifications / dissolution parameters and "0", 3rd & 6th month testing has been completed and results are complying with innovator specification. (Reports and chromatogram are attached for kind perusal). **Batch No.** **LP-25** **LP-26** **LP-27** Batch Size 700 tablets 700 tablets 700 tablets Manufacturing Date 04-2022 04-2022 04-2022 Date of Initiation 18-04-2022 18-04-2022 18-04-2022 **CONCLUSION:** Therefore, we have performed 0, 3, & 6th month stability studies as per innovator's specifications / dissolution parameters and the results are complying with innovator's specifications. The firm submitted that we have revised the specification and included the test for identification test for active substance, uniformity of dosage units in finished product specification as recommended by innovator product review document and submitted revised specifications
3.2.P.8	• Justification is required since composition of dissolution media (0.03M Potassium dihydrogen phosphate) mentioned in dissolution test for applied drug product in stability summary sheets is different than that recommended by innovator product review document (0.1N HCl) • Justification is required for setting dissolution specification NLT 75% in 45minutes in stability study summary sheets instead of NLT 75% in 30minutes as recommended by innovator product review document. • Submit documents for procurement of API with approval from DRAP • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) • Submit compliance Record of HPLC software 21CFR & audit trail reports on product testing	• The firm submitted that initially we performed dissolution by using following parameters: Media: 0.03 M Potassium Dihydrogen phosphate RPM: 75 rpm Apparatus: II (Paddle) Time 45 min. • Stability batches were analyzed at 0 & 3 months on in house testing but after innovator's product literature review, we revised our testing method and performed 6th month stability studies (accelerated + long run) as per innovator's specifications with below parameters. (Revised stability study summary sheets are attached) **Media: 0.1M HCl** **RPM: 50 rpm** **Apparatus: II (Paddle)** **Time 30 min.** • Moreover, we manufactured 3 new batches (Batch numbers: LP-25, LP-26 and LP-27) for performance of accelerated and long run stability testing as per innovator's specifications / dissolution parameters and "0", & 3rd and 6th month

testing has been completed and results are complying with innovator specification (Reports and chromatogram are submitted).

Batch No.	**LP-25**	**LP-26**	**LP-27**
Batch Size	700 tablets	700 tablets	700 tablets
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	18-04-2022	18-04-2022	18-04-2022

CONCLUSION:

Therefore, we have performed 0, 3 & 6th month stability studies as per innovator's specifications / dissolution parameters and the results are complying with innovator's specifications.

- The firm has submitted copy of invoice No. EXP/321/20-21 dated 18-05-2020 in name of M/s Titli Pharma for import of Metformin HCl (Batch No. MEF/10041416) 1000kg attested by AD (I&E) DRAP Lahore.
- Firm has submitted copy of Form 6 for import of 0.220kg of Linagliptin from M/s Fuxin Long Rui Pharmaceutical Co., Ltd., China attested by AD (I&E) DRAP Lahore dated 09-08-2021.
- Firm has also submitted copy invoice No. HN210713-J dated 13-07-2021 for import of 0.22kg Linagliptin in name of M/s Titlis Pharma attested AD (I&E) DRAP Lahore dated 09-08-2021.
- Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted
- Certificate for compliance Record of HPLC software 21CFR is submitted. *Audit trial report is not submitted.* The firm submitted that date and time of this HPLC (QC-HPLC-001) is locked and data alteration/editing is strictly restricted. Moreover this HPLC (QC-HPLC-001) has access control and only two authorized QC analysts have authorization to access and operate this HPLC (QC-HPLC-001).

Decision: Deferred for submission of following:

- **Clarification for using the type of enantiomeric form of Linagliptin used in product development and stability studies and test performed for enantiomeric purity from drug substance manufacturer and drug product manufacturer**

- **Clarification for not using arginine in finished product as stabilizer as recommended by innovator product**
- **Fee of Rs. 75,000/- for revision in stability data, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.**

Case No. 06; Deferred Registration applications of human drugs on Form 5F (New DML)

863.	Name, address of Applicant / Marketing Authorization Holder	M/s Biogen Life Sciences, 8-km Chakbeli Road Rawat Rawalpindi
	Name, address of Manufacturing site.	M/s Biogen Life Sciences, 8-km Chakbeli Road Rawat Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 28774 dated 11-10-2022
	Details of fee submitted	Not submitted
	The proposed proprietary name / brand name	**Fusigen-H 15gm Cream**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram cream contains: Fusidic Acid (BP)……..….20mg (2% w/w) Hydrocortisone Acetate……10mg (1% w/w)
	Pharmaceutical form of applied drug	White to off white color cream.
	Pharmacotherapeutic Group of (API)	Antibiotics & corticosteroid For Topical Use
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Fucidin H cream MHRA approved
	For generic drugs (me-too status)	Fusimax-H 2%+1% Cream by M/s Maxitech Pharma (Reg# 83733)
	GMP status of the Finished product manufacturer	New license granted on 13/02/2020
	Name and address of API manufacturer.	**Fusidic Acid**: Joyang Laboratories., Haidu North Road, Sheyang Economic Development Zone, Jiangsu, China **Hydrocortisone Acetate:** Henan Lihua Pharmaceutical Co Ltd., Middle of Huanghe Street, Anyang Hi-Tech Industry Development Zone, Henan China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers,

		description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities impurities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**Fusidic Acid:** Firm has submitted stability study data of fusidic acid. Stability study is conducted Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months and at Accelerated conditions 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (121002FA, 121003FA, 121004FA) Batches: (150501FB, 150502FB, 150503FB) **Hydrocortisone Acetate:** Firm has submitted stability study data of Hydrocortisone acetate. Stability study is conducted Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months and at Accelerated conditions 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (160801, 160802, 160803)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand Genidic-H Cream by performing quality tests (Identification, Assay, Uniformity of dosage, pH).
	Analytical method validation/verification of product	Method verification studies have submitted including specificity, repeatibility, recovery and accuracy.

STABILITY STUDY DATA	
Manufacturer of API	**Fusidic Acid**: Joyang Laboratories., Haidu North Road, Sheyang Economic Development Zone, Jiangsu, China **Hydrocortisone Acetate:** Henan Lihua Pharmaceutical Co Ltd., Middle of Huanghe Street, Anyang Hi-Tech Industry Development Zone, Henan China
API Lot No.	**Fusidic Acid:** 200507 FB **Hydrocortisone Acetate:** K06M20210604
Description of Pack (Container closure system)	Cream filled in Aluminium pre-printed tube packed in unit carton

Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	500 tubes	500 tubes	500 tubes
Manufacturing Date	10-2021	10-2020	10-2021
Date of Initiation	14-10-2021	14-10-2021	14-10-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Fusidic Acid:** Firm has submitted GMP certificate No#CQ20180013 in the name of M/s Joyang Laboratories., Haidu North Road, Sheyang Economic Development Zone, Jiangsu, China issued by Chonging Food and Drug administration China valid upto 06-06-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Fusidic Acid:** Firm has submitted copy of invoice No# 00025096 dated 02-04-2020 in name of M/s Biogen Pharmaceuticals for import of 1.5kg of Fusidic Acid. ***However, the invoice is not attested by AD (I&E) DRAP Field office.***
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.1	• Fee for registration of applied product is not submitted	
1.6.5	• Details of each drug substance manufacturer should be provided in this section separately • Valid GMP certificate / DML of drug substance manufacturer for hydrocortisone acetate issued by relevant regulatory authority of country of origin is required	
1.3.2	• The name of applicant as per form 5F is Biogen Life sciences while name mentioned on DML is Biogen Pharmaceuticals. Clarification is required	

2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient fusidic acid by Drug product manufacturer is required. • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient hydrocortisone acetate by both drug substance and Drug product manufacturer is required • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) i.e. fusidic acid and hydrocortisone acetate shall be submitted.	
3.2.P.2	• Submit details of reference / comparator product including batch numbers, manufacturing & expiry date, name of manufacturer in pharmaceutical equivalence • Justify why Pharmaceutical equivalence of the applied product has not been performed against the innovator product?	
3.2.P.3	• Description of manufacturing process does not include the step in which the hydrocortisone is added in the formulation in manufacturing process, clarification is required	
3.2.P.8	• Documents for procurement of API with approval from DRAP • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Previous Decision (322nd–DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response of the Firm:

Section	Observations	Response
1.1	• Fee for registration of applied product is not submitted	Firm has submitted challan No. 78950080271 dated 07-11-2022 for registration fee of Rs. 30000/- submitted for applied product Fusigen H Cream
1.6.5	• Details of each drug substance manufacturer should be provided in this section separately • Valid GMP certificate / DML of drug substance manufacturer for hydrocortisone acetate issued by relevant regulatory authority of country of origin is required	• Firm has submitted details of each drug substance manufacturer in this section **Fusidic Acid**: Joyang Laboratories., Haidu North Road, Sheyang Economic Development Zone, Jiangsu, China **Hydrocortisone Acetate:** Henan Lihua Pharmaceutical Co Ltd., Middle of Huanghe Street, Anyang Hi-Tech Industry Development Zone, Henan China • Firm has submitted GMP certificate No. HA20170054 of M/s Henan Lihua Pharmaceutical Co Ltd., Middle of Huanghe Street, Anyang Hi-Tech Industry Development Zone, Henan China issued by Henan Province Food and Drug Administration for hydrocortisone acetate ***valid upto 26-10-2022*** • Firm has also submitted DML No. Yu 20150014 of M/s Henan Lihua Pharmaceutical Co Ltd.,

		Middle of Huanghe Street, Anyang Hi-Tech Industry Development Zone, Henan China valid upto 31-12-2025.
1.3.2	• The name of applicant as per form 5F is Biogen Life sciences while name mentioned on DML is Biogen Pharmaceuticals. Clarification is required	The firm submitted letter No. 1-2/2019-Lic dated 18th March 2021 for change of title of the firm from M/s Biogen Pharmaceuticals to Biogen Lifesciences.
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	Firm has submitted copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient fusidic acid by Drug product manufacturer is required. • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient hydrocortisone acetate by both drug substance and Drug product manufacturer is required • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) i.e. fusidic acid and hydrocortisone acetate shall be submitted.	• Firm has submitted copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance fusidic acid by Drug product manufacturer • Firm has submitted copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance hydrocortisone acetate by both drug substance and Drug product manufacturer • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) i.e. fusidic acid and hydrocortisone acetate is submitted.
3.2.P.2	• Submit details of reference / comparator product including batch numbers, manufacturing & expiry date, name of manufacturer in pharmaceutical equivalence • Justify why Pharmaceutical equivalence of the applied product has not been performed against the innovator product?	• The firm submitted details of reference / comparator product. The details of comparator product are: Name: Genidic-H Cream; B. No: 2204, Mfg Date: 05-21, Expiry Date: 05-23 Manufacturer by: Biogen Pharma., 8-Km chakbeli Road Rawat Rawalpindi • The firm submitted that due to Easley Access of comparator *(Genidic-H manufacturer by Biogen pharma)* that's why perform pharmaceuticals equivalence study.
3.2.P.3	• Description of manufacturing process does not include the step in which the hydrocortisone is added in the formulation in	The firm submitted that due to Typographically mistake hydrocortisone acetate was not mentioned. The firm has submitted revised manufacturing process

	manufacturing process, clarification is required	
3.2.P.8	• Documents for procurement of API with approval from DRAP • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	• The firm has submitted copy of invoice No. 2021LH-0785 dated 29-07-2021 in name of M/s Biogen Lifesciences *Plot No. 260, Industrial Triangle, Kahuta Road, Islamabad for* Hydrocortisone Acetate (Batch No. K06M20210604) 10kg. *The invoice is not attested by AD (I&E) Field office. Further the address of firm mentioned in invoice is different from the actual address of the firm* • The firm has submitted copy of invoice No. 00025096 dated Apr 02-2020 in name of M/s Biogen Pharmaceuticals 8-km Chakbeli Road Rawat Rawalpindi for Fusidic Acid (Batch No. 190713FB) 1.5kg. *The invoice is not attested by AD (I&E) Field office. The batch No. of drug substance mentioned in invoice is different from that mentioned in batch analysis* • Firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Previous Decision (324-DRB): Deferred for Documents for procurement of drug substance with approval from DRAP I&E office.

Evaluation by PEC:

- Firm has again submitted copy of commercial invoice No. 2021LH-0785 dated 29-07-2021 wherein M/s Biogen Life Sciences have imported 0.5kg of Hydrocortisone Acetate (Batch No. K06M20210604). It is submitted that quantity mentioned in already submitted invoice was 10kg. Firm has submitted DHL invoice for hydrocortisone Acetate. *However, DRAP attested clearance is not provided.*
- The firm has again submitted copy of invoice No. 00025096 dated Apr 02-2020 in name of M/s Biogen Pharmaceuticals for Fusidic Acid (Batch No. 200507FB) 1.5kg. *However, in the submitted document Batch number is over written and changed from original ones. Furthermore, DRAP attested clearance is not provided for the same.* Firm has submitted DHL invoice for fusidic acid

Decision: Deferred for submission of following:

- **Documents for procurement of drug substance with approval from DRAP I&E office.**
- **Pharmaceutical equivalence studies of the applied product against the innovator product**

864.	Name, address of Applicant / Marketing Authorization Holder	M/s Biogen Life Sciences, 8-km Chakbeli Road Rawat Rawalpindi
	Name, address of Manufacturing site.	M/s Biogen Life Sciences, 8-km Chakbeli Road Rawat Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy.No 27911 dated 03-10-2022

	Details of fee submitted	Rs.30,000/- dated 14-07-2022 (Deposit Slip#86318672487)
	The proposed proprietary name / brand name	**Fusigen-B Cream**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tube contains: Fusidic Acid……..….20mg Betamethasone (as valerate)……1mg
	Pharmaceutical form of applied drug	Cream.
	Pharmacotherapeutic Group of (API)	Antibiotics & corticosteroid For Topical Use
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Fusidic acid/Betamethasone 20 mg/g + 1 mg/g cream MHRA approved
	For generic drugs (me-too status)	Fudic-B Cream by M/s Shaigan Pharmaceutical (Reg# 83599)
	GMP status of the Finished product manufacturer	New license granted on 13/02/2020
	Name and address of API manufacturer.	**Fusidic Acid**: Joyang Laboratories., Haidu North Road, Sheyang Economic Development Zone, Jiangsu, China **Betamethasone valerate:** Envee Drugs Pvt. Ltd., N. H. No. 8, Dumral-387 355, Ta. Nadiad, Dist: Kheda, Gujarat, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities impurities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**Fusidic Acid:** Firm has submitted stability study data of fusidic acid. Stability study is conducted Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months and at Accelerated conditions 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (121002FA, 121003FA, 121004FA)

		Batches: (150501FB, 150502FB, 150503FB) **Betamethasone Valerate:** Firm has submitted stability study data of Betamethasone Valerate. Stability study is conducted Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48months and at Accelerated conditions 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (EV/00808, EV/06308, EV/10507)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand Fuciden cream Cream by performing quality tests (Identification, Assay, pH, average weight).
	Analytical method validation/verification of product	Method validation studies have been submitted including accuracy, repeatability (method precision), linearity and range, specificity, system suitability.

STABILITY STUDY DATA

Manufacturer of API	**Fusidic Acid**: Joyang Laboratories., Haidu North Road, Sheyang Economic Development Zone, Jiangsu, China **Betamethasone valerate:** Envee Drugs Pvt. Ltd., N. H. No. 8, Dumral-387 355, Ta. Nadiad, Dist: Kheda, Gujarat, India		
API Lot No.	**Fusidic Acid:** 200507 FB **Betamethasone Valerate:** EV/BV-256/20		
Description of Pack (Container closure system)	Cream filled in Aluminium pre-printed tube packed in unit carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	**T#2004FB**	**T#2005FB**	**T#2006FB**
Batch Size	500 tubes	500 tubes	500 tubes
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	12-10-2021	12-10-2021	12-10-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	**Fusidic Acid:** Firm has submitted GMP certificate No#CQ20180013 in the name of M/s Joyang Laboratories., Haidu North Road, Sheyang Economic Development Zone, Jiangsu, China issued by Chonging Food and Drug administration China valid upto 06-06-2023 **Betamethasone valerate:** Firm has submitted GMP certificate No#S-GMP & GLP / 21072790 in the name of Envee Drugs Pvt. Ltd., N. H. No. 8, Dumral-387 355, Tal. Nadiad, Dist: Kheda, Gujarat, India issued by Food and Drugs control administration Gandinagar, Gujarat State India valid upto 06-07-2023
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Fusidic Acid:** Firm has submitted copy of invoice No# 00025096 dated 02-04-2020 in name of M/s Biogen Pharmaceuticals for import of 1.5kg of Fusidic Acid. ***However, the invoice is not attested by AD (I&E) DRAP Field office.*** **Betamethasone valerate:** Firm has submitted copy of invoice No# 93 dated 02-11-2020 in name of M/s Biogen Life sciences for import of 03kg of Betamethasone valerate. ***However, the invoice is not attested by AD (I&E) DRAP Field office.***
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks of Evaluator [XI]:

Section	Observations	Response
1.3.2	• The name of applicant as per form 5F is Biogen Life sciences while name mentioned on DML is Biogen Pharmaceuticals. Clarification is required	
1.5.2	• Revise label claim as per reference formulation along with submission of applicable fee	
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	
3.2.S.4	• Copies of the analytical procedures used for routine testing of the Drug substance fusidic acid by both drug substance manufacturer and Drug product manufacturer is required. • Copies of the Drug substance specifications of drug substance fusidic acid by Drug product manufacturer is required.	

	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance Betamethasone Valerate by Drug product manufacturer is required • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) i.e. fusidic acid and betamethasone valerate shall be submitted. • Certificate of Analysis of the same batch of fusidic acid used during product development and stability studies from Drug Substance manufacturer is required.	
3.2.P.2	• Submit details of reference / comparator product including batch numbers, manufacturing & expiry date, name of manufacturer in pharmaceutical equivalence	
3.2.P.6	• Submit readable copy of reference standard of fusidic acid and betamethasone valerate	
3.2.P.8	• Submit stability summary sheet of batch #2006FB at accelerated conditions • Documents for procurement of API with approval from DRAP • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	

Previous Decision (322nd–DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response of the Firm:

Section	Observations	Response
1.3.2	• The name of applicant as per form 5F is Biogen Life sciences while name mentioned on DML is Biogen Pharmaceuticals. Clarification is required	The firm submitted letter No. 1-2/2019-Lic dated 18th March 2021 for change of title of the firm from M/s Biogen Pharmaceuticals to M/s Biogen Lifesciences.
1.5.2	• Revise label claim as per reference formulation along with submission of applicable fee	The firm has submitted revised label claim as per reference formulation. The revised label claim is: Each gram Contains: Fusidic Acid…….20mg (2 % w/w) Betamethasone as valerate…1mg (0.1%w/w)
2.3.R.1	• Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>	Firm has submitted copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3>
3.2.S.4	• Copies of the analytical procedures used for routine testing of the Drug substance fusidic acid by both drug substance manufacturer and Drug product manufacturer is required. • Copies of the Drug substance specifications of drug substance fusidic acid by Drug product manufacturer is required. • Copies of the Drug substance specifications and analytical procedures used for routine testing	• Copies of the analytical procedures used for routine testing of the Drug substance fusidic acid by both drug substance manufacturer and Drug product manufacturer is not submitted • Copies of the Drug substance specifications of drug substance fusidic acid by Drug product manufacturer is submitted. • Firm has submitted copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance betamethasone valerate by Drug product manufacturer. *However, the limits of LOD (1.4% to*

	of the Drug substance Betamethasone Valerate by Drug product manufacturer is required • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) i.e. fusidic acid and betamethasone valerate shall be submitted. • Certificate of Analysis of the same batch of fusidic acid used during product development and stability studies from Drug Substance manufacturer is required.	*2%) mentioned in specifiations is different than USP (NMT 0.5%).* • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) i.e. fusidic acid and betamethasone valerate is submitted. • Certificate of Analysis of the same batch of fusidic acid used during product development and stability studies from Drug Substance manufacturer is not submitted
3.2.P.2	• Submit details of reference / comparator product including batch numbers, manufacturing & expiry date, name of manufacturer in pharmaceutical equivalence	• The firm submitted details of reference / comparator product. The details of comparator product are: Name: Genidic-G Cream; B. No: 2212, Mfg Date: 05-21, Expiry Date: 05-23 Manufacturer by: Biogen Pharma., 8-Km chakbeli Road Rawat Rawalpindi
3.2.P.6	• Submit readable copy of reference standard of fusidic acid and betamethasone valerate	• Firm has submitted readable copy of reference standard of fusidic acid and betamethasone valerate
3.2.P.8	• Submit stability summary sheet of batch #2006FB at accelerated conditions • Documents for procurement of API with approval from DRAP • Submit Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	• Stability summary sheet of batch #2006FB at accelerated conditions is not submitted • The firm has submitted copy of invoice No. 00025096 dated Apr 02-2020 in name of M/s Biogen Pharmaceuticals 8-km Chakbeli Road Rawat Rawalpindi for Fusidic Acid (Batch No. 190713FB) 1.5kg. *The invoice is not attested by AD (I&E) Field office. The batch No. of drug substance mentioned in invoice is different from that mentioned in batch analysis* • The firm has submitted copy of invoice No. 10 dated 03-08-2019 in name of M/s Biogen Pharma 8-km Chakbeli Road Rawat Rawalpindi for Betamethasone valerate (Batch No. EV/BV-060/19) 03kg. *The invoice is not attested by AD (I&E) Field office. The batch No. of drug substance mentioned in invoice is different from that mentioned in batch analysis* • Firm has submitted Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)

Previous Decision (324-DRB): Deferred for Documents for procurement of drug substance with approval from DRAP I&E office.

Evaluation by PEC:

- The firm has again submitted copy of invoice No. 00025096 dated Apr 02-2020 in name of M/s Biogen Pharmaceuticals for Fusidic Acid (Batch No. 200507FB) 1.5kg. *However, in the submitted document*

Batch number is over written and changed from original ones. Furthermore, DRAP attested clearance is not provided for the same. Firm has submitted DHL invoice for fusidic acid • The firm has submitted copy of invoice No. 93 dated 02-11-2020 in name of M/s Biogen Pharmaceuticals for Betamethasone valerate (Batch No. EV/BV-256/20) 0.3kg. *However, DRAP attested clearance is not provided.* Firm has submitted DHL invoice for Betamethasone valerate.
Decision: Deferred for submission of following: • **Documents for procurement of drug substance with approval from DRAP I&E office.** • **Pharmaceutical equivalence studies of the applied product against the innovator product**

Case No. 07: Deferred cases of Priority Registration of Fludrocortisone tablets on Form 5:

The Drug Regulatory Authority of Pakistan in its 91st meeting held on 4th September 2020, exercising its power under Rule 26 of Drugs (LRA) Rules amended vide SRO 713(I)/2018 dated 8th June, 2018, allowed to submit registration applications on Form 5 / Form 5-A / Form 5-D instead of Form 5F, for Registration of Fludrocortisone tablets in light of approvals granted by the reference regulatory authorities and with the following additional conditions:

i. The applicants can submit their applications till 30-09-2020 and these applications will be considered out of queue.
ii. Registration Board may consider grant of registration and submission of data of product development and 6 months accelerated and 6 months real time stability studies data before sale of product along with other data as may be required.

865.	Name and address of manufacture / Applicant	M/s Pharma wise Labs Pvt Ltd., 25-M. Q.A Industrial Estate, Kot Lakhpat Lahore, Pakistan
	Brand Name+Dosage Form+Strength	Floricort 0.1mg Tablet
	Composition	Each Tablet Contains: Fludrocortisone Acetate…….0.1mg
	Dairy No. date of R &I fee	Form-5D Dy.No 25498 dated 29-09-2020 Rs.50,000/- 29-09-2020
	Pharmacological Group	Mineralocorticoid
	Type of form	Form 5D
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Fludrocortisone Acetate 0.1mg Tablets MHRA Approved
	Me-too-status	
	GMP Status	GMP certificate issued to M/s Pharma Wise Labs (Pvt.) Ltd on 13.12.2019 based on inspection conducted on 16.10.2019
	Previous Remark of Evaluator [XI]	• The firm submitted revised layout plan approved for regularization of sections mentioned vide covering letter No. F. 1-7/85-Lic (Vol-II) dated 18/12/2017 showing steroidal tablet section. • The firm submitted GMP certificate issued on 13.12.2019 based on inspection conducted on 16.10.2019 having tablet steroidal section. However, the conclusion of inspection report contains the following statement: • The resumption of production activities in the following sections: a. Oral liquid section (syrup/suspension b. Antiseptic section c. Cream/Ointment section d. General tablet section

		• Resumption of production activities in the following sections be allowed only after installation of 400 KVA transformer. The installation / operations would be verified by area FID and forwarded to DRAP, Islamabad for resumption. a. Sachet section b. Repacking section c. Capsule section d. General antibiotic tablet section e. General antibiotic dry powder section f. Steroid tablet section • Panel did not recommend the resumption in penicillin area
	Previous Decision (297-DRB)	• Deferred for updated status of GMP of the firm as explanation letter issued to the firm on 11th January 2021 from QA & LT division.
	Evaluation by PEC	• The firm have submitted inspection report conducted by FID dated 25-10-2021 and conclusion of inspection was: In view of above inspection proceedings, it was observed that the firm had rectified most of the deficiencies pointed out during last GMP inspection, hence the firm display positive approach towards compliance.
	Previous Decision (316-DRB)	• Deferred for confirmation of manufacturing facility i.e. Steroid tablet section from Licensing Division
	Evaluation by PEC	• The firm has submitted panel inspection report dated 21-03-2023 for renewal of DML and Regularization of Layout plan wherein the panel has recommended the grant of renewal of DML and regularization of Layout plan to M/s Pharma wise Labs (Pvt.,) Ltd., 25-M, Kot Lakhpat Industrial Estate, Lahore for following sections: 1. Oral liquid section (syrup/suspension) 2. External Applications/Antiseptic Liquid section 3. Cream/Ointment section 4. Tablet section (General) 5. Oral Dry powder Sachet section 6. Repacking section 7. Capsule section 8. Oral Dry Powder for suspension (General antibiotic) 9. Tablet (General antibiotic) section 10. Tablet (Steroid) section
	Decision:	

Agenda of Evaluator PEC-XIII.

Case 01; Registration applications of Routine cases (Human) drugs on Form 5F.

866.	Name, address of Applicant / Marketing Authorization Holder	M/s Ferozsons Laboratories Ltd., Amangarh, Nowshera, Khyber Pakhtunkhwa.
	Name, address of Manufacturing site.	M/s Ferozsons Laboratories Ltd., Amangarh, Nowshera, Khyber Pakhtunkhwa.
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3417 dated 04-02-2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 426086645 dated 07-12-2021.
	The proposed proprietary name / brand name	Nebita 2.5mg tablets.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Nebivolol HCl eq. to Nebivolol ……2.5mg
	Pharmaceutical form of applied drug	Tablet.
	Pharmacotherapeutic Group of (API)	Beta blocking agents, selective ATC code: C07AB
	Reference to Finished product specifications	Innovator specifications.
	Proposed Pack size	10's, 14's, 20's, 28's & 30's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	BYSTOLIC® (Nebivolol) 2.5mg, 5mg, 10mg & 20mg tablets, USFDA approved
	For generic drugs (me-too status)	Nebix Tablet 2.5 mg, Highnoon laboratories, Reg. No. 062776,
	GMP status of the Finished product manufacturer	GMP certificate issued on 25-08-2021 on the basis of inspection conducted on 10-08-2021.
	Evidence of section approval.	Tablet (general) section approved vide letter No. F. 3-14/2004-Lic dated 08-04-2015.
	Name and address of API manufacturer.	M/s Cadila Pharmaceuticals Ltd., 294, G.I.D.C. Estate, City: - Ankleshwar – 393 002, Dist. Bharuch Gujrat State, India. Copy of GMP certificate No. 21102987 dated 21-10-2021 issued by Food & Drug Control Administration Gujrat State, India on the basis of inspection conducted on 32-24/09/2021 & 16/10/2021 valid till 20-10-2024 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module III (Drug Substance)	Firm has submitted detail of nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis (20NV023, mfg. date 06-2020) and justification of specification, reference standard, container closure system and stability studies of drug substances.
	Stability studies (Drug substance.)	Stability study conditions:

		Real time: 30°C ± 2°C / 75% ± 5% RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5% RH for 6 months. Batch No. 17NV001, 17NV002 & 17NV003.
	Module-III (Drug Product):	Firm has submitted detail of description & composition of the drug product, formulation development, manufacturer, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is performed against the innovator product i.e. Bystolic 2.5mg manufactured by Janssen Pharmaceutica N.V., Belgium, batch No. W03791, Expiry date 06-2022 by performing quality tests i.e. Identification, Average, weight, impurities, Dissolution and Assay. CDP has been performed against the innovator product i.e. Bystolic by Allergan USA, batch No. W03791, Expiry date 06-2022 in three different medias i.e. Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). F2 values are in acceptable range.
	Analytical method validation/verification of product	Method Validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Cadila Pharmaceuticals Ltd., 294, G.I.D.C. Estate, City: - Ankleshwar – 393 002, Dist. Bharuch Gujrat State, India.		
API Lot No.	20NV023.		
Description of Pack (Container closure system)	14 core tablets packed in a blister made up of Alu-Alu foil. Two blisters packed in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	NVTab-001.	NVTab-002.	NVTab-003.
Batch Size	3000 tablets	3000 tablets	3000 tablets
Manufacturing Date	01-2021	01-2021	01-2021
Date of Initiation	04-02-2021	04-02-2021	04-02-2021
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

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

Administrative Portion

13.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their product Empagen 10mg & Empagen 25mg Tablets which was approved in 294th Meeting of Registration Board held on 09th April 2020. Inspection was conducted on 25th October, 2019. According to the report following points were confirmed.

		• The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers.
14.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 21102987 dated 21-10-2021 issued by Food & Drug Control Administration Gujrat State, India on the basis of inspection conducted on 32-24/09/2021 & 16/10/2021 valid till 20-10-2024 is submitted.
15.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form-6 No. 00764/2020-DRAP/PS/3300 Dated: 09-09-2020 wherein they have imported 125gm of Nebivolol hydrochloride with batch No. 20NV023 from M/s Cadila Pharmaceuticals Ltd., India. Form-6 is also attested by the Assistant Drug controller, DRAP, Peshawar. Firm has also submitted commercial invoice No. 3202040484 dated 26-08-2020 mentioning Nebivolol hydrochloride 125gm with batch No. 20NV023 from M/s Cadila Pharmaceuticals Ltd., India
16.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
17.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
18.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.		CDP report has mentioned API lot No. 20NV027 while the stability data sheets and procurements have shown 20NV023 as API lot number. Clarification shall be submitted.	Firm has submitted that batch number i.e. 20NV027 mentioned in CDP report is of that lot which was standardized against vendor working standard and utilized throughout analytical testing as working reference standard and the same was procured during import of trial/stability batches lot i.e. batch No. 20NV023. Firm has also provided attested form 6 for ready reference of both the API lot and working standard.
2.		Specifications of the drug product has mentioned dissolution specifications of NLT 80% (Q + 5 = 85%) released in 45 minutes. While the literature review of the innovator product has mentioned dissolution specifications in 15 minutes. Justification shall be submitted.	Firm has submitted that their specifications are not as per innovator specifications. However, results of the already conducted testing are in accordance with the specifications of the innovator literature i.e. NLT 80% (80 +5 = 85%) release in 15 minutes. *They further revised their specifications for dissolution from NLT 80% (Q + 5 = 85%) released in 45 minutes to NLT 80% (Q + 5 =*

		85%) released in 15 minutes with submission of 7500/- fee vide slip No. 85095863182 dated 18-05-2023.
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
867.	Name, address of Applicant / Marketing Authorization Holder	M/s Ferozsons Laboratories Ltd., Amangarh, Nowshera, Khyber Pakhtunkhwa.
	Name, address of Manufacturing site.	M/s Ferozsons Laboratories Ltd., Amangarh, Nowshera, Khyber Pakhtunkhwa.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3418 dated 04-02-2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 7344224325 dated 07-12-2021.
	The proposed proprietary name / brand name	Nebita 5mg tablets.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Nebivolol HCl eq. to Nebivolol ……5mg
	Pharmaceutical form of applied drug	Tablet.
	Pharmacotherapeutic Group of (API)	Beta blocking agents, selective ATC code: C07AB
	Reference to Finished product specifications	Innovator specifications.
	Proposed Pack size	10’s, 14’s, 20’s, 28’s & 30’s.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	BYSTOLIC® (Nebivolol) 2.5mg, 5mg, 10mg & 20mg tablets, USFDA approved
	For generic drugs (me-too status)	Nebix Tablet 5 mg, Highnoon laboratories, Reg. No. 062777.
	GMP status of the Finished product manufacturer	GMP certificate issued on 25-08-2021 on the basis of inspection conducted on 10-08-2021.
	Evidence of section approval.	Tablet (general) section approved vide letter No. F. 3-14/2004-Lic dated 08-04-2015.
	Name and address of API manufacturer.	M/s Cadila Pharmaceuticals Ltd., 294, G.I.D.C. Estate, City: - Ankleshwar – 393 002, Dist. Bharuch Gujrat State, India.

		Copy of GMP certificate No. 21102987 dated 21-10-2021 issued by Food & Drug Control Administration Gujrat State, India on the basis of inspection conducted on 32-24/09/2021 & 16/10/2021 valid till 20-10-2024 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module III (Drug Substance)	Firm has submitted detail of nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis (20NV023, mfg. date 06-2020) and justification of specification, reference standard, container closure system and stability studies of drug substances.
	Stability studies (Drug substance.)	Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5% RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 6 months. Batch No. 17NV001, 17NV002 & 17NV003.
	Module-III (Drug Product):	Firm has submitted detail of description & composition of the drug product, formulation development, manufacturer, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is performed against the innovator product i.e. Bystolic 5mg manufactured by Janssen Pharmaceutica N.V., Belgium, batch No. W04451, Expiry date 02-2023 by performing quality tests i.e. Identification, Average, weight, impurities, Dissolution and Assay. CDP has been performed against the innovator product i.e. Bystolic by Allergan USA, batch No. W04451, Expiry date 02-2023 in three different medias i.e. Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). F2 values are in acceptable range.
	Analytical method validation/verification of product	Method Validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Cadila Pharmaceuticals Ltd., 294, G.I.D.C. Estate, City: - Ankleshwar – 393 002, Dist. Bharuch Gujrat State, India.		
API Lot No.	20NV023.		
Description of Pack (Container closure system)	14 core tablets packed in a blister made up of Alu-Alu foil. Two blisters packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	NVTab-004.	NVTab-005.	NVTab-006.

Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	01-2021	01-2021	01-2021
Date of Initiation	04-02-2021	04-02-2021	04-02-2021
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

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

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their product Empagen 10mg & Empagen 25mg Tablets which was approved in 294th Meeting of Registration Board held on 09th April 2020. Inspection was conducted on 25th October, 2019. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 21102987 dated 21-10-2021 issued by Food & Drug Control Administration Gujrat State, India on the basis of inspection conducted on 32-24/09/2021 & 16/10/2021 valid till 20-10-2024 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form-6 No. 00764/2020-DRAP/PS/3300 Dated: 09-09-2020 wherein they have imported 125gm of Nebivolol hydrochloride with batch No. 20NV023 from M/s Cadila Pharmaceuticals Ltd., India. Form-6 is also attested by the Assistant Drug controller, DRAP, Peshawar. Firm has also submitted commercial invoice No. 3202040484 dated 26-08-2020 mentioning Nebivolol hydrochloride 125gm with batch No. 20NV023 from M/s Cadila Pharmaceuticals Ltd., India
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.		CDP report has mentioned API lot No. 20NV027 while the stability data sheets and procurements have shown 20NV023 as API lot number. Clarification shall be submitted.	Firm has submitted that batch number i.e. 20NV027 mentioned in CDP report is of that lot which was standardized against vendor working standard and utilized throughout analytical testing as working reference standard and the same was procured during

		import of trial/stability batches lot i.e. batch No. 20NV023. Firm has also provided attested form 6 for ready reference of both the API lot and working standard.
2.	Specifications of the drug product has mentioned dissolution specifications of NLT 80% (Q + 5 = 85%) released in 45 minutes. While the literature review of the innovator product has mentioned dissolution specifications in 15 minutes. Justification shall be submitted.	Firm has submitted that their specifications are not as per innovator specifications. However, results of the already conducted testing are in accordance with the specifications of the innovator literature i.e. NLT 80% (80 +5 = 85%) release in 15 minutes. *They further revised their specifications for dissolution from NLT 80% (Q + 5 = 85%) released in 45 minutes to NLT 80% (Q + 5 = 85%) released in 15 minutes with submission of 7500/- fee vide slip No. 93217501 dated 18-05-2023.*

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

868.	Name, address of Applicant / Marketing Authorization Holder	M/s Ferozsons Laboratories Ltd., Amangarh, Nowshera, Khyber Pakhtunkhwa.
	Name, address of Manufacturing site.	M/s Ferozsons Laboratories Ltd., Amangarh, Nowshera, Khyber Pakhtunkhwa.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3419 dated 04-02-2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 29783993078 dated 07-12-2021.
	The proposed proprietary name / brand name	Nebita 10mg tablets.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Nebivolol HCl eq. to Nebivolol …… 10mg
	Pharmaceutical form of applied drug	Tablet.
	Pharmacotherapeutic Group of (API)	Beta blocking agents, selective ATC code: C07AB
	Reference to Finished product specifications	Innovator specifications.
	Proposed Pack size	10’s, 14’s, 20’s, 28’s & 30’s.

	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	BYSTOLIC® (Nebivolol) 2.5mg, 5mg, 10mg & 20mg tablets, USFDA approved
	For generic drugs (me-too status)	Nebix Tablet 10 mg, Highnoon laboratories, Reg. No. 062778.
	GMP status of the Finished product manufacturer	GMP certificate issued on 25-08-2021 on the basis of inspection conducted on 10-08-2021.
	Evidence of section approval.	Tablet (general) section approved vide letter No. F. 3-14/2004-Lic dated 08-04-2015.
	Name and address of API manufacturer.	M/s Cadila Pharmaceuticals Ltd., 294, G.I.D.C. Estate, City: - Ankleshwar – 393 002, Dist. Bharuch Gujrat State, India. Copy of GMP certificate No. 21102987 dated 21-10-2021 issued by Food & Drug Control Administration Gujrat State, India on the basis of inspection conducted on 32-24/09/2021 & 16/10/2021 valid till 20-10-2024 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS details as per WHO QOS PD template.
	Module III (Drug Substance)	Firm has submitted detail of nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, tests for impurities & related substances, specifications, analytical procedures and its verification, batch analysis (20NV023, mfg. date 06-2020) and justification of specification, reference standard, container closure system and stability studies of drug substances.
	Stability studies (Drug substance.)	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5% RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5% RH for 6 months. Batch No. 17NV001, 17NV002 & 17NV003.
	Module-III (Drug Product):	Firm has submitted detail of description & composition of the drug product, formulation development, manufacturer, description of manufacturing process and controls, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is performed against the innovator product i.e. Bystolic 10mg manufactured by Janssen Pharmaceutica N.V., Belgium, batch No. W04638, Expiry date 05-2023 by performing quality tests i.e. Identification, Average, weight, impurities, Dissolution and Assay. CDP has been performed against the innovator product i.e. Bystolic by Allergan USA, batch No. W04638, Expiry date 05-2023 in three different medias i.e. Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). F2 values are in acceptable range.
	Analytical method validation/verification of product	Method Validation studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		

Manufacturer of API	M/s Cadila Pharmaceuticals Ltd., 294, G.I.D.C. Estate, City: - Ankleshwar – 393 002, Dist. Bharuch Gujrat State, India.		
API Lot No.	20NV023.		
Description of Pack (Container closure system)	14 core tablets packed in a blister made up of Alu-Alu foil. Two blisters packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	NVTab-007.	NVTab-008.	NVTab-009.
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	01-2021	01-2021	01-2021
Date of Initiation	04-02-2021	04-02-2021	04-02-2021
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

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

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to their product Empagen 10mg & Empagen 25mg Tablets which was approved in 294th Meeting of Registration Board held on 09th April 2020. Inspection was conducted on 25th October, 2019. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 21102987 dated 21-10-2021 issued by Food & Drug Control Administration Gujrat State, India on the basis of inspection conducted on 32-24/09/2021 & 16/10/2021 valid till 20-10-2024 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of form-6 No. 00764/2020-DRAP/PS/3300 Dated: 09-09-2020 wherein they have imported 125gm of Nebivolol hydrochloride with batch No. 20NV023 from M/s Cadila Pharmaceuticals Ltd., India. Form-6 is also attested by the Assistant Drug controller, DRAP, Peshawar. Firm has also submitted commercial invoice No. 3202040484 dated 26-08-2020 mentioning Nebivolol hydrochloride 125gm with batch No. 20NV023 from M/s Cadila Pharmaceuticals Ltd., India
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.		CDP report has mentioned API lot No. 20NV027 while the stability data sheets and procurements have shown 20NV023 as API lot number. Clarification shall be submitted.	Firm has submitted that batch number i.e. 20NV027 mentioned in CDP report is of that lot which was standardized against vendor working standard and utilized throughout analytical testing as working reference standard and the same was procured during import of trial/stability batches lot i.e. batch No. 20NV023. Firm has also provided attested form 6 for ready reference of both the API lot and working standard.
2.		Specifications of the drug product has mentioned dissolution specifications of NLT 80% (Q + 5 = 85%) released in 45 minutes. While the literature review of the innovator product has mentioned dissolution specifications in 15 minutes. Justification shall be submitted.	Firm has submitted that their specifications are not as per innovator specifications. However, results of the already conducted testing are in accordance with the specifications of the innovator literature i.e. NLT 80% (80 +5 = 85%) release in 15 minutes. *They further revised their specifications for dissolution from NLT 80% (Q + 5 = 85%) released in 45 minutes to NLT 80% (Q + 5 = 85%) released in 15 minutes with submission of 7500/- fee vide slip No. 28172908844 dated 18-05-2023.*

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

869.	Name, address of Applicant / Marketing Authorization Holder	M/s Global Pharmaceuticals (Pvt.) Ltd., Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad.
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd., Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5221: dated 24-02-2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 112209478751 dated 14/02/2022.

	The proposed proprietary name / brand name	Cina 30mg Tablets.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated Tablet Contains: Cinacalcet as hydrochloride ……..…..…30mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	Anti-Parathyroid Agents. ATC Code: H05BX01.
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	10's
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	SENSIPAR® (Cinacalcit) film coated tablets, 30mg, 60mg and 90mg USFDA Approved.
	For generic drugs (me-too status)	Mimcipar 30mg Tablets, Genome Pharmaceutical, Reg. No. 082301.
	GMP status of the Finished product manufacturer	Copy of GMP certificate No. F. 3-16/2018-Addl. Dir. (QA&LT)-1 dated 04-01-2022 on the basis of inspection conducted on 03-01-2022 is submitted.
	Evidence of section approval.	Tablet section (general) vide letter No. F. 1-1/96-Lic. (Vol-II) dated 13-06-2017 is approved.
	Name and address of API manufacturer.	M/s Mehta API (Pvt.) Ltd., Gut No. 546, 571, 519 & 520, Village Kumbhavali, Tarapur, Boisar, Dist. Palghar, Maharashtra, India. Copy of GMP certificate No. NEW-WHO-GMP/CERT/KD/84495/2019/11/29495 dated 19-09-2019 valid till 18-09-2022 issued by FDA, Maharashtra, India is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detail of the drug substance regarding its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (LT-OCLL/003/20-21SF1, mfg. date 05-2020) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 48 months. Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months. Batches: (LT-OCLH/001/15-16, LT-OCLH/002/15-16 & LT-OCLH/003/15-16)

	Module-III (Drug Product):	Firm has submitted detail of the drug product including its description and composition, manufacturer, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the product Mimcipar 30mg tablets manufactured by Genome Pharmaceuticals (Pvt.) Ltd., (Batch No: 006, Mfg. 02-2021) by performing quality tests (Identification, Assay and Dissolution). CDP has been performed against the same brand that is Mimcipar 30mg tablets manufactured by Genome Pharmaceuticals (Pvt.) Ltd., (Batch No: 006, Mfg. 02-2021) in three different mediums i.e. pH 1.2 in 0.1 N HCl, pH 4.5 Acetate buffer & pH 6.8 Phosphate buffer. F2 values calculated for all the three mediums are in acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including specificity, linearity, accuracy, precision, System suitability & robustness.

STABILITY STUDY DATA			
Manufacturer of API	M/s Mehta API (Pvt.) Ltd., Gut No. 546, 571, 519 & 520, Village Kumbhavali, Tarapur, Boisar, Dist. Palghar, Maharashtra, India.		
API Lot No.	LT-OCLL/003/20-21SF1		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (14's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	ST21K004	ST21K005	ST21K006
Batch Size	5000 tabs	5000 tabs	5000 tabs
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	02-11-2021	02-11-2021	02-11-2021
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION		
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.		
Administrative Portion		
19.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product Promig plus tablets 375mg/20mg which was conducted on 1st, 13th & 14th March 2019 and was presented in 289th meeting of Registration Board held on 14-16th May, 2019.

		According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers.
20.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. NEW-WHO-GMP/CERT/KD/84495/2019/11/29495 dated 19-09-2019 valid till 18-09-2022 issued by FDA, Maharashtra, India is submitted.
21.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of NOC with diary No: 1434 dated 24/09/2020 is submitted wherein the permission to import Cinacalcet hydrochloride for the purpose of test/analysis and stability studies is granted. Firm has also submitted commercial invoice No. 2021/LUT00036 dated 24-08-2020 wherein they have imported 03kg of Cinacalcet HCl with Batch No. LT-OCLL/003/20-21SF1 attested by Assistant Director I&E, DRAP, Islamabad dated 24-09-2020.
22.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
23.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
24.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML of the applicant shall be submitted as the submitted one is w.e.f. 26-02-2018.	Firm has once again submitted the previously submitted copy of DML w.e.f. 26-02-2018. ***Firm has also submitted copy of receiving for renewal of DML dated 21-02-2023.***
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. NEW-WHO-GMP/CERT/KD/11960/2022 /11/42037 dated 09-09-2022 valid till 08-09-2025 issued by FDA, Maharashtra, India.
3.	3.2.S.5	COA of the provided reference standard has mentioned that use before 02-11-2020. Justification shall be submitted.	Firm has submitted that attached COA of Reference standard was the part of DMF, and they didn't use in testing. We have attached the actual one that had been used for testing in product part of the dossier.
4.	3.2.P.2.2	• Justification for not performing CDP & PE against the innovator product shall be submitted.	Firm has submitted that Innovator's pack was not available at time of study due to Covid -19 that's why they have performed CDP and pharmaceutical equivalence study with competitor brand as per DRAP guidelines. They also provided new CDP results with reference product i.e. Sinsipar 30mg tablets with batch No. 182541, Exp. date of 04-2024 in

		all the three mediums with similarity factor F2 value in acceptable range.
	• Justification for not performing most of the quality test to be performed on tablets dosage form in PE.	Firm has submitted that in pharmaceutical equivalence studies all the test were performed. However, they have not mentioned all the test in submitted report. They also submitted new report for pharmaceutical equivalence wherein they have mentioned all the tests.
5.	• Justify the dispensing of drug substance for trial batch manufacturing without potency adjustment.	Firm has replied as follows; In BMR of Cina 30mg & 60mg tablets potency is adjusted, as 30mg of Cinacalcet is eq. to 33.06mg of Cinacalcet HCl and 60mg of Cinacalcet is eq. to 66.12mg of Cinacalcet HCl. Water content is 0.249% so calculation of potency in assay of API on OAB is 99.38% and on as basis is 99.14%. Molecular weight of Cinacalcet HCl is 393.9 g/mol. & molecular weight of Cinacalcet is 357.4 g/mol. Now calculation of Cinacalcet on as basis is below, 99.14 x 357.4/393.9 = 89.9% Calculation for 30mg tablet = 100/89.9 x 30 = 33.3mg Calculation for 60mg tablet = 100/89.9 x 60 = 66.7mg The difference without water adjustment in Cina 30mg tablet is 0.24% and for Cina 60mg is 0.5%. Assay Limit is 95.0% - 105.0% and our result is in between 98.0% - 102.0% uptill now so the change is negligible with respect to water content but we commit that water content will be adjusted on commercial batches.
	• Justify the potency used in the calculation of both assay dissolution test with respect to the potency of the drug substance used in development batches. As 90% is used in assay calculation while the COA has mentioned 99%.	Firm has submitted that 90% potency of the drug substance is due to HCl factor. They also submitted calculation for the HCl factor in Cinacalcet HCL.
	• Batch analysis has not performed most of the tests as required by the tablets. • Complete six-month stability data shall be submitted.	Firm has submitted revised batch analysis wherein they have added all the tests performed on the applied formulation. Firm has submitted complete six-month stability data for all the three trial batches both at real time and accelerated conditions.
6.	Clarification is required for clearance of Cinacalcet HCl that commercial invoice is in the name of M/s Global pharmaceutical while form 6 is in the name of M/s Vision pharmaceutical Islamabad.	Firm has submitted that basically import department of both Global Pharmaceuticals & Vision Pharmaceuticals sit together beside to Regulatory department at our premises. That had caused this confusion and instead of attaching Form-6 of Global Pharmaceuticals

		for CINACALCET clearance, we sent the other one from Vision Pharmaceuticals. They also provided copy of form 6 in the name of M/s Global pharmaceuticals they also submitted copy of Form 6 for Global pharma attested by Assistant Director I&E, DRAP, Islamabad.
Decision: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
870.	Name, address of Applicant / Marketing Authorization Holder	M/s Global Pharmaceuticals (Pvt.) Ltd., Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad.
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd., Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5222: dated 24-02-2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 7340054871 dated 14/02/2022.
	The proposed proprietary name / brand name	Cina 60mg Tablets.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated Tablet Contains: Cinacalcet as hydrochloride ……..…..…60mg
	Pharmaceutical form of applied drug	Film coated tablets.
	Pharmacotherapeutic Group of (API)	Anti-Parathyroid Agents. ATC Code: H05BX01.
	Reference to Finished product specifications	Innovator Specifications
	Proposed Pack size	10’s
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	SENSIPAR® (Cinacalcit) film coated tablets, 30mg, 60mg and 90mg USFDA Approved.
	For generic drugs (me-too status)	Mimcipar 60mg Tablets, Genome Pharmaceutical, Reg. No. 082302.
	GMP status of the Finished product manufacturer	Copy of GMP certificate No. F. 3-16/2018-Addl. Dir. (QA&LT)-1 dated 04-01-2022 on the basis of inspection conducted on 03-01-2022 is submitted.
	Evidence of section approval.	Tablet section (general) vide letter No. F. 1-1/96-Lic. (Vol-II) dated 13-06-2017 is approved.

	Name and address of API manufacturer.	M/s Mehta API (Pvt.) Ltd., Gut No. 546, 571, 519 & 520, Village Kumbhavali, Tarapur, Boisar, Dist. Palghar, Maharashtra, India. Copy of GMP certificate No. NEW-WHO-GMP/CERT/KD/84495/2019/11/29495 dated 19-09-2019 valid till 18-09-2022 issued by FDA, Maharashtra, India is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detail of the drug substance regarding its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (LT-OCLL/003/20-21SF1, mfg. date 05-2020) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48 months. Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months. Batches: (LT-OCLH/001/15-16, LT-OCLH/002/15-16 & LT-OCLH/003/15-16)
	Module-III (Drug Product):	Firm has submitted detail of the drug product including its description and composition, manufacturer, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the product Mimcipar 60mg tablets manufactured by Genome Pharmaceuticals (Pvt.) Ltd., (Batch No: 004, Mfg. 08-2020) by performing quality tests (Identification, Assay and Dissolution). CDP has been performed against the same brand that is Mimcipar 60mg tablets manufactured by Genome Pharmaceuticals (Pvt.) Ltd., (Batch No: 004, Mfg. 08-2020) in three different mediums i.e. pH 1.2 in 0.1 N HCl, pH 4.5 Acetate buffer & pH 6.8 Phosphate buffer. F2 values calculated for all the three mediums are in acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including specificity, linearity, accuracy, precision, System suitability & robustness.

STABILITY STUDY DATA			
Manufacturer of API	M/s Mehta API (Pvt.) Ltd., Gut No. 546, 571, 519 & 520, Village Kumbhavali, Tarapur, Boisar, Dist. Palghar, Maharashtra, India.		
API Lot No.	LT-OCLL/003/20-21SF1		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (14's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	ST21K007	ST21K008	ST21K009
Batch Size	5000 tabs	5000 tabs	5000 tabs
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	02-11-2021	02-11-2021	02-11-2021
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION		
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.		
Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product Promig plus tablets 375mg/20mg which was conducted on 1st, 13th & 14th March 2019 and was presented in 289th meeting of Registration Board held on 14-16th May, 2019. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. NEW-WHO-GMP/CERT/KD/84495/2019/11/29495 dated 19-09-2019 valid till 18-09-2022 issued by FDA, Maharashtra, India is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of NOC with diary No: 1434 dated 24/09/2020 is submitted wherein the permission to import Cinacalcet hydrochloride for the purpose of test/analysis and stability studies is granted. Firm has also submitted commercial invoice No. 2021/LUT00036 dated 24-08-2020 wherein they have imported 03kg of Cinacalcet HCl with Batch No. LT-OCLL/003/20-21SF1 attested by Assistant Director I&E, DRAP, Islamabad dated 24-09-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML of the applicant shall be submitted as the submitted one is w.e.f. 26-02-2018.	Firm has once again submitted the previously submitted copy of DML w.e.f. 26-02-2018. *Firm has also submitted copy of receiving for renewal of DML dated 21-02-2023.*
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. NEW-WHO-GMP/CERT/KD/11960/2022 /11/42037 dated 09-09-2022 valid till 08-09-2025 issued by FDA, Maharashtra, India.
3.	3.2.S.5	COA of the provided reference standard has mentioned that use before 02-11-2020. Justification shall be submitted.	Firm has submitted that attached COA of Reference standard was the part of DMF, and they didn't use in testing. We have attached the actual one that had been used for testing in product part of the dossier.
4.	3.2.P.2.2	• Justification for not performing CDP & PE against the innovator product shall be submitted.	Firm has submitted that Innovator's pack was not available at time of study due to Covid -19 that's why they have performed CDP and pharmaceutical equivalence study with competitor brand as per DRAP guidelines. They also provided new CDP results with reference product i.e. Sinsipar 60mg tablets with batch No. 182547, Exp. date of 04-2024 in all the three mediums with similarity factor F2 value in acceptable range.
		• Justification for not performing most of the quality test to be performed on tablets dosage form in PE.	Firm has submitted that in pharmaceutical equivalence studies all the test were performed. However, they have not mentioned all the test in submitted report. They also submitted new report for pharmaceutical equivalence wherein they have mentioned all the tests.
5.		• Justify the dispensing of drug substance for trial batch manufacturing without potency adjustment.	Firm has replied as follows; In BMR of Cina 30mg & 60mg tablets potency is adjusted, as 30mg of Cinacalcet is eq. to 33.06mg of Cinacalcet HCl and 60mg of Cinacalcet is eq. to 66.12mg of Cinacalcet HCl. Water content is 0.249% so calculation of potency in assay of API on OAB is 99.38% and on as basis is 99.14%. Molecular weight of Cinacalcet HCl is 393.9 g/mol. & molecular weight of Cinacalcet is 357.4 g/mol. Now calculation of Cinacalcet on as basis is below, 99.14 x 357.4/393.9 = 89.9% Calculation for 30mg tablet = 100/89.9 x 30 = 33.3mg

		Calculation for 60mg tablet = 100/89.9 x 60 = 66.7mg The difference without water adjustment in Cina 30mg tablet is 0.24% and for Cina 60mg is 0.5%. Assay Limit is 95.0% - 105.0% and our result is in between 98.0% - 102.0% uptill now so the change is negligible with respect to water content but we commit that water content will be adjusted on commercial batches. Firm has submitted that 90% potency of the drug substance is due to HCl factor. They also submitted calculation for the HCl factor in Cinacalcet HCL.
	• Justify the potency used in the calculation of both assay dissolution test with respect to the potency of the drug substance used in development batches. As 90% is used in assay calculation while the COA has mentioned 99%. • Batch analysis has not performed most of the tests as required by the tablets. • Complete six-month stability data shall be submitted.	Firm has submitted revised batch analysis wherein they have added all the tests performed on the applied formulation. Firm has submitted complete six-month stability data for all the three trial batches both at real time and accelerated conditions.
6.	Clarification is required for clearance of Cinacalcet HCl that commercial invoice is in the name of M/s Global pharmaceutical while form 6 is in the name of M/s Vision pharmaceutical Islamabad.	Firm has submitted that basically import department of both Global Pharmaceuticals & Vision Pharmaceuticals sit together beside to Regulatory department at our premises. That had caused this confusion and instead of attaching Form-6 of Global Pharmaceuticals for CINACALCET clearance, we sent the other one from Vision Pharmaceuticals. They also provided copy of form 6 in the name of M/s Global pharmaceuticals they also submitted copy of Form 6 for Global pharma attested by Assistant Director I&E, DRAP, Islamabad.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

871.	Name, address of Applicant / Marketing Authorization Holder	M/s Stallion Pharmaceuticals (Pvt.) Ltd., Plot No. 581, Sunder Industrial Estate, Lahore.
	Name, address of Manufacturing site.	M/s Bio-Mark Pharmaceuticals, Plot No. 527, Sunder Industrial Estate, Lahore.
	Status of the applicant	☐Manufacturer ☐ Importer ☒Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5385; dated 25/02/2022.
	Details of fee submitted	PKR 75 ,000/-: vide slip No.9775953749 dated 28/12/2021.
	The proposed proprietary name / brand name	Staesso 20mg capsules.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Esomeprazole (as enteric coated pellets) ……... 20mg.
	Pharmaceutical form of applied drug	Oral capsule.
	Pharmacotherapeutic Group of (API)	PPI (Proton Pump Inhibitors).
	Reference to Finished product specifications	USP specifications.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Nexium 20mg & 40mg delayed release capsule, USFDA Approved.
	For generic drugs (me-too status)	Nexum 20mg Capsule, Getz Pharma, Reg. No. 033890.
	GMP status of the Finished product manufacturer	**Contract giver:** Copy of GMP certificate No. 131/2020-DRAP (AD-1952624-1099) dated 02-10-2020 issued on the basis of inspection conducted on 22-09-2020 is submitted. **Contract acceptor:** Copy of GMP certificate No. 47/2020-DRAP (AD-849966-789) dated 26-02-2020 issued on the basis of inspection conducted on 13-02-2020 is submitted.
	Evidence of section approval.	Capsule General section is approved in the above mentioned GMP certificate.
	Name and address of API manufacturer.	M/s Vision pharmaceuticals, Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad. Copy of GMP certificate No. 3-26/2019-Addl. Dir. (QA&LT-I) dated 31-07-2019 on the basis of inspection conducted on 11-02-2019 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detail of the drug substance regarding its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures, batch analysis (EMZ045931, Mfg. date 27-09-2019) and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Stability studies (Drug substance.)	Firm has submitted both real time and accelerated stability study data for the drug substance for three batches. Stability study conditions: Real time: 30˚C ± 2˚C /65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (EMZ044440, EMZ044265 & EMZ044152).
	Module-III (Drug Product):	The firm has submitted detail of the drug product including its description & composition, Pharmaceutical equivalence, manufacturers, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand Nexium 20 mg Capsules manufactured by Getz Pharma by performing quality tests (Identification, weight variation, loss on drying, Dissolution in acidic and buffer stage, uniformity of dosage units & Assay). CDP is performed against the brand Nexium 20mg capsules batch No. 883C19 manufactured by Novartis Pharma in acidic media of pH 1.2 and buffer media of pH 6.8. values of F2 are in acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Vision pharmaceuticals, Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad.		
API Lot No.	EMZ045931.		
Description of Pack (Container closure system)	14 capsules are sealed in Alu-Alu blister with aluminum foil having leaflet and packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	20L560	20F525	20C516
Batch Size	140,000 Capsules	140,000 Capsules	140,000 Capsules
Manufacturing Date	06-2020	06-2020	06-2020
Date of Initiation	05-06-2020	09-06-2020	13-06-2020
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.
Administrative Portion

25.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
26.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of manufacturing license No. Lu 20150511 valid till 26-10-2025. (Raw materials, Sterile raw materials)
27.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
28.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
29.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
30.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks by the Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	• Valid copy of DML of the manufacturer shall be submitted.	Firm has submitted copy of receiving in DRAP dated 06-06-2022 wherein they have applied for renewal of their DML with a fee of 75000/- vide slip No. 4594197690 dated 28-05-2022.
		• Valid copy of GMP certificate of the contract acceptor shall be submitted.	Firm has submitted copy of GMP certificate No. 47/2020-DRAP (AD-849966-789) dated 26-02-2020 issued on the basis of inspection conducted on 13-02-2020. *GMP certificate is not within last three years.*
2.	2.3	• Justification shall be submitted for providing information regarding Esomeprazole instead of Esomeprazole magnesium trihydrate pellets in section 2.3.	Firm has submitted that as Identified by you, it's been a Drafting error. Esomeprazole Magnesium Trihydrate has been used & same could be verified by Nomenclature in open part of DMF by Vision Pharmaceuticals & also by COA of Drug substance manufacturer which is attached. Nomenclature and COA provide by the firm has mentioned Esomeprazole Magnesium Trihydrate.
		• Revised table for literature references with correct information regarding the drug substance with applicable fee shall be submitted.	Revised table for literature references with correct information regarding the drug substance is submitted. ***Fee for pre-registration variation is not submitted.***
3.	2.3.R.1.1	Provide copy of Batch manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Submitted.
4.	3.2.S.4.1	Specifications of the drug substance by the drug substance manufacturer	Firm has submitted that no USP monograph is available for the Esomeprazole pellets, the

		has mentioned USP specification while there is no monograph available for Esomeprazole magnesium trihydrate pellets. Justification shall be submitted.	specifications were referred as USP since the limits of several tests have been adopted form the USP monograph of Esomeprazole delayed release capsules. Kindly consider it as in-house.
5.	3.2.S.4.2	Analytical procedures for the drug substance from the drug substance manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
7.	3.2.S.4.4	Batch analysis has performed dissolution test on UV method. Justification shall be submitted.	Firm has submitted that Drug substance analytical method does not exist in any Pharmacopeia, that's why test method from API supplier was used for the analysis of Pellets.
8.	3.2.S.5	Details/COA of the working standard used for analysis of the trial batches shall be submitted.	Submitted.
9.	3.2.P.1	This section has mentioned that 102.2mg of Esomeprazole pellets (22.5%) is equivalent to 20mg of Esomeprazole. Justification shall be submitted.	The filled weight is calculated on basis of the Assay results of Esomeprazole magnesium on as is basis which is further adjusted for the factor of Magnesium to get the label claim of Esomeprazole.
10.	3.2.P.2.2	• Justification shall be submitted for not performing CDP and PE against the innovator product. • Details of the comparator product shall be submitted. • Justification shall be submitted for carrying CDP in acidic media for 60 minutes only.	Firm has submitted that since the innovator product is not registered in Pakistan hence the CDP studies were performed against the comparator product. Comparator product Details: Product name: Nexum capsule. By Getz Pharma Firm has submitted that it was an error in compiling record for CDP Report. They further submitted that they perform CDP in acidic medium till 120 minutes and the results are satisfactory. They also provided the results of CDP in 0.1 N HCl till 120 minutes and values of F2 are in acceptable range.
11.	3.2.P.5.4	Uniformity of dosage units is not performed in batch analysis. Justify.	Firm has submitted that they performed Uniformity of dosage units, however, in compilation it was missed. They submitted revised batch analysis wherein they have added Uniformity of dosage units for the applied product.
12.	3.2.P.8	• Stability data sheets has mentioned 06-2020 as manufacturing date while stability conclusion has mentioned 01-2021 as manufacturing date. Justification is required. • Documents for procurement of API shall be submitted.	As identified by your good office, there was a Drafting mistake in drafting i.e., Stability summary and conclusions, all three batches were manufactured in 06/2020 & same could be verified with Analytical record that is attached in 3.2.8.3 i.e., stability. Firm has submitted copy of invoice No. 601023 dated 08-10-2019 mentioning 45kg of 22.5% pellets with batch No. EMZ045931, Mfg. date 09-2019)

	• Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Firm has submitted that it is not applicable.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter will be issued upon submission of latest GMP certificate/last inspection report of the contract acceptor within last three years and fee of Rs. 7,500/- fee for revision as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.**

872.	Name, address of Applicant / Marketing Authorization Holder	M/s Stallion Pharmaceuticals (Pvt.) Ltd., Plot No. 581, Sunder Industrial Estate, Lahore.
	Name, address of Manufacturing site.	M/s Bio-Mark Pharmaceuticals, Plot No. 527, Sunder Industrial Estate, Lahore.
	Status of the applicant	☐Manufacturer ☐ Importer ☒Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3725; dated 09/02/2022.
	Details of fee submitted	PKR 75 ,000/-: vide slip No.1131824421 dated 28/12/2021.
	The proposed proprietary name / brand name	Staesso 40mg capsules.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Esomeprazole (as enteric coated pellets) ……... 40mg.
	Pharmaceutical form of applied drug	Oral capsule.
	Pharmacotherapeutic Group of (API)	PPI (Proton Pump Inhibitors).
	Reference to Finished product specifications	USP specifications.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Nexium 20mg & 40mg delayed release capsule, USFDA Approved.
	For generic drugs (me-too status)	Nexum 40mg Capsule, Getz Pharma, Reg. No. 033891.
	GMP status of the Finished product manufacturer	**Contract giver:** Copy of GMP certificate No. 131/2020-DRAP (AD-1952624-1099) dated 02-10-2020 issued on the basis of inspection conducted on 22-09-2020 is submitted.

		Contract acceptor: Copy of GMP certificate No. 47/2020-DRAP (AD-849966-789) dated 26-02-2020 issued on the basis of inspection conducted on 13-02-2020 is submitted.
	Evidence of section approval.	Capsule General section is approved in the above mentioned GMP certificate.
	Name and address of API manufacturer.	M/s Vision pharmaceuticals, Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad. Copy of GMP certificate No. 3-26/2019-Addl. Dir. (QA&LT-I) dated 31-07-2019 on the basis of inspection conducted on 11-02-2019 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detail of the drug substance regarding its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity, specifications, analytical procedures, batch analysis (EMZ046197, Mfg. date 11-09-2020) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted both real time and accelerated stability study data for the drug substance for three batches. Stability study conditions: Real time: 30˚C ± 2˚C /65% ± 5% RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 6 months Batches: (EMZ044440, EMZ044265 & EMZ044152)
	Module-III (Drug Product):	The firm has submitted detail of the drug product including its description & composition, Pharmaceutical equivalence, manufacturers, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand Nexium 40 mg Capsules manufactured by Getz Pharma by performing quality tests (Identification, weight variation, loss on drying, Dissolution in acidic and buffer stage, uniformity of dosage units & Assay). CDP is performed against the brand Nexium 40mg capsules batch No. 883C19 manufactured by Novartis Pharma in acidic media of pH 1.2 and buffer media of pH 6.8. values of F2 are in acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, accuracy, precision, specificity.
STABILITY STUDY DATA		

Manufacturer of API	M/s Vision pharmaceuticals, Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad.		
API Lot No.	EMZ046197.		
Description of Pack (Container closure system)	14 capsules are sealed in Alu-Alu blister with aluminum foil having leaflet and packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	20M564	21B507	21B509
Batch Size	70000 Capsules	70000 Capsules	70000 Capsules
Manufacturing Date	02-2021	02-2021	02-2021
Date of Initiation	15-02-2021	20-02-2021	22-02-2021
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

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

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has submitted that Bio-Mark is new license facility, hence no such inspection has been conducted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 3-26/2019-Addl. Dir. (QA&LT-I) dated 31-07-2019 on the basis of inspection conducted on 11-02-2019 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks by the Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	• Valid copy of DML of the manufacturer shall be submitted.	Firm has submitted copy of receiving in DRAP dated 06-06-2022 wherein they have applied for renewal of their DML with a fee of 75000/- vide slip No. 4594197690 dated 28-05-2022.

		• Valid copy of GMP certificate of the contract acceptor shall be submitted.	Firm has submitted copy of GMP certificate No. 47/2020-DRAP (AD-849966-789) dated 26-02-2020 issued on the basis of inspection conducted on 13-02-2020. *GMP certificate is not within last three years.*
2.	2.3	• Justification shall be submitted for providing information regarding Esomeprazole instead of Esomeprazole magnesium trihydrate pellets in section 2.3.	Firm has submitted that as Identified by you, it's been a Drafting error. Esomeprazole Magnesium Trihydrate has been used & same could be verified by Nomenclature in open part of DMF by Vision Pharmaceuticals & also by COA of Drug substance manufacturer which is attached. Nomenclature and COA provide by the firm has mentioned Esomeprazole Magnesium Trihydrate.
		• Revised table for literature references with correct information regarding the drug substance with applicable fee shall be submitted.	Revised table for literature references with correct information regarding the drug substance is submitted. *Fee for pre-registration variation is not submitted.*
3.	2.3.R.1.1	Provide copy of Batch manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3 section 3.2.P.8.3	Submitted.
4.	3.2.S.4.1	Specifications of the drug substance by the drug substance manufacturer has mentioned USP specification while there is no monograph available for Esomeprazole magnesium trihydrate pellets. Justification shall be submitted.	Firm has submitted that no USP monograph is available for the Esomeprazole pellets, the specifications were referred as USP since the limits of several tests have been adopted form the USP monograph of Esomeprazole delayed release capsules. Kindly consider it as in-house.
5.	3.2.S.4.2	Analytical procedures for the drug substance from the drug substance manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
7.	3.2.S.4.4	Batch analysis has performed dissolution test on UV method. Justification shall be submitted.	Firm has submitted that Drug substance analytical method does not exist in any Pharmacopeia, that's why test method from API supplier was used for the analysis of Pellets.
8.	3.2.S.5	Details/COA of the working standard used for analysis of the trial batches shall be submitted.	Submitted.
9.	3.2.P.1	This section has mentioned that 204.4mg of Esomeprazole pellets (22.5%) is equivalent to 40mg of Esomeprazole. Justification shall be submitted.	The filled weight is calculated on basis of the Assay results of Esomeprazole magnesium on as is basis which is further adjusted for the factor of Magnesium to get the label claim of Esomeprazole.
10.	3.2.P.2.2	• Justification shall be submitted for not performing CDP and PE against the innovator product.	Firm has submitted that since the innovator product is not registered in Pakistan hence the CDP studies were performed against the comparator product.
		• Details of the comparator product shall be submitted.	Comparator product Details: Product name: Nexum capsule.

		• Justification shall be submitted for carrying CDP in acidic media for 60 minutes only.	By Getz Pharma Firm has submitted that it was an error in compiling record for CDP Report. They further submitted that they perform CDP in acidic medium till 120 minutes and the results are satisfactory. They also provided the results of CDP in 0.1 N HCl till 120 minutes and values of F2 are in acceptable range.
11.	3.2.P.5.4	Uniformity of dosage units is not performed in batch analysis. Justify.	Firm has submitted that they performed Uniformity of dosage units, however, in compilation it was missed. They submitted revised batch analysis wherein they have added Uniformity of dosage units for the applied product.
12.	3.2.P.8	• Documents for procurement of API shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Firm has submitted copy of invoice No. 601023 dated 08-10-2019 mentioning 45kg of 22.5% pellets with batch No. EMZ045931, Mfg. date 09-2019) Firm has submitted that it is not applicable.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter will be issued upon submission of latest GMP certificate/last inspection report of the contract acceptor within last three years and fee of Rs. 7,500/- fee for revision as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.**

Case 02; Registration applications of deferred locally manufactured cases (Human) drugs on Form 5F.

873.	Name, address of Applicant / Marketing Authorization Holder	M/s Pinnacle Biotech (Pvt.) Ltd., Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd., Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 846; dated 10-01-2023.

	Details of fee submitted	PKR 30,000/- vide slip No. 868427408767 dated 16/11/2022.
	The proposed proprietary name / brand name	Gasdex 30mg Capsules.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Dexlansoprazole Dual Delayed Released Pellets (17%) Equivalent to Dexlansoprazole ……30mg
	Pharmaceutical form of applied drug	Pellet Filled HPMC Capsule, Size 2
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI).
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dexilant Capsules 30mg & 60mg, USFDA Approved.
	For generic drugs (me-too status)	Razodex 30mg Capsules, M/s Getz Pharma Pakistan (Pvt.) Ltd., Reg. No. 086976.
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021 Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved. GMP certificate No. 182/022-DRAP (K) dated 21-10-2022 issued on the basis of inspection conducted on 21-10-2022 is submitted.
	Evidence of section approval.	Capsule general section approved vide letter No. F. 2-10/2011-Lic(Vol-I) dated 13-09-2021.
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan. Copy of GMP certificate No.F. 3-26/2019-Addl. Dir. (QA&LT-I)-56 dated 22-08-2022 on the basis of inspection conducted on 14-06-2022 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detail of drug substance related to its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis (B. No. DLP864, mfg. date 24-02-2022) and

		justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted both real time and accelerated stability data sheets for drug substance. Stability data conditions are as follows: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months. Accelerated: 40°C ± 2°C / 75% ± 5%RH for 06 months. Batch No. (DLP260, DLP252 & DLP253)
	Module-III (Drug Product):	Firm has submitted detail of the drug product regarding its description & composition, pharmaceutical development, manufacturers, description of manufacturing process and controls, impurities, Process validation protocol, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand leader that is Razodex 30mg Capsules, B. No. 064C47, mfg. date 08-2021 manufactured by M/s Getz Pharma, by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP is also performed against the same brand that is Razodex 30mg Capsules, B. No. 064C47, mfg. date 08-2021 manufactured by M/s Getz Pharma, in Acid media of 0.1N, Buffer (pH 5.5) and Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including Accuracy, Precision (Repeatability), specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad-Pakistan.		
API Lot No.	Not submitted.		
Description of Pack (Container closure system)	Alu. Alu. Blister strips of 3x10 Capsules packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T062	T063	T064
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules

Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	17-06-2022	17-06-2022	17-06-2022
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

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

Administrative Portion

31.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
32.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. F. 3-26/2019-Addl. Dir. (QA&LT-I)-56 dated 22-08-2022 on the basis of inspection conducted on 14-06-2022 is submitted.
33.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
34.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
35.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
36.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks by the Evaluator:

Sr. No.	Section	Observation	Response by the firm
1.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	Firm has submitted 30's as proposed pack size for the applied formulation.
2.	3.2.S.4.1	Neither drug substance manufacturer nor drug product manufacturer has mentioned that assay in on anhydrous basis or as is basis.	Firm has submitted that drug pellets manufacturer has claimed assay of drug substance on as is basis and same is from finished product manufacturer.
3.	3.2.S.4.4	COA from drug substance manufacturer potency is on anhydrous basis or as is basis.	Firm has submitted COA from the drug substance manufacturer wherein the potency is on as is basis.
4.	3.2.S.5	Details and COA of the working standard used during formulation development shall be submitted.	Submitted.
5.	3.2.S.6	Justification shall be submitted regarding packaging material used during the stability studies of the drug substance as section 3.2.S.6 has mentioned LDPE and HDPE while the stability data sheets has mentioned PET bottles.	Firm has submitted that stability samples are filled in polybags and finally packed in HDPE bottles, they also submitted corrected and updated stability data for the drug substance.
6.	3.2.P.2.2	• Justification for not performing CDP & PE against the innovator product shall be submitted.	Firm has submitted that Dexilant is innovator product and at the time of studies the innovator sample was not available in the

			local market and we performed CDP & PE against razodex 30mg capsules manufactured by Getz pharma.
		• Comparison of CDP in all the three mediums separately shall be submitted.	Firm has submitted revised CDP results for the applied formulation in acidic medium pH 1.2 and buffer pH 6.8.
7.	3.2.P.5.1	Drug product specifications has mentioned assay as BP specifications. Clarify.	Firm has submitted revised specifications for the drug product wherein they have changed BP specifications to Innovator's specifications. *Fee required for pre-registration variation is not submitted.*
8.	3.2.P.5.2	• Analytical procedures for assay test of the finished product has mentioned 0.01mg/ml standard solution while the descriptive procedure has strength of 0.05mg/ml strength of standard solution. Clarification shall be submitted. • Similarly, sample solution has mentioned 0.01mg/ml standard solution while the descriptive procedure has strength of 0.025mg/ml strength of sample solution. Clarification shall be submitted. • Calculation formula for assay test is also different from the analytical procedure. Justify.	Firm has submitted that it was typo error and concentration of both sample and standard preparation 0.01mg/ml. they also submitted corrected and revised testing method. Firm has also submitted calculation formula.
9.	3.2.P.8	• Justify the weight of standard in assay test with respect to the analytical procedure for assay test. • Justify the weight of standard in dissolution test with respect to the analytical procedure for dissolution test.	Firm has submitted that this mistake was due to typo error in the testing method which has now been rectified. Firm has submitted rectified testing method wherein the standard preparation in the dissolution test has mentioned that "take accurately weghed Dexlansoprazole working standard (on anhydrous basis) equivalent to 50mg" *However, the raw data sheets have clearly mentioned 30mg which is not justified by the firm.*
		• 92.56% potency used in assay and dissolution test shall be justified.	Firm has submitted COA of the working standard used in the trial batches and has potency of 92.56.
		• Stability data shall be as per decision of 293rd meeting with inclusion of API lot number in the stability data sheets.	Firm has submitted revised stability data sheets with inclusion of API lot number. *However, the API lot number mentioned in the stability data sheets is RLP-0360321 while the batch analysis provided by the firm in 3.2.S.4.4 is having lot no. DLP 864.*
		• Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	*Not submitted.*
		• Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	*Not submitted.*

- Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.

Decision of 326th meeting of Registration Board: Deferred for following:

- Justification for variation in the standard solution concentration as declared n raw data sheets from that mention din the drug product analytical procedure for Assay & Dissolution test.
- Justification for variation in calculation formula applied in the raw data sheet from that mentioned in the drug product analytical procedure for Assay test.
- Clarification for variation in the API lot# mentioned in the stability summary sheet from that declared on the drug substance COA.
- Submission of fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021

Reply by the firm:

Sr. No.	Reason for deferment	Reply submitted by the firm
1.	Justification for variation in the standard solution concentration as declared n raw data sheets from that mention than the drug product analytical procedure for Assay & Dissolution test.	Firm has submitted that it was a typo error in assay Method, concentration of sample and standard is 0.015mg/ml, correction made revised testing method is attached. As per testing method for dissolution testing, 50mg of standard required for dissolution testing but only at initial testing that is zero (0) frequency, analyst by mistake weigh 30mg of standard and the same weight will be used for calculation. Throughout the stability studies testing that is at 3rd & 6th month of both accelerated and long term, 50mg of standard weight is used and same will be used in calculation. Raw data for stability are attached for your reference
2.	Justification for variation in calculation formula applied in the raw data sheet from that mentioned in the drug product analytical procedure for Assay test.	Firm has submitted that it was typo error and they also provided corrected calculation formula.
3.	Clarification for variation in the API lot# mentioned in the stability summary sheet from that declared on the drug substance COA.	Firm has submitted revised stability data sheets wherein they have changed API lot No. as per the API lot No. mentioned in the COA of the drug substance.
4.	Submission of fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021	Firm has submitted 7500/- fee vide sip No. 100610619966 dated 10-03-2023.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

874.	Name, address of Applicant / Marketing Authorization Holder	M/s Pinnacle Biotech (Pvt.) Ltd., Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.

	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd., Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 847; dated 10-01-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 23808790439 dated 16/11/2022.
	The proposed proprietary name / brand name	Gasdex 60mg Capsules.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Dexlansoprazole Dual Delayed Released Pellets (22.5%) Equivalent to Dexlansoprazole ……60mg
	Pharmaceutical form of applied drug	Pellet Filled HPMC Capsule, Size 2
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI).
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dexilant Capsules 30mg & 60mg, USFDA Approved.
	For generic drugs (me-too status)	Razodex 60mg Capsules, M/s Getz Pharma Pakistan (Pvt.) Ltd., Reg. No. 086977.
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021 Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved. GMP certificate No. 182/022-DRAP (K) dated 21-10-2022 issued on the basis of inspection conducted on 21-10-2022 is submitted.
	Evidence of section approval.	Capsule general section approved vide letter No. F. 2-10/2011-Lic(Vol-I) dated 13-09-2021.
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan. Copy of GMP certificate No. F. 3-26/2019-Addl. Dir. (QA&LT-I)-56 dated 22-08-2022 on the basis of inspection conducted on 14-06-2022 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties,

		solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detail of drug substance related to its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis (B. No. DLP865, mfg. date 24-03-2022) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted both real time and accelerated stability data sheets for drug substance. Stability data conditions are as follows: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months. Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months. Batch No. (DLP125T, DLP124T & DLP123T)
	Module-III (Drug Product):	Firm has submitted detail of the drug product regarding its description & composition, pharmaceutical development, manufacturers, description of manufacturing process and controls, impurities, Process validation protocol, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand leader that is Razodex 60mg Capsules, B. No. 061C48, mfg. date 08-2021 by M/s Getz Pharma, by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP is also performed against the same brand that is Razodex 60mg Capsules, B. No. 061C48, mfg. date 08-2021 by M/s Getz Pharma, in Acid media of 0.1N, Buffer (pH 5.5) and Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including Accuracy, Precision (Repeatability), specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad-Pakistan.
API Lot No.	NA
Description of Pack (Container closure system)	Alu. Alu. Blister strips of 3x10 Capsules packed in unit carton.

Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T065	T066	T070
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	17-06-2022	17-06-2022	17-06-2022
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

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

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No.F. 3-26/2019-Addl. Dir. (QA&LT-I)-56 dated 22-08-2022 on the basis of inspection conducted on 14-06-2022 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks by the Evaluator:

Sr. No.	Section	Observation	Response by the firm
1.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	Firm has submitted 30's as proposed pack size for the applied formulation.
2.	2.3.R	Table for literature references has mentioned USP for drug substance and drug product while there is no official monograph for dexlansoprazole pellets. Revised table for literature references with applicable fee shall be submitted.	Firm has submitted revised table for literature references wherein they have not mentioned anything against the drug substance and drug product with submission of 7500/- fee vide slip No. 1377271048 dated 02-03-2023.
3.	3.2.S.4.1	Neither drug substance manufacturer nor drug product manufacturer has	Firm has submitted that drug pellets manufacturer has claimed assay of drug

		mentioned that assay in on anhydrous basis or as is basis.	substance on as is basis and same is from finished product manufacturer.
4.	3.2.S.4.4	COA from drug substance manufacturer potency is on anhydrous basis or as is basis.	Firm has submitted COA from the drug substance manufacturer wherein the potency is on as is basis.
5.	3.2.S.5	Details and COA of the working standard used during formulation development shall be submitted.	Submitted.
6.	3.2.S.6	Justification shall be submitted regarding packaging material used during the stability studies of the drug substance as section 3.2.S.6 has mentioned LDPE and HDPE while the stability data sheets has mentioned PET bottles.	Firm has submitted that stability samples are filled in polybags and finally packed in HDPE bottles, they also submitted corrected and updated stability data for the drug substance.
7.	3.2.S.7.3	• Specifications has mentioned release in buffer pH 5.5 of 15-40% in one hour while the stability data sheet has mentioned NMT 30%. Clarification shall be submitted. • Similarly, the release in pH 7 medium has different values than mentioned in specifications. Justify.	Firm has submitted that previously submitted stability data was of trial batches and testing performed on stringent specifications, to get confidence on formulation prior to commercialize. But from very first commercial consignment, specifications were same as mentioned in shared COA and recently provided stability data is of commercial lots and on the same specifications.
8.	3.2.P.2.2	• Justification for not performing CDP & PE against the innovator product shall be submitted. • Comparison of CDP in all the three mediums separately shall be submitted.	Firm has submitted that Dexilant is innovator product and at the time of studies the innovator sample was not available in the local market and we performed CDP & PE against razodex 60mg capsules manufactured by Getz pharma. Firm has submitted revised CDP results for the applied formulation in acidic medium pH 1.2 and buffer pH 6.8.
9.	3.2.P.5.1	Drug product specifications has mentioned assay as BP specifications. Clarify.	Firm has submitted revised specifications for the drug product wherein they have changed BP specifications to Innovator's specifications.
10.	3.2.P.5.2	• Analytical procedures for assay test of the finished product has mentioned 0.01mg/ml standard solution while the descriptive procedure has strength of 0.05mg/ml strength of standard solution. Clarification shall be submitted. • Similarly, sample solution has mentioned 0.01mg/ml standard solution while the descriptive procedure has strength of 0.025mg/ml strength of sample solution. Clarification shall be submitted. • Calculation formula for assay test is also different from the analytical procedure. Justify.	Firm has submitted that it was typo error and concentration of both sample and standard preparation 0.01mg/ml. they also submitted corrected and revised testing method. Firm has also submitted calculation formula.

11.	3.2.P.8	• Justify the weight of standard in assay test with respect to the analytical procedure for assay test.	Firm has submitted that this mistake was due to typo error in the testing method which has now been rectified. Firm has submitted rectified testing method wherein the standard preparation in the dissolution test has mentioned that "take accurately weighed Dexlansoprazole working standard (on anhydrous basis) equivalent to 50mg" *However, the raw data sheets have clearly mentioned 30mg which is not justified by the firm.*
		• Stability data shall be as per decision of 293rd meeting with inclusion of API lot number in the stability data sheets.	Firm has submitted revised stability data sheets with inclusion of API lot number. *However, the API lot number mentioned in the stability data sheets is RLP-0360321 while the batch analysis provided by the firm in 3.2.S.4.4 is having lot no. DLP 864.*
		• Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	*Not submitted.*
		• Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	*Not submitted.*
		• Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	

Decision of 326th meeting of Registration Board: Deferred for following:

- Justification for variation in the standard solution concentration as declared n raw data sheets from that mention than the drug product analytical procedure for Assay & Dissolution test.
- Justification for variation in calculation formula applied in the raw data sheet from that mentioned in the drug product analytical procedure for Assay test.
- Clarification for variation in the API lot# mentioned in the stability summary sheet from that declared on the drug substance COA.
- Submission of fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.

Reply by the firm:

Sr. No.	Reason for deferment	Reply submitted by the firm
1.	Justification for variation in the standard solution concentration as declared n raw data sheets from that mention than the drug product analytical procedure for Assay & Dissolution test.	Firm has submitted that it was a typo error in assay Method, concentration of sample and standard is 0.015mg/ml, correction made revised testing method is attached. As per testing method for dissolution testing, 50mg of standard required for dissolution testing but only at initial testing that is zero (0) frequency, analyst by mistake weigh 30mg of standard and the same weight will be used for calculation. Throughout the stability studies testing that is at 3rd & 6th month of both accelerated and long term, 50mg of standard weight is used and same will be used in calculation. Raw data for stability are attached for your reference

2.	Justification for variation in calculation formula applied in the raw data sheet from that mentioned in the drug product analytical procedure for Assay test.	Firm has submitted that it was typo error and they also provided corrected calculation formula.
3.	Clarification for variation in the API lot# mentioned in the stability summary sheet from that declared on the drug substance COA.	Firm has submitted revised stability data sheets wherein they have changed API lot No. as per the API lot No. mentioned in the COA of the drug substance.
4.	Submission of fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021	Firm has submitted 7500/- fee vide sip No. 1377271048 dated 02-03-2023.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

875.	Name, address of Applicant / Marketing Authorization Holder	M/s Pinnacle Biotech (Pvt.) Ltd., Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd., Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 368; dated 04-01-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 788738343417 dated 16/11/2022.
	The proposed proprietary name / brand name	Gabstar 50mg Capsules
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Pregabalin …….……50mg
	Pharmaceutical form of applied drug	Hard Gelatin Capsules.
	Pharmacotherapeutic Group of (API)	Other Analgesics and *Antipyretics.*
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Lyrica (Pregabalin) 50mg, 75mg, 100mg, 150mg, 200mg Capsules, USFDA Approved.
	For generic drugs (me-too status)	Gabica 50mg Capsules, Getz Pharma Pakistan (Pvt.) Ltd., Reg. No. 048725
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021 Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved. GMP certificate No. 182/022-DRAP (K) dated 21-10-2022 issued on the basis of inspection conducted on 21-10-2022 is submitted.
	Evidence of section approval.	Capsule general section approved vide letter No. F. 2-10/2011-Lic(Vol-I) dated 13-09-2021.
	Name and address of API manufacturer.	M/s Almelo Private Limited. Unit-II Survey No. 227, 228 & 136, 137 Shabashpally (V), Shivampet (M) Medak District, Telangana-502334. India. Copy of GMP certificate No. L. Dis. No. 101460/TS/2022 dated 04-11-2022 issued by the DCA, Telangana State in the name of M/s Almelo Private Limited, Plot No. A-38 & 39, Road No.7, IDA Kukatpally, Gandhi Nagar, Hyderabad-500037., Balangar Village, Balangar Mandal, Medchal-Malkajgri District, Telangana State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The official monograph of Pregabalin is present in USP & BP. Firm as submitted detail of the drug substance regarding its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (PBF/K/21/0014, mfg. date 15-11-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies (Drug substance.)	Firm has submitted stability data sheets for both real time and accelerated stability data as per zone IV-A for three batches. Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 24 months. Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months. Batch No. (PEF/H/18/0003, PEF/H/18/0004 & PEF/H/18/0005)

	Module-III (Drug Product):	Firm has submitted detail of drug product regarding its description & composition, pharmaceutical development, Process validation protocol, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand leader that is Gabica 50mg Capsules, Batch No. 244C28, mfg. date 03-2022 manufactured by M/s Getz Pharma, by performing quality tests (Identification, Average weight content, Disintegration time, Dissolution & Assay). Results of both the products are comparable. CDP is also performed against the same brand that is Gabica 50mg Capsules, Batch No. 244C28, mfg. date 03-2022 manufactured by M/s Getz Pharma, in Acid media (pH 1.2) & Phosphate Buffer (pH 6.8) and acetate Buffer (pH 4.5). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Analytical Method verification studies have submitted including Accuracy, Precision (Repeatability), specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Almelo Private Limited. Unit-II Survey No. 227, 228 & 136, 137 Shabashpally (V), Shivampet (M) Medak District, Telangana- 502334. India.		
API Lot No.	PBF/K/21/0014		
Description of Pack (Container closure system)	Alu/Alu Blister strips of 2x7 Capsules packed in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T072	T076	T077
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	30-06-2022	30-06-2022	30-06-2022
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION		
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.		
Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. L. Dis. No. 101460/TS/2022 dated 04-11-2022 issued by the DCA, Telangana State in the name of M/s Almelo Private Limited, Plot No. A-38 & 39, Road No.7, IDA Kukatpally, Gandhi Nagar, Hyderabad-500037., Balangar Village, Balangar Mandal, Medchal-Malkajgri District, Telangana State, India. Valid till 03/11/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted computerized certificate No. K-399471413819 dated 28/04/2022 wherein they have imported 2kg of Pregabalin USP from M/s Almelo Private Limited., Unit-II Survey No. 227, 228 & 136, 137 Shabashpally(V), Shivampet(M) Medak District, Telangana- 502334 India.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks by the Evaluator:

Sr. No.	Section	Observation	Response by the firm
1.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	Firm has submitted 10's, 14's, 20's, 30's as proposed pack sizes for the applied formulation.
2.	1.5.5	Revise pharmacological group as per WHO ATC classifications with applicable fee shall be submitted.	Firm has revised pharmacological group as per WHO ATC classifications with submission of 7500/- fee vide slip No. 17180803563 dated 23-02-2023.
3.	1.6.5	• Address of the drug substance manufacturer mentioned in section this section, Clearance certificate and on DMF is completely different from that mentioned on GMP certificate. Justification shall be submitted. • Furthermore, valid copy of GMP certificate of M/s Almelo Private Limited., Unit-II Survey No. 227, 228 & 136, 137 Shabashpally(V), Shivampet(M) Medak District, Telangana- 502334 India.	Firm has submitted that they have mistakenly attached GMP certificate having different address in our dossier. They also provided copy of GMP certificate No. L. Dis. No: 92502/TS/2022 Dated:11/07/2022 issued by Drugs Control Administration Government of Telangana in the name of M/s Almelo Private Limited Unit Ii Situated at Address Survey Nos. 227, 228 & 137, 136, Shabashpally Village, Shivampet Mandal, Medak District, Pin code 502334, Telangana State, India. Valid till 10/07/2023.
4.	2.3.R	Table for literature references has mentioned USP for drug substance only. However, it is also available in BP and other. Revised table for literature references with applicable fee shall be submitted.	Firm has submitted correct table for literature references.

5.	3.2.S.4.3	Verification of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.4	COA of the drug substance from both the drug substance manufacturer and finished product manufacturer with same batch number shall be submitted.	*Firm has once again submitted the same COA with different batch number from that of the drug substance manufacturer*.
7.	3.2.P.1.3	This section has mentioned Alu/Alu Blister strips of 2x7 Tablets packed in unit carton. Clarify.	Firm has submitted that It was Typographic mistake and they also submitted revised copy of Section 3.2.P.1.3. wherein they have replaced tablets with capsules.
8.	3.2.P.2.2	Justification for not performing CDP & PE against the innovator product shall be submitted.	Firm has submitted that Lyrica is an innovator of pregabalin capsule. In local market at the time of study only Lyrica 75mg capsule is available so we have chosen another market leader for performing CDP that is Gabica 50mg capsule manufactured by Getz Pharma.
9.	3.2.P.5.1	Specifications and stability data sheets have not mentioned any dissolution time. Justify.	Firm has submitted that dissolution time is mentioned on testing method and they also submitted revised specification & Stability Summary sheets wherein they have added dissolution time.
10.	3.2.P.8	• Stability data shall be as per decision of 293rd meeting with inclusion of API lot number in the stability data sheets. • Complete six-month stability data shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Firm has submitted revised stability data sheets wherein they have included API lot number. Complete six-month stability data is submitted by the firm. Firm has submitted that in DRB 323 Meeting our 8 Products of tablet section was approved. Submitted.
11.		Justification shall be submitted for using 2 different volumes in sample one and two for preparation of test solution in calculation of assay of trial batches.	Firm has submitted that It was typo graphical error, as per testing method it is 250 instead of 100 correction made revised reports are also submitted.

Decision of 326th meeting of Registration Board: Deferred for justification for variation in batch no. of COAs provided from drug substance manufacturer and drug product manufacturer.
Reply submitted by the firm:
Firm has submitted that it was a typo error and they also provided corrected COA with same batch number as that of the drug substance manufacturer.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

876.	Name, address of Applicant / Marketing Authorization Holder	M/s Pinnacle Biotech (Pvt.) Ltd., Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.

	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd., Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 369; dated 04-01-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 22232543805 dated 16/11/2022.
	The proposed proprietary name / brand name	Gabstar 75mg Capsules
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Pregabalin …….……75mg
	Pharmaceutical form of applied drug	Hard Gelatin Capsules.
	Pharmacotherapeutic Group of (API)	Analgesics and *Anticonvulsant drug.*
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lyrica (Pregabalin) 50mg, 75mg, 100mg, 150mg, 200mg Capsules, USFDA Approved.
	For generic drugs (me-too status)	Gabica 75mg Capsules, Getz Pharma Pakistan (Pvt.) Ltd., Reg. No. 047365
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021 Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved. GMP certificate No. 182/022-DRAP (K) dated 21-10-2022 issued on the basis of inspection conducted on 21-10-2022 is submitted.
	Evidence of section approval.	Capsule general section approved vide letter No. F. 2-10/2011-Lic(Vol-I) dated 13-09-2021.
	Name and address of API manufacturer.	M/s Almelo Private Limited. Unit-II Survey No. 227, 228 & 136, 137 Shabashpally (V), Shivampet (M) Medak District, Telangana-502334. India. Copy of GMP certificate No. L. Dis. No. 101460/TS/2022 dated 04-11-2022 issued by the DCA, Telangana State in the name of M/s Almelo Private Limited, Plot No. A-38 & 39, Road No.7, IDA Kukatpally, Gandhi Nagar, Hyderabad-500037., Balangar Village, Balangar Mandal, Medchal-Malkajgri District, Telangana State, India.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The official monograph of Pregabalin is present in USP & BP. Firm as submitted detail of the drug substance regarding its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (KBF/K/21/0014, mfg. date 15-11-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted stability data sheets for both real time and accelerated stability data as per zone IV-A for three batches. Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 24 months. Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months. Batch No. (PEF/H/18/0003, PEF/H/18/0004 & PEF/H/18/0005)
	Module-III (Drug Product):	Firm has submitted detail of drug product regarding its description & composition, pharmaceutical development, Process validation protocol, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the innovator brand that is Lyrica 75mg Capsules, Batch No. EY7448, mfg. date 01-2021 manufactured by M/s Pfizer Pharma, Germany by performing quality tests (Identification, Average weight content, Disintegration time, Dissolution & Assay). Results of both the products are comparable. CDP is also performed against the same brand that is Lyrica 75mg Capsules, Batch No. EY7448, mfg. date 01-2021 manufactured by M/s Pfizer Pharma, Germany in Acid media (pH 1.2) & Phosphate Buffer (pH 6.8) and acetate Buffer (pH 4.5). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Analytical Method verification studies have submitted including Accuracy, Precision (Repeatability), specificity.
STABILITY STUDY DATA		

Manufacturer of API	M/s Almelo Private Limited. Unit-II Survey No. 227, 228 & 136, 137 Shabashpally (V), Shivampet (M) Medak District, Telangana- 502334. India.		
API Lot No.	KBF/K/21/0014		
Description of Pack (Container closure system)	Alu/Alu Blister strips of 2x7 Capsules packed in unit carton.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T071	T074	T075
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	30-06-2022	30-06-2022	30-06-2022
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

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

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. L. Dis. No. 101460/TS/2022 dated 04-11-2022 issued by the DCA, Telangana State in the name of M/s Almelo Private Limited, Plot No. A-38 & 39, Road No.7, IDA Kukatpally, Gandhi Nagar, Hyderabad-500037., Balangar Village, Balangar Mandal, Medchal-Malkajgri District, Telangana State, India. Valid till 03/11/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted computerized certificate No. K-399471413819 dated 28/04/2022 wherein they have imported 2kg of Pregabalin USP from M/s Almelo Private Limited., Unit-II Survey No. 227, 228 & 136, 137 Shabashpally(V), Shivampet(M) Medak District, Telangana- 502334 India.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks by the Evaluator:

Sr. No.	Section	Observation	Response by the firm
1.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	Firm has submitted 10's, 14's, 20's, 30's as proposed pack sizes for the applied formulation.
2.	1.5.5	Revise pharmacological group as per WHO ATC classifications with applicable fee shall be submitted.	Firm has revised pharmacological group as per WHO ATC classifications with submission of 7500/- fee vide slip No. 306443220047 dated 23-02-2023.
3.	1.6.5	• Address of the drug substance manufacturer mentioned in section this section, Clearance certificate and on DMF is completely different from that mentioned on GMP certificate. Justification shall be submitted. • Furthermore, valid copy of GMP certificate of M/s Almelo Private Limited., Unit-II Survey No. 227, 228 & 136, 137 Shabashpally(V), Shivampet(M) Medak District, Telangana- 502334 India.	Firm has submitted that they have mistakenly attached GMP certificate having different address in our dossier. They also provided copy of GMP certificate No. L. Dis. No: 92502/TS/2022 Dated:11/07/2022 issued by Drugs Control Administration Government of Telangana in the name of M/s Almelo Private Limited Unit Ii Situated at Address Survey Nos. 227, 228 & 137, 136, Shabashpally Village, Shivampet Mandal, Medak District, Pin code 502334, Telangana State, India. Valid till 10/07/2023.
4.	2.3.R	Table for literature references has mentioned USP for drug substance only. However, it is also available in BP and other. Revised table for literature references with applicable fee shall be submitted.	Firm has submitted correct table for literature references.
5.	3.2.S.4.3	Verification of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.4	COA of the drug substance from both the drug substance manufacturer and finished product manufacturer with same batch number shall be submitted.	*Firm has once again submitted the same COA with different batch number from that of the drug substance manufacturer.*
7.	3.2.P.1.3	This section has mentioned Alu/Alu Blister strips of 2x7 Tablets packed in unit carton. Clarify.	Firm has submitted that It was Typographic mistake and they also submitted revised copy of Section 3.2.P.1.3. wherein they have replaced tablets with capsules.
8.	3.2.P.2.2	Evidence of the pack of the innovator product shall be submitted.	Firm has submitted evidence of the innovator product with same batch number and manufacturing date as mentioned in CDP and PE.
9.	3.2.P.5.1	Specifications and stability data sheets have not mentioned any dissolution time. Justify.	Firm has submitted that dissolution time is mentioned on testing method and they also submitted revised specification & Stability Summary sheets wherein they have added dissolution time.
10.	3.2.P.8	• Stability data shall be as per decision of 293rd meeting with inclusion of API lot number in the stability data sheets. • Complete six-month stability data shall be submitted. • Reference of previous approval of applications with stability study data	Firm has submitted revised stability data sheets wherein they have included API lot number. Complete six-month stability data is submitted by the firm. Firm has submitted that in DRB 323 Meeting our 8 Products of tablet section was approved.

	of the firm (if any) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Submitted.
11.	Justification shall be submitted for using 2 different volumes in sample one and two for preparation of test solution in calculation of assay of trial batches.	Firm has submitted that It was typo graphical error, as per testing method it is 250 instead of 100 correction made revised reports are also submitted.

Decision of 326th meeting of Registration Board: Deferred for justification for variation in batch no. of COAs provided from drug substance manufacturer and drug product manufacturer.

Reply submitted by the firm:

Firm has submitted that it was a typo error and they also provided corrected COA with same batch number as that of the drug substance manufacturer.

Decision:

877.	Name, address of Applicant / Marketing Authorization Holder	M/s Pinnacle Biotech (Pvt.) Ltd., Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Name, address of Manufacturing site.	M/s Pinnacle Biotech (Pvt.) Ltd., Plot No. FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 370; dated 04-01-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 908689580 dated 16/11/2022.
	The proposed proprietary name / brand name	Gabstar 100mg Capsules
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Pregabalin ……100mg
	Pharmaceutical form of applied drug	Hard Gelatin Capsules.
	Pharmacotherapeutic Group of (API)	Analgesics and *Anticonvulsant drug.*
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Lyrica (Pregabalin) 50mg, 75mg, 100mg, 150mg, 200mg Capsules, USFDA Approved.
	For generic drugs (me-too status)	Gabica 100mg Capsules, Getz Pharma Pakistan (Pvt.) Ltd., Reg. No. 047366
	GMP status of the Finished product manufacturer	New license granted on 13/09/2021

		Tablet (general), Capsule (general), Sachet (general) and Research and Development Laboratory section is approved. GMP certificate No. 182/022-DRAP (K) dated 21-10-2022 issued on the basis of inspection conducted on 21-10-2022 is submitted.
	Evidence of section approval.	Capsule general section approved vide letter No. F. 2-10/2011-Lic(Vol-I) dated 13-09-2021.
	Name and address of API manufacturer.	M/s Almelo Private Limited. Unit-II Survey No. 227, 228 & 136, 137 Shabashpally (V), Shivampet (M) Medak District, Telangana-502334. India. Copy of GMP certificate No. L. Dis. No. 101460/TS/2022 dated 04-11-2022 issued by the DCA, Telangana State in the name of M/s Almelo Private Limited, Plot No. A-38 & 39, Road No.7, IDA Kukatpally, Gandhi Nagar, Hyderabad-500037., Balangar Village, Balangar Mandal, Medchal-Malkajgri District, Telangana State, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The official monograph of Pregabalin is present in USP & BP. Firm as submitted detail of the drug substance regarding its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (KBF/K/21/0014, mfg. date 15-11-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted stability data sheets for both real time and accelerated stability data as per zone IV-A for three batches. Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 24 months. Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months. Batch No. (PEF/H/18/0003, PEF/H/18/0004 & PEF/H/18/0005)
	Module-III (Drug Product):	Firm has submitted detail of drug product regarding its description & composition, pharmaceutical development, Process validation protocol, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard,

		container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand leader that is Gabica 100mg Capsules, Batch No. 165C26, mfg. date 02-2022 manufactured by M/s Getz Pharma, by performing quality tests (Identification, Average weight content, Disintegration time, Dissolution & Assay). Results of both the products are comparable. CDP is also performed against the same brand that is Gabica 100mg Capsules, Batch No. 165C26, mfg. date 02-2022 manufactured by M/s Getz Pharma, in Acid media (pH 1.2) & Phosphate Buffer (pH 6.8) and acetate Buffer (pH 4.5). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Analytical Method verification studies have submitted including Accuracy, Precision (Repeatability), specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Almelo Private Limited. Unit-II Survey No. 227, 228 & 136, 137 Shabashpally (V), Shivampet (M) Medak District, Telangana- 502334. India.		
API Lot No.	KBF/K/21/0014		
Description of Pack (Container closure system)	Alu/Alu Blister strips of 2x7 Capsules packed in unit carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T073	T078	T079
Batch Size	1500 Capsules	1500 Capsules	1500 Capsules
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	30-06-2022	30-06-2022	30-06-2022
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION		
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.		
Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	NA

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. L. Dis. No. 101460/TS/2022 dated 04-11-2022 issued by the DCA, Telangana State in the name of M/s Almelo Private Limited, Plot No. A-38 & 39, Road No.7, IDA Kukatpally, Gandhi Nagar, Hyderabad-500037., Balangar Village, Balangar Mandal, Medchal-Malkajgri District, Telangana State, India. Valid till 03/11/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted computerized certificate No. K-399471413819 dated 28/04/2022 wherein they have imported 2kg of Pregabalin USP from M/s Almelo Private Limited., Unit-II Survey No. 227, 228 & 136, 137 Shabashpally(V), Shivampet(M) Medak District, Telangana- 502334 India.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks by the Evaluator:

Sr. No.	Section	Observation	Response by the firm
1.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	Firm has submitted 10's, 14's, 20's, 30's as proposed pack sizes for the applied formulation.
2.	1.5.5	Revise pharmacological group as per WHO ATC classifications with applicable fee shall be submitted.	Firm has revised pharmacological group as per WHO ATC classifications with submission of 7500/- fee vide slip No. 061760215445 dated 23-02-2023.
3.	1.6.5	• Address of the drug substance manufacturer mentioned in section this section, Clearance certificate and on DMF is completely different from that mentioned on GMP certificate. Justification shall be submitted. • Furthermore, valid copy of GMP certificate of M/s Almelo Private Limited., Unit-II Survey No. 227, 228 & 136, 137 Shabashpally(V), Shivampet(M) Medak District, Telangana- 502334 India.	Firm has submitted that they have mistakenly attached GMP certificate having different address in our dossier. They also provided copy of GMP certificate No. L. Dis. No: 92502/TS/2022 Dated:11/07/2022 issued by Drugs Control Administration Government of Telangana in the name of M/s Almelo Private Limited Unit Ii Situated at Address Survey Nos. 227, 228 & 137, 136, Shabashpally Village, Shivampet Mandal, Medak District, Pin code 502334, Telangana State, India. Valid till 10/07/2023.
4.	2.3.R	Table for literature references has mentioned USP for drug substance only. However, it is also available in BP and other. Revised table for literature references with applicable fee shall be submitted.	Firm has submitted correct table for literature references.

5.	3.2.S.4.3	Verification of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.4	COA of the drug substance from both the drug substance manufacturer and finished product manufacturer with same batch number shall be submitted.	*Firm has once again submitted the same COA with different batch number from that of the drug substance manufacturer*.
7.	3.2.P.1.3	This section has mentioned Alu/Alu Blister strips of 2x7 Tablets packed in unit carton. Clarify.	Firm has submitted that It was Typographic mistake and they also submitted revised copy of Section 3.2.P.1.3. wherein they have replaced tablets with capsules.
8.	3.2.P.2.2	Justification for not performing CDP & PE against the innovator product shall be submitted.	Firm has submitted that Lyrica is an innovator of pregabalin capsule. In local market at the time of study only Lyrica 75mg capsule is available so we have chosen another market leader for performing CDP that is Gabica 50mg capsule manufactured by Getz Pharma.
9.	3.2.P.5.1	Specifications and stability data sheets have not mentioned any dissolution time. Justify.	Firm has submitted that dissolution time is mentioned on testing method and they also submitted revised specification & Stability Summary sheets wherein they have added dissolution time.
10.	3.2.P.8	• Stability data shall be as per decision of 293rd meeting with inclusion of API lot number in the stability data sheets. • Complete six-month stability data shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Firm has submitted revised stability data sheets wherein they have included API lot number. Complete six-month stability data is submitted by the firm. Firm has submitted that in DRB 323 Meeting our 8 Products of tablet section was approved. Submitted.
11.		Justification shall be submitted for using 2 different volumes in sample one and two for preparation of test solution in calculation of assay of trial batches.	Firm has submitted that It was typo graphical error, as per testing method it is 250 instead of 100 correction made revised reports are also submitted.

Decision of 326th meeting of Registration Board: Deferred for justification for variation in batch no. of COAs provided from drug substance manufacturer and drug product manufacturer.
Reply submitted by the firm:
Firm has submitted that it was a typo error and they also provided corrected COA with same batch number as that of the drug substance manufacturer.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

878.	Name, address of Applicant / Marketing Authorization Holder	M/s Akhsah Pharmaceuticals (Pvt.) Ltd., Plot No. 47, Street No. S-10, RCCI Industrial Estate, Rawat.
	Name, address of Manufacturing site.	M/s Akhsah Pharmaceuticals (Pvt.) Ltd., Plot No. 47, Street No. S-10, RCCI Industrial Estate, Rawat.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 31014; dated 01/11/2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 949224949258 dated 22/08/2022.
	The proposed proprietary name / brand name	Rescar 1% w/w Cream.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram Contains: Silver Sulfadiazine ……..…10mg
	Pharmaceutical form of applied drug	Topical Cream.
	Pharmacotherapeutic Group of (API)	D06B Chemotherapeutics For Topical Use.
	Reference to Finished product specifications	USP specifications.
	Proposed Pack size	20gm and 50gm.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Silvadene 1% (Silver Sulfadiazine) cream, USFDA approved.
	For generic drugs (me-too status)	Quench 1% cream, Ferozsons laboratory, Reg. No. 013090.
	GMP status of the Finished product manufacturer	New License issued on 14-09-2021.
	Evidence of section approval.	Cream/Ointment section (general) approved vide No. F 1-7/2012-Lic dated 14-09-2021.
	Name and address of API manufacturer.	M/s Shenyang Funing Pharmaceutical Co., Ltd. No.115, Hushitai North street, Shenbeixinqu, Shenyang China. Copy of GMP certificate No. LN20160005 issued by CFDA in the name of M/s Shenyang Funing Pharmaceutical Co., Ltd. Dated 12-01-2016 valid till 11-01-2021 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Silver sulfadiazine is present in USP. Firm has submitted detail of nomenclature, structure,

		general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for organic impurities, specifications, analytical procedures and its verification, batch analysis (B. No. 20210801, mfg. date, 11-08-2021) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months. Accelerated: 40˚C±2˚C / 75% ± 5% RH for 6 months. Batches: (20171201, 20171202 &20171203)
	Module-III (Drug Product):	Official monograph of the applied formulation is present in USP. Firm has submitted detail of the drug product including its description, composition, manufacturer, description of manufacturing process and controls, process validation protocol, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the brand leader that is Quench 1% cream, Batch No. 4401, Mfg. date 03-2022 manufactured by Ferozsons Laboratory by performing quality tests (Identification, pH and Assay).
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Shenyang Funing Pharmaceutical Co., Ltd. No.115, Hushitai North street, Shenbeixinqu, Shenyang China.		
API Lot No.	20210801.		
Description of Pack (Container closure system)	Aluminum tube packed in unit carton (1's , 20gram).		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 03 months Accelerated: 03 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	CR-01/R20	CR-02/R20	CR-03/R20
Batch Size	237 tubes.	237 tubes	237 tubes
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	16-03-2022	16-03-2022	10-03-2022
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

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

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. LN20160005 issued by CFDA in the name of M/s Shenyang Funing Pharmaceutical Co., Ltd. Dated 12-01-2016 valid till 11-01-2021 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks by the Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.5.5	Revise pharmacological group as per WHO ATC code with submission of applicable fee.	
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	
3.	3.2.S.4.1	Specification of the drug substance by the drug product manufacturer shall be submitted.	
4.	3.2.S.4.2	• Analytical procedures for the drug substance by the drug product manufacturer shall be submitted. • Mobile phase, Composition of the diluent, wave length of the detector, flow rate in the assay test of analytical procedure provided by the Drug Substance manufacturer is different from USP. Clarification shall be submitted.	
5.	3.2.S.4.3	Analytical method verification protocol shall be submitted.	
6.	3.2.S.4.4	• COA of the drug substance provided by the drug product manufacturer has no test for content of nitrate and silver content. Clarification shall be submitted. • COA of the drug substance provided by the drug product manufacturer has supplier name of Mansoor Chemicals. Justification shall be submitted.	
7.	3.2.S.5	Details and COAs of the working standard used in the development of trial batches shall be submitted.	

8.	3.2.P.5.2	• Calculation formula for assay in the analytical procedure for the finished product is different from USP. Clarify. • Analytical procedures for all the test of the finished product shall be submitted.	
9.	3.2.P.5.3	• Minimum fill and microbial enumeration test are not performed in the provided COA of trial batches. • COAs of the finished product are for Adapalene instead of silver sulfadiazine. Clarification shall be submitted.	
10.	3.2.P.8	• Submitted chromatograms does not reflect any wave length, injection volume etc. • Submitted chromatograms also does not reflect any resolution between sulfadiazine and sulfamerazine as required by the official monograph. • Justification shall be submitted for two different form of chromatograms. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

Decision of 326th meeting of Registration Board: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Reply submitted by the firm

Observation	Reply by the firm
Revise pharmacological group as per WHO ATC code with submission of applicable fee.	Firm has revised pharmacological group for the applied formulation as Sulfonamide antibiotic/chemotherapeutic as per WHO ATC code. ***However, fee required for pre-registration variation is not submitted by the firm.***
Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Firm has submitted copy of license No. Liao 20150048 issued by Liaoning Provincial Drug Administration in the name of M/s Shenyang Funing Pharmaceutical Co., Ltd. Valid till 20-12-2025.
Specification of the drug substance by the drug product manufacturer shall be submitted.	Submitted.
• Analytical procedures for the drug substance by the drug product manufacturer shall be submitted.	Firm has submitted analytical procedures for the drug substance in line with USP.
• Mobile phase, Composition of the diluent, wave length of the detector, flow rate in the assay test of analytical procedure provided by the Drug Substance	Firm has submitted revised analytical procedures for the drug substance and are in line with USP pharmacopoeia.

manufacturer is different from USP. Clarification shall be submitted.	
Analytical method verification protocol shall be submitted.	Submitted.
• COA of the drug substance provided by the drug product manufacturer has no test for content of nitrate and silver content. Clarification shall be submitted.	Firm has submitted revised COA of the drug substance wherein they have added nitrate and silver content test in the submitted COA.
• COA of the drug substance provided by the drug product manufacturer has supplier name of Mansoor Chemicals. Justification shall be submitted.	Firm has submitted that Mansoor chemical is the indenter, that why his name is written on COA.
Details and COAs of the working standard used in the development of trial batches shall be submitted.	Firm has submitted COA of the working standard.
• Calculation formula for assay in the analytical procedure for the finished product is different from USP. Clarify.	Firm has submitted that in analytical procedure for the finished product, calculation formula from USP is followed.
• Analytical procedures for all the test of the finished product shall be submitted.	They also attached the analytical procedures for the finished product.
• Minimum fill and microbial enumeration test are not performed in the provided COA of trial batches.	Firm has submitted that both the tests were performed on the trial batches. However, they were not added in the COA. They further submitted revised COAs for all the three trial batches with inclusion of above mentioned tests.
• COAs of the finished product are for Adapalene instead of silver sulfadiazine. Clarification shall be submitted.	Firm has submitted that it was a compilation mistake and they now submitted corrected ones.
• Submitted chromatograms does not reflect any wave length, injection volume etc.	Firm has submitted that their HPLC software by default not show the wavelength, injection volume mentioned on chromatograms.
• Submitted chromatograms also does not reflect any resolution between sulfadiazine and sulfamerazine as required by the official monograph.	Firm has submitted that they perform resolution between sulfadiazine and sulfamerazine in the next time point. Two peaks are completely separate from each other and hence no calculation is required. They also submitted the next time point chromatograms wherein two different peaks are clearly visible.
• Justification shall be submitted for two different form of chromatograms.	Firm has submitted that they have two HPLC systems i.e. Water and Perkin Elmer. Sometimes due to malfunctioning of one system, sample is run on another HPLC system because the stability time is due. That's why two different type of chromatograms are submitted.
• Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	Firm has submitted computerized clearance certificate No. E-114180281593 dated 24-02-2022 mentioning 0.15kg of silver sulfadiazine USP with batch No. 20210801, mfg. date of 11-08-2021 attested by assistant director I&E, DRAP, Islamabad.
• Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Firm has submitted that they are newly licensed unit, therefore, HPLC software 21CFR is not applicable. However, they have submitted audit trial report.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.** • **Registration letter will be issued after submission of pharmaceutical equivalence against the innovator product and Rs. 7,500/- fee for pre-registration variation as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.**		
879.	Name, address of Applicant / Marketing Authorization Holder	M/s Atco Laboratories Limited., B-18, S.I.T.E. Karachi.
	Name, address of Manufacturing site.	M/s Atco Laboratories Limited., B-18, S.I.T.E. Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5219 dated 24/02/2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 3813214571 dated 27/01/2022.
	The proposed proprietary name / brand name	Silodosin 4mg Capsule.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Silodosin ……4mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Urological, alpha-adrenoreceptor antagonists. ATC Code: G04CA04
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's, 60's, 90's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	RAPAFLO® 4mg & 8mg (silodosin) capsules, USFDA approved.
	For generic drugs (me-too status)	Sildat 4mg Capsule, Sami Pharmaceutical, Reg. No. 105264.
	GMP status of the Finished product manufacturer	DML Renewal receipt, dated 17-03-2021 submitted along with previous copy DML w.e.f. 11-04-2016. Copy of GMP certificate No. 160/2020-DRAP (K) dated 24-12-2020 on the basis of inspection conducted on 06-11-2020 is submitted by the firm.
	Evidence of section approval.	Capsule general section approved vide letter No. F. No.F.2-5/85-Lic (Vol-VI) dated 23-01-2019.
	Name and address of API manufacturer.	Anhui Haikang Pharmaceutical Co., Ltd. No.21 Huancheng West Road, Daguan District, Anqing, Anhui, 246000 China. Copy of GMP certificate issued by Anhui Anqing Daguan Economy Development Area Management

		Committee Environmental Protection Agency in the name of M/s Anhui Haikang Pharmaceutical Co., Ltd., dated 09-11-2018. Valid till 07-11-2022.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detail of drug substance regarding its manufacturers, structure, general properties, manufacturer, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis (Batch No. 20092102, mfg. date 21-09-2020) and justification of specification, reference standard, container closure system and stability studies of drug product.
	Stability studies (Drug substance.)	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5% RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (20170218, 20170205, 20170212)
	Module-III (Drug Product):	Firm has submitted detail of the drug product including its description, composition, manufacturers, description of manufacturing process and controls, Batch formula, process validation protocol, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against innovator product that is Rapaflo 4mg Capsule, Batch No. K58138 manufactured by Allergan Inc. Markham by performing quality tests (Identification, disintegration, Dissolution & Assay). Comparative Dissolution is also performed against the same brand in Acid media 0.1 N HCl, Acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. Both applied formulation and reference product shows more than 85% release within 15 minutes hence F2 is not calculated.
	Analytical method validation/verification of product	Method validation studies are submitted including specificity, linearity, accuracy, range, precision and robustness.

STABILITY STUDY DATA	
Manufacturer of API	Anhui Haikang Pharmaceutical Co., Ltd. No.21 Huancheng West Road, Daguan District, Anqing, Anhui, 246000 China.
API Lot No.	20092102.

Description of Pack (Container closure system)	Size "3" hard gelatin capsules with white body and purple cap filled with white to off white granular powder packed in Alu-Alu blister further packed in printed carton (1 x 7's).		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 06 months Accelerated:06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	FE038C.	MA113C.	MA114C.
Batch Size	2500 capsules.	2500 capsules.	2500 capsules.
Manufacturing Date	03-2021.	03-2021.	03-2021.
Date of Initiation	24-03-2021.	24-03-2021.	24-03-2021.
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

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

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Rofl 500mcg Tablets" which was conducted on 10-10-2017, and was presented in 277th meeting of Registration Board (27 - 29 December, 2017). Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. ✓ Audit trail reports on the testing were verifiable. Firm has adequate monitoring and controls for stability chambers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by Anhui Anqing Daguan Economy Development Area Management Committee Environmental Protection Agency in the name of M/s Anhui Haikang Pharmaceutical Co., Ltd., dated 09-11-2018. Valid till 07-11-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Invoice No. WD20201020 dated 20-10-2020 mentioning 400gm of Silodosin, Batch No. 20092102, mfg. date 21-09-2020 attested by Assistant Director I&E, DRAP, Karachi dated 07-11-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML of the applicant shall be submitted.	Firm has submitted copy of DML No. 000188 w.e.f. 11-04-2021.
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by the concerned/relevant regulatory authority shall be submitted.	Firm has submitted copy of License No. 20190399 for Anhui Haikang Pharmaceutical Co., Ltd. No.21 Huancheng West Road, Daguan District, Anqing, Anhui, 246000 China valid till 31-12-2025. License is verified from official website of NMPA and they also have scope of production of silodosin.
3.	2.3.R	Revised table for literature references with correct information regarding the drug substance with applicable fee shall be submitted.	Firm has submitted revised table for literature references wherein they have updated pharmacopoeial status of the drug substance. *However, fee applicable for pre-registration variation is not submitted.*
4.	3.2.S.4.1	• Specifications of the drug substance from drug substance manufacturer shall be submitted. • Justification shall be submitted regarding most of the specifications of the drug substance provided by both the drug substance manufacturer and finished product manufacturer as they are different from Japanese pharmacopoeia.	Submitted. Firm has submitted revised specifications and COA from both the drug substance and finished product manufacturer as per Japanese pharmacopoeia.
5.	3.2.S.4.2	• Justify the standard preparation and sample preparation in assay test with respect to that of the drug substance standard and test preparation. • Justification shall be submitted regarding the standard preparation and sample preparation in assay test with respect to that of the Japanese pharmacopoeia as final concentration is different.	Firm has submitted that analytical method according to Japanese pharmacopoeia has been adopted and applied on the drug substance analysis. They also submitted analytical methods from both drug substance and finished product manufacturer. *However, the submitted analytical procedures in the initial dossier the standard and test preparation both are different from drug substance manufacturer and Japanese pharmacopoeia.*
6.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
7.	3.2.S.7	Justification shall be submitted regarding the container closure system of the drug substance as it is mentioned to be packed in LLDPE while the official monograph has mentioned Well-closed containers. Storage—Light-resistant.	Firm has submitted that drug substance manufacturer has performed stability studies in the same container closure system as marketed previously and now they have adopted Japanese pharmacopoeia specifications. They will provide upcoming consignment according to updated specifications using the same container closure system as recommended by the JP monograph.
8.	3.2.S.7.3	Most of the specifications of the drug substance provided in 3.2.S.4.1 are changed in the stability data sheets. Clarification shall be submitted.	Firm has submitted that drug substance was comply with in house specifications in which critical test required in stability studies were covered and already adopted from Japanese

			pharmacopoeia. Further relevant section of drug substance part will be updated as attached letter from drug substance manufacturer in section 3.2.S.7.3.
9.	3.2.P.2.2	Justification shall be submitted for not performing Uniformity of dosage units in pharmaceutical equillance.	Firm has submitted that uniformity of dosage unit is a parameter to ensure the consistency of the dosage form. We have performed this test on all stability batches of both applied strength in initial stages to comply with the release requirements and found complies with the established criteria.
10.	3.2.P.8	Silodosin is a light sensitive material therefore the whole analytical procedures should avoid exposure to light using brown volumetric flask and sampler vials. Justify the performance of analytical procedures in volumetric flasks and other glassware without taking this precaution.	Firm has submitted that precaution as recommended for drug substance by JP monograph has been adopted for analysis of drug product and applied the same throughout the development studies of applied product. They also provided updated analytical procedures.

Decision of 326th meeting of Registration Board: Deferred for following:

- Justification shall be submitted regarding the standard preparation and sample preparation in assay test of the drug substance as it is different from both the drug substance manufacturer and Japanese pharmacopoeia.
- Submission of updated stability data for drug substance with revised specifications and container closure system as recommended by the JP monograph.
- Submission of Rs. 7,500/- fee for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.

Reply submitted by the firm;

Reason for deferment	Submission by the frim
Justification shall be submitted regarding the standard preparation and sample preparation in assay test of the drug substance as it is different from both the drug substance manufacturer and Japanese pharmacopoeia.	Firm has submitted that they have applied analytical method according to Japanese Pharmacopoeia which has been adopted and applied on the drug substance analysis. They have also provided copy from both the drug substance and drug product manufacturer.
Submission of updated stability data for drug substance with revised specifications and container closure system as recommended by the JP monograph.	Firm has submitted revised specifications for the drug substance. They also provided stability study data for the drug substance against the revised specifications. Batch No. 20021101, 20021301 & 20021501 Sheets have mentioned that "Samples are packed under simulated market container."
Submission of Rs. 7,500/- fee for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.	Firm has submitted 7500/- fee vide slip No. 28546366031 dated 16-03-2023.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

880.	Name, address of Applicant / Marketing Authorization Holder	M/s Atco Laboratories Limited., B-18, S.I.T.E. Karachi.

	Name, address of Manufacturing site.	M/s Atco Laboratories Limited., B-18, S.I.T.E. Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4387; dated 16/02/2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 0047238468 dated 27/01/2022.
	The proposed proprietary name / brand name	Silodosin 8mg Capsule.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Silodosin ……8mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Urological, alpha-adrenoreceptor antagonists. ATC Code: G04CA04
	Reference to Finished product specifications	Innovator's specifications.
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's, 60's, 90's.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	RAPAFLO® 4mg & 8mg (silodosin) capsules, USFDA approved.
	For generic drugs (me-too status)	Sildat 8mg Capsule, Sami Pharmaceutical, Reg. No. 105265.
	GMP status of the Finished product manufacturer	DML Renewal receipt, dated 17-03-2021 submitted along with previous copy DML w.e.f. 11-04-2016. Copy of GMP certificate No. 160/2020-DRAP (K) dated 24-12-2020 on the basis of inspection conducted on 06-11-2020 is submitted by the firm.
	Evidence of section approval.	Capsule general section approved vide letter No. F. No.F.2-5/85-Lic (Vol-VI) dated 23-01-2019.
	Name and address of API manufacturer.	Anhui Haikang Pharmaceutical Co., Ltd. No.21 Huancheng West Road, Daguan District, Anqing, Anhui, 246000 China. Copy of GMP certificate issued by Anhui Anqing Daguan Economy Development Area Management Committee Environmental Protection Agency in the name of M/s Anhui Haikang Pharmaceutical Co., Ltd., dated 09-11-2018. Valid till 07-11-2022.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities,

		specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detail of drug substance regarding its manufacturers, structure, general properties, manufacturer, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis (Batch No. 20092102, mfg. date 21-09-2020) and justification of specification, reference standard, container closure system and stability studies of drug product.
	Stability studies (Drug substance.)	Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5% RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (20170218, 20170205, 20170212)
	Module-III (Drug Product):	Firm has submitted detail of the drug product including its description, composition, manufacturers, description of manufacturing process and controls, Batch formula, process validation protocol, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against innovator product that is Rapaflo 8mg Capsule, Batch No. K59657 manufactured by Allergan Inc. Markham by performing quality tests (Identification, disintegration, Dissolution & Assay). Comparative Dissolution is also performed against the same brand in Acid media 0.1 N HCl, Acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. Both applied formulation and reference product shows more than 85% release within 15 minutes hence F2 is not calculated.
	Analytical method validation/verification of product	Method validation studies are submitted including specificity, linearity, accuracy, range, precision and robustness.

STABILITY STUDY DATA	
Manufacturer of API	Anhui Haikang Pharmaceutical Co., Ltd. No.21 Huancheng West Road, Daguan District, Anqing, Anhui, 246000 China.
API Lot No.	20092102.
Description of Pack (Container closure system)	Size “1” hard gelatin capsules with white body and blue cap filled with white to off white granular powder packed in Alu-Alu blister further packed in printed carton (1 x 7’s).
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 06 months Accelerated:06 months

Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)	
Batch No.		MA116C.	MA117C.	MA118C.
Batch Size		2666 capsules.	2666 capsules.	2666 capsules.
Manufacturing Date		03-2021.	03-2021.	03-2021.
Date of Initiation		07-04-2021.	07-04-2021.	07-04-2021.
No. of Batches		03		
REQUEST OF EXEMPTION FROM ON SITE INSPECTION			
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.			
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product "Rofl 500mcg Tablets" which was conducted on 10-10-2017, and was presented in 277th meeting of Registration Board (27 - 29 December, 2017). Following observations were reported in the report: ✓ The HPLC software is 21CFR Compliant. ✓ Audit trail reports on the testing were verifiable. Firm has adequate monitoring and controls for stability chambers.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by Anhui Anqing Daguan Economy Development Area Management Committee Environmental Protection Agency in the name of M/s Anhui Haikang Pharmaceutical Co., Ltd., dated 09-11-2018. Valid till 07-11-2022.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Invoice No. WD20201020 dated 20-10-2020 mentioning 400gm of Silodosin, Batch No. 20092102, mfg. date 21-09-2020 attested by Assistant Director I&E, DRAP, Karachi dated 07-11-2020.	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted	

Remarks of Evaluator**:**

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML of the applicant shall be submitted.	Firm has submitted copy of DML No. 000188 w.e.f. 11-04-2021.
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by the concerned/relevant regulatory authority shall be submitted.	Firm has submitted copy of License No. 20190399 for M/s Anhui Haikang Pharmaceutical Co., Ltd. No.21 Huancheng

			West Road, Daguan District, Anqing, Anhui, 246000 China valid till 31-12-2025. License is verified from official website of NMPA and they also have scope of production of silodosin.
3.	2.3.R	Revised table for literature references with correct information regarding the drug substance with applicable fee shall be submitted.	Firm has submitted revised table for literature references wherein they have updated pharmacopoeial status of the drug substance. *However, fee applicable for pre-registration variation is not submitted.*
4.	3.2.S.4.1	• Specifications of the drug substance from drug substance manufacturer shall be submitted. • Justification shall be submitted regarding most of the specifications of the drug substance provided by both the drug substance manufacturer and finished product manufacturer as they are different from Japanese pharmacopoeia.	Submitted. Firm has submitted revised specifications and COA from both the drug substance and finished product manufacturer as per Japanese pharmacopoeia.
5.	3.2.S.4.2	• Justify the standard preparation and sample preparation in assay test with respect to that of the drug substance standard and test preparation. • Justification shall be submitted regarding the standard preparation and sample preparation in assay test with respect to that of the Japanese pharmacopoeia as final concentration is different.	Firm has submitted that analytical method according to Japanese pharmacopoeia has been adopted and applied on the drug substance analysis. They also submitted analytical methods from both drug substance and finished product manufacturer. *However, the submitted analytical procedures in the initial dossier the standard and test preparation both are different from drug substance manufacturer and Japanese pharmacopoeia.*
6.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
7.	3.2.S.7	Justification shall be submitted regarding the container closure system of the drug substance as it is mentioned to be packed in LLDPE while the official monograph has mentioned Well-closed containers. Storage—Light-resistant.	Firm has submitted that drug substance manufacturer has performed stability studies in the same container closure system as marketed previously and now they have adopted Japanese pharmacopoeia specifications. They will provide upcoming consignment according to updated specifications using the same container closure system as recommended by the JP monograph.
8.	3.2.S.7.3	Most of the specifications of the drug substance provided in 3.2.S.4.1 are changed in the stability data sheets. Clarification shall be submitted.	Firm has submitted that drug substance was comply with in house specifications in which critical test required in stability studies were covered and already adopted from Japanese pharmacopoeia. Further relevant section of drug substance part will be updated as attached letter from drug substance manufacturer in section 3.2.S.7.3.
9.	3.2.P.2.2	Justification shall be submitted for not performing Uniformity of dosage units in pharmaceutical equillance.	Firm has submitted that uniformity of dosage unit is a parameter to ensure the consistency of the dosage form. We have performed this test on all stability batches of both applied strength

			in initial stages to comply with the release requirements and found complies with the established criteria.
10.	3.2.P.8	Silodosin is a light sensitive material therefore the whole analytical procedures should avoid exposure to light using brown volumetric flask and sampler vials. Justify the performance of analytical procedures in volumetric flasks and other glassware without taking this precaution.	Firm has submitted that precaution as recommended for drug substance by JP monograph has been adopted for analysis of drug product and applied the same throughout the development studies of applied product. They also provided updated analytical procedures.

Decision of 326th meeting of Registration Board: Deferred for following:

- Justification shall be submitted regarding the standard preparation and sample preparation in assay test of the drug substance as it is different from both the drug substance manufacturer and Japanese pharmacopoeia.
- Submission of updated stability data for drug substance with revised specifications and container closure system as recommended by the JP monograph.
- Submission of Rs. 7,500/- fee for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.

Reply submitted by the firm:

Reason for deferment	**Submission by the frim**
Justification shall be submitted regarding the standard preparation and sample preparation in assay test of the drug substance as it is different from both the drug substance manufacturer and Japanese pharmacopoeia.	Firm has submitted that they have applied analytical method according to Japanese Pharmacopoeia which has been adopted and applied on the drug substance analysis. They have also provided copy from both the drug substance and drug product manufacturer.
Submission of updated stability data for drug substance with revised specifications and container closure system as recommended by the JP monograph.	Firm has submitted revised specifications for the drug substance. They also provided stability study data for the drug substance against the revised specifications. Batch No. 20021101, 20021301 & 20021501 Sheets have mentioned that "Samples are packed under simulated market container."
Submission of Rs. 7,500/- fee for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.	Firm has submitted 7500/- fee vide slip No. 74102816257 dated 16-03-2023.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

881.	Name, address of Applicant / Marketing Authorization Holder	M/s Safina Pharmaceuticals (Pvt.) Ltd., 17 Km, Lahore Sheikhupura Road, Lahore.
	Name, address of Manufacturing site.	M/s Safina Pharmaceuticals (Pvt.) Ltd., 17 Km, Lahore Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30367; dated 26-10-2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 8595581239 dated 27/09/2022.
	The proposed proprietary name / brand name	Sinocef 250mg Suspension.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Cephradine ……..…… 250mg
	Pharmaceutical form of applied drug	Oral Suspension.
	Pharmacotherapeutic Group of (API)	First generation cephalosporin.
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	1 x 60ml and 1 x 90ml.
	Proposed unit price	As per approved price.
	The status in reference regulatory authorities	Nicef Syrup 250mg/5ml / Cefradine Syrup 250mg/5ml MHRA approved. Active Ingredient Per 5ml Cefradine 250 mg
	For generic drugs (me-too status)	Velosef 250mg Suspension, GSK Pakistan, Reg. No. 001868.
	GMP status of the Finished product manufacturer	New license granted on 18/02/2021 Tablet (General & General Antibiotic) section, General Capsule Section, Cream Ointment & Gel and Cephalosporin (Capsule & Dry Suspension) Section approved.
	Evidence of section approval.	Oral Dry Powder Suspension (Cephalosporin) section vide No.F.1-43/2006-Lic (Vol-I) dated 10-06-2021.
	Name and address of API manufacturer.	M/s Pharmagen Limited. Kot Nabi Bukshwala, 34 km Ferozepur Road Lahore. Copy of GMP certificate No. 129/2020-DRAP (AD/1998630-530) dated 02/09/2020 issued on the basis of inspection conducted on 22-06-2020 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Cephradine is available in USP & BP. Firm has submitted detail of the drug

		substance regarding nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis (B. No. 00203/038/2022, mfg. date 03-2022) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted both real time and accelerated stability study data for the drug substance. Stability study conditions: Real time: 5˚C ± 3˚C %RH for 36 months Accelerated: 25˚C ± 2˚C / 60% ± 5%RH for 6 months Batch No. (00202/001/2008, 00202/050/2008 & 00202/100/2008)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted Pharmaceutical Equivalence against the cephradine suspension 250mg/5ml, manufactured by M/s Sami, by performing quality tests (Identification, Assay, and Uniformity of dosage form).
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Limited. Kot Nabi Bukshwala, 34 km Ferozepur Road Lahore.		
API Lot No.	Not mentioned.		
Description of Pack (Container closure system)	Amber colour PET Bottle with white cap 90ml.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-004	TR-005	TR-006
Batch Size	263 Bottle	263 Bottle	263 Bottle
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	25-06-2022	25-06-2022	25-06-2022
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION		
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board.		
Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 129/2020-DRAP (AD/1998630-530) dated 02/09/2020 issued on the basis of inspection conducted on 22-06-2020 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks by the Evaluator:

Sr. No.	Section number	Observation	Response by the firm.
1.	1.5.2	Justification shall be submitted regarding the label claim of the applied formulation as the label claim has only cephradine while the executed BMR's, Batch formula and COA for the finished product has Cephradine as monohydrate.	
2.	3.2.S.4.1	• Specification for the drug substance by the drug product manufacturer shall be submitted. • Firm has submitted BP and USP specifications for the drug substance wherein no limits for 4,5 dihydrocefradine are given while BP has mentioned the same. Clarify.	
3.	3.2.S.4.2	• Analytical procedures for the drug substance by the drug product manufacturer shall be submitted. • Concentration of the standard and test samples in analytical procedures from the drug substance manufacturer are different from BP. Justification shall be submitted.	
4.	3.2.S.4.3	Verification studies for the drug substance performed by the drug product manufacturer shall be submitted.	
5.	3.2.S.4.4	• Justify the physical form of the drug substance whether monohydrate or otherwise.	

		• COAs from both the drug substance manufacturer and drug product manufacturer having same batch number shall be submitted. • COA submitted by the drug substance manufacturer has mentioned that it complies with BP specifications while submitted COA have no limits for 4,5 dihydrocepfradine and BP has mentioned it. Justify.
6.	3.2.S.5.	• Specifications has mentioned BP specifications for the drug substance while the reference standard provided is that of the USP. Clarification shall be submitted. • Working standard standardized against the reference standard has mentioned that use before 26, October 2016. Clarify.
7.	3.2.P.1	Qualitative composition of the applied formulation is different from reference product. Justification shall be submitted.
8.	3.2.P.2	• Justification for not performing Pharmaceutical Equivalence against the innovator brand shall be submitted. • In one page PE against Sami pharma product is established while on another page PE against Velosef suspension by GSK pharma is submitted. Calrify. • Justification shall be submitted for using UV method in assay test for PE while the official method has assay test on HPLC method. • No details of mfg. date, Exp. Date & batch numbers are provided in pharmaceutical equivalence studies.
9.	3.2.P.5.1	Specification provided for drug product by the drug product manufacturer has different pH limits from pharmacopoeia and also not mentioned cephalexin in assay test.
10.	3.2.P.5.4	COA for the finished product has only mentioned cephradine while the USP has mentioned sum of Cephradine and cephalexin. Clarification shall be submitted.
11.	3.2.P.5.3	• Method verification protocol shall be submitted. • Sample and standard solution preparation used in method verification studies shall be submitted. • Provide justification for accuracy range i.e 90% - 110%.
12.	3.2.P.8	• Justify the label claim of the applied formulation in the assay calculation of submitted chromatograms as 25mg is claimed while the actual value is 50mg. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.

	• API lot number used during the development studies shall be mentioned in the stability data sheets. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Complete six months stability study data shall be submitted.	

Decision of 326th meeting of Registration Board: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Reply submitted by the Firm:

Sr. No.	Section number	Observation	Response by the firm.
1.	1.5.2	Justification shall be submitted regarding the label claim of the applied formulation as the label claim has only cephradine while the executed BMR's, Batch formula and COA for the finished product has Cephradine as monohydrate.	Firm has submitted that label claim of the applied formulation is cephradine anhydrous. Cephradine as monohydrate was typo error. They also provided COA from the drug substance manufacturer wherein Cephradine anhydrous is mentioned.
2.	3.2.S.4.1	• Specification for the drug substance by the drug product manufacturer shall be submitted. • Firm has submitted BP and USP specifications for the drug substance wherein no limits for 4,5 dihydrocefradine are given while BP has mentioned the same. Clarify.	Firm has submitted specification of the drug substance from drug substance manufacturer. Firm has also mentioned limits for 4,5 dihydrocefradine as per official pharmacopoeia.
3.	3.2.S.4.2	• Analytical procedures for the drug substance by the drug product manufacturer shall be submitted. • Concentration of the standard and test samples in analytical procedures from the drug substance manufacturer are different from BP. Justification shall be submitted.	Submitted. Firm has submitted revised analytical procedures as per official monograph.
4.	3.2.S.4.3	Verification studies for the drug substance performed by the drug product manufacturer shall be submitted.	Firm has submitted method verification studies of the drug substance.
5.	3.2.S.4.4	• Justify the physical form of the drug substance whether monohydrate or otherwise. • COAs from both the drug substance manufacturer and drug product manufacturer having same batch number shall be submitted.	Firm has submitted that physical form of cephradine is anhydrous. Firm has submitted COA of the drug substance from both the drug substance manufacturer and finished product manufacturer with same batch number.

		• COA submitted by the drug substance manufacturer has mentioned that it complies with BP specifications while submitted COA have no limits for 4,5 dihydrocepfradine and BP has mentioned it. Justify.	Firm has submitted limits for 4,5 dihydrocepfradine in the submitted COA as per BP specifications
6.	3.2.S.5.	• Specifications has mentioned BP specifications for the drug substance while the reference standard provided is that of the USP. Clarification shall be submitted. • Working standard standardized against the reference standard has mentioned that use before 26, October 2016. Clarify.	Firm has submitted that during compilation of dossier, COA of the reference standard of USP was submitted. However, actually they have used another one. Firm has submitted new working standard details that actually this working standard was used in the trial batches.
7.	3.2.P.1	Qualitative composition of the applied formulation is different from reference product. Justification shall be submitted.	Firm has submitted that only one inactive is different from the reference product. However, their product is stable and has shown no change during stability studies.
8.	3.2.P.2	• Justification for not performing Pharmaceutical Equivalence against the innovator brand shall be submitted. • In one page PE against Sami pharma product is established while on another page PE against Velosef suspension by GSK pharma is submitted. Calrify. • Justification shall be submitted for using UV method in assay test for PE while the official method has assay test on HPLC method. • No details of mfg. date, Exp. Date & batch numbers are provided in pharmaceutical equivalence studies.	Firm has submitted new report for pharmaceutical equivalence performed against Velosef suspension 250mg, B. No. B54H, Mfg. date 11-, by performing quality tests (Identification, Assay, and Uniformity of dosage form). Firm has submitted that it was typo error. Firm has submitted new results for pharmaceutical equivalence wherein they have performed assay test on HPLC. Velosef suspension 250mg by GSK B. No. B54H, Mfg. date 11- 202
9.	3.2.P.5.1	Specification provided for drug product by the drug product manufacturer has different pH limits from pharmacopoeia and also not mentioned cephalexin in assay test.	Firm has submitted revised specifications for the finished product with corrected limits of pH and cephalexin content.
10.	3.2.P.5.4	COA for the finished product has only mentioned cephradine while the USP has mentioned sum of Cephradine and cephalexin. Clarification shall be submitted.	Revised and corrected COA is submitted.
11.	3.2.P.5.3	• Method verification protocol shall be submitted. • Sample and standard solution preparation used in method verification studies shall be submitted. • Provide justification for accuracy range i.e 90% - 110%.	Submitted. Submitted. Firm has submitted that accuracy range was mistakenly written as 90% - 110%, now we have corrected the range and our results were within the limit of ±2% as defined by ICH guidelines.
12.	3.2.P.8	• Justify the label claim of the applied formulation in the assay calculation of	Firm has submitted that it was typo error.

	submitted chromatograms as 25mg is claimed while the actual value is 50mg. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • API lot number used during the development studies shall be mentioned in the stability data sheets. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Complete six months stability study data shall be submitted.	Firm has submitted purchase invoice for the drug substance. Firm has submitted revised stability data sheets with inclusion of API lot number. Firm has submitted that they are newly licensed pharmaceutical unit. Submitted. Not applicable Submitted.
Decision: Registration Board decided to defer the case for onsite inspection for verification and authenticity of the submitted stability data.		
882.	Name, address of Applicant / Marketing Authorization Holder	M/s Safina Pharmaceuticals (Pvt.) Ltd., 17 Km, Lahore Sheikhupura Road, Lahore.
	Name, address of Manufacturing site.	M/s Safina Pharmaceuticals (Pvt.) Ltd., 17 Km, Lahore Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30370; dated 26-10-2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 2161416456 dated 27/09/2022.
	The proposed proprietary name / brand name	S- Xime 100mg/ 5ml Dry Suspension.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Cefixime as trihydrate …….…… 100mg
	Pharmaceutical form of applied drug	Oral Suspension.
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporin.
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	1 x 30ml.
	Proposed unit price	As per approved price.
	The status in reference regulatory authorities	Suprax 100mg /5ml Dry Suspension by M/s Lupin Pharma, USFDA Approved.

		Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons
	For generic drugs (me-too status)	Caricef 100mg /5ml Dry Suspension, M/s Sami Pharmaceuticals, Reg. No. 022415.
	GMP status of the Finished product manufacturer	New license granted on 18/02/2021 Tablet (General & General Antibiotic) section, General Capsule Section, Cream Ointment & Gel and Cephalosporin (Capsule & Dry Suspension) Section approved.
	Evidence of section approval.	Oral Dry Powder Suspension (Cephalosporin) section vide No.F.1-43/2006-Lic (Vol-I) dated 10-06-2021.
	Name and address of API manufacturer.	M/s Pharmagen Limited. Kot Nabi Bukshwala, 34 km Ferozepur Road Lahore. Copy of GMP certificate No. 129/2020-DRAP (AD/1998630-530) dated 02/09/2020 issued on the basis of inspection conducted on 22-06-2020 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis (B. No. 00243/081/22 date of analysis 12-05-2022) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted stability study data of 03 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 b months. Batches: (00244/135/2010, 00244/136/2010 & 00244/137/2010)

	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted Pharmaceutical Equivalence against the brand Caricef 100mg/5ml Dry Suspension, manufactured by M/s Sami, by performing quality tests (Identification, Assay, and Uniformity of dosage form).
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Limited. Kot Nabi Bukshwala, 34 km Ferozepur Road Lahore.		
API Lot No.	00243/081/2022		
Description of Pack (Container closure system)	Amber colour PET Bottle with white cap 60ml.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-007	TR-008	TR-009
Batch Size	275 Bottle	275 Bottle	275 Bottle
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	30-06-2022	30-06-2022	30-06-2022
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

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

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 129/2020-DRAP (AD/1998630-530) dated 02/09/2020 issued on the basis of inspection conducted on 22-06-2020 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks by the Evaluator:

Sr. No.	Section number	Observation	Response by the firm.
1.	3.2.S.4.1	Specification for the drug substance by the drug product manufacturer shall be submitted.	
2.	3.2.S.4.2	Analytical procedures for the drug substance by the drug product manufacturer shall be submitted.	
3.	3.2.S.4.3	Verification studies for the drug substance performed by the drug product manufacturer shall be submitted.	
4.	3.2.S.4.4	COAs from both the drug substance manufacturer and drug product manufacturer having same batch number shall be submitted.	
5.	3.2.S.7.3	Justification shall be submitted for performing only few tests in the stability studies of drug substance.	
6.	3.2.P.2	pH of the product mentioned in pharmaceutical development is 2.6 – 4.1 while official pharmacopoeia has mentioned 2.5 – 4.5. justify.	
7.	3.2.P.2	• Justification shall be submitted for using UV method in assay test for PE while the official method has assay test on HPLC method. • No details of mfg. date, Exp. Date & batch numbers are provided in pharmaceutical equivalence studies.	
8.	3.2.P.3.2.	Batch formula has mentioned Cefixime trihydrate 100 instead of Cefixime as trihydrate 100. Revised batch formula along with applicable fee shall be submitted.	
9.	3.2.P.5.3	• Method verification protocol shall be submitted. • Sample and standard solution preparation used in method verification studies shall be submitted. • Provide justification for accuracy range i.e 90% - 110%.	

10.	3.2.P.8	• Official pharmacopoeia has mentioned that Adjust flow rate so that the retention time of Cefixime is about 10 min while all the submitted chromatograms has run time of 6 to 7 minutes and retention time is about 3 minutes. • Submitted chromatograms does not reveal system suitability parameters as required by the USP monograph. Justify. • Submitted chromatograms does not column efficiency as required by the USP monograph. Justify. • API lot number is not mentioned in stability data sheets. • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Complete six months stability study data shall be submitted.	

Decision of 326th meeting of Registration Board: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Reply by the firm:

Sr. No.	Section number	Observation	Response by the firm.
1.	3.2.S.4.1	Specification for the drug substance by the drug product manufacturer shall be submitted.	Submitted.
2.	3.2.S.4.2	Analytical procedures for the drug substance by the drug product manufacturer shall be submitted.	Submitted.
3.	3.2.S.4.3	Verification studies for the drug substance performed by the drug product manufacturer shall be submitted.	Firm has submitted verification studies of the drug substance including specificity, accuracy and precision.
4.	3.2.S.4.4	COAs from both the drug substance manufacturer and drug product manufacturer having same batch number shall be submitted.	COAs of the drug substance from both drug substance manufacturer and finished product manufacturer having batch No. 00243/081/2022 with manufacturing date of April, 2022 are submitted.

5.	3.2.S.7.3	Justification shall be submitted for performing only few tests in the stability studies of drug substance.	Firm has submitted that stability studies are conducted on stability specifications which are different from the release or shelf life specifications. Usually those tests are performed in stability studies which are expected to be affected by temperature and humidity conditions over the period of time. Pharmagen is a DRAP approved API manufacturer and its stability study data for Cefixime has been accepted by Registration Board in various meetings.
6.	3.2.P.2	pH of the product mentioned in pharmaceutical development is 2.6 – 4.1 while official pharmacopoeia has mentioned 2.5 – 4.5. justify.	Firm has submitted revised pH for the product as per official pharmacopoeia i.e. 2.5 – 4.5.
7.	3.2.P.2	• Justification shall be submitted for using UV method in assay test for PE while the official method has assay test on HPLC method.	Firm has submitted that they perform pharmaceutical equivalence studies using the same method provided in 3.2.P.5.1 & 3.2.P.5.2 and there was some typographical mistake while compiling dossier and by mistake some UV method was attached. They also provided the results of HPLC.
		• No details of mfg. date, Exp. Date & batch numbers are provided in pharmaceutical equivalence studies.	Firm has submitted details of the innovator product as follows; Batch No. D1836, Mfg. date 06-2022, Exp. Date 05, 2024
8.	3.2.P.3.2.	Batch formula has mentioned Cefixime trihydrate 100 instead of Cefixime as trihydrate 100. Revised batch formula along with applicable fee shall be submitted.	Firm has submitted revised batch formula for the applied formulation without submission of applicable fee.
9.	3.2.P.5.3	• Method verification protocol shall be submitted.	Submitted.
		• Sample and standard solution preparation used in method verification studies shall be submitted.	Firm has submitted that sample and standard preparation method used in verification studies are exactly same as defined in the analytical procedures of drug product.
		• Provide justification for accuracy range i.e 90% - 110%.	Firm has submitted that accuracy range was mistakenly written as 90% - 110%, now we have corrected the range and our results were within the limit of ±2% as defined by ICH guidelines.
10.	3.2.P.8	• Official pharmacopoeia has mentioned that Adjust flow rate so that the retention time of Cefixime is about 10 min while all the submitted chromatograms has run time of 6 to 7 minutes and retention time is about 3 minutes.	Firm has submitted that they have performed verification studies and system suitability studies as defined by USP. During verifications studies they have performed HPLC analysis for run time greater than 10 minutes, but our analyte peak was observed from 3 to 4 minutes so as per USP recommendations they adjusted the HPLC run time to 07 minutes. Both standard as well as sample analysis show similar retention time which justify the identification as well as other analytical tests.
		• Submitted chromatograms does not reveal system suitability	Firm has submitted that their default software for HPLC show limited options while printing HPLC chromatograms

	parameters as required by the USP monograph. Justify. • Submitted chromatograms does not column efficiency as required by the USP monograph. Justify. • API lot number is not mentioned in stability data sheets. • • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Complete six months stability study data shall be submitted.	however, all parameters related to system suitability like number of theoretical plates, tailing factor, column efficiency etc. are recorded and saved within the system for each chromatograms. API lot No. is 00243/081/22. Firm has submitted purchase invoice for the drug substance. Firm has submitted that they have newly licensed facility therefore, this point is not applicable. Submitted. Not applicable. Firm has submitted complete six month stability studies for all the three trial batches as per decision of the 293rd meeting of Registration Board.
Decision: Registration Board decided to defer the case for onsite inspection for verification and authenticity of the submitted stability data.		
883.	Name, address of Applicant / Marketing Authorization Holder	M/s Safina Pharmaceuticals (Pvt.) Ltd., 17 Km, Lahore Sheikhupura Road, Lahore.
	Name, address of Manufacturing site.	M/s Safina Pharmaceuticals (Pvt.) Ltd., 17 Km, Lahore Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 30368; dated 26-10-2022.
	Details of fee submitted	PKR 30,000/-: vide slip No. 467147674916 dated 27/09/2022.
	The proposed proprietary name / brand name	S- Xime 200mg/ 5ml Dry Suspension.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains: Cefixime as trihydrate ……..…… 200mg
	Pharmaceutical form of applied drug	Oral Suspension.
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporin.
	Reference to Finished product specifications	USP Specifications.

	Proposed Pack size	1 x 30ml.
	Proposed unit price	As per approved price.
	The status in reference regulatory authorities	Suprax 200mg /5ml Dry Suspension by M/s Lupin Pharma, USFDA Approved.
	For generic drugs (me-too status)	Caricef DS 200mg /5ml Dry Suspension, M/s Sami Pharmaceuticals, Reg. No. 044340.
	GMP status of the Finished product manufacturer	New license granted on 18/02/2021 Tablet (General & General Antibiotic) section, General Capsule Section, Cream Ointment & Gel and Cephalosporin (Capsule & Dry Suspension) Section approved.
	Evidence of section approval.	Oral Dry Powder Suspension (Cephalosporin) section vide No.F.1-43/2006-Lic (Vol-I) dated 10-06-2021.
	Name and address of API manufacturer.	M/s Pharmagen Limited. Kot Nabi Bukshwala, 34 km Ferozepur Road Lahore. Copy of GMP certificate No. 129/2020-DRAP (AD/1998630-530) dated 02/09/2020 issued on the basis of inspection conducted on 22-06-2020 is submitted.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed data for drug substance data related to nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis (B. No. 00243/081/22 date of analysis 12-05-2022) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Drug substance.)	Firm has submitted stability study data of 03 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 36 b months. Batches: (00244/135/2010, 00244/136/2010 & 00244/137/2010)

	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted Pharmaceutical Equivalence against the brand Caricef 200mg/5ml Dry Suspension, manufactured by M/s Sami, by performing quality tests (Identification, Assay, and Uniformity of dosage form).
	Analytical method validation/verification of product	Firm has submitted verification studies of the drug substance and the drug product.

STABILITY STUDY DATA

Manufacturer of API	M/s Pharmagen Limited. Kot Nabi Bukshwala, 34 km Ferozepur Road Lahore.		
API Lot No.	00243/081/2022		
Description of Pack (Container closure system)	Amber colour PET Bottle with white cap 60ml.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-010	TR-011	TR-012
Batch Size	275 Bottle	275 Bottle	275 Bottle
Manufacturing Date	06-2022	06-2022	06-2022
Date of Initiation	30-06-2022	30-06-2022	30-06-2022
No. of Batches	03		

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

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

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 129/2020-DRAP (AD/1998630-530) dated 02/09/2020 issued on the basis of inspection conducted on 22-06-2020 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms,	Submitted

	Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Submitted

Remarks by the Evaluator:

Sr. No.	Section number	Observation	Response by the firm.
1.	3.2.S.4.1	Specification for the drug substance by the drug product manufacturer shall be submitted.	Submitted.
2.	3.2.S.4.2	Analytical procedures for the drug substance by the drug product manufacturer shall be submitted.	Submitted.
3.	3.2.S.4.3	Verification studies for the drug substance performed by the drug product manufacturer shall be submitted.	Firm has submitted verification studies of the drug substance including specificity, accuracy and precision. Linearity and range are not verified.
4.	3.2.S.4.4	COAs from both the drug substance manufacturer and drug product manufacturer having same batch number shall be submitted.	COAs of the drug substance from both drug substance manufacturer and finished product manufacturer are submitted.
5.	3.2.S.7.3	Justification shall be submitted for performing only few tests in the stability studies of drug substance.	Firm has submitted that stability studies are conducted on stability specifications which are different from the release or shelf life specifications. Usually those tests are performed in stability studies which are expected to be affected by temperature and humidity conditions over the period of time. Pharmagen is a DRAP approved API manufacturer and its stability study data for Cefixime has been accepted by Registration Board in various meetings.
6.	3.2.P.2	• Justification shall be submitted for using UV method in assay test for PE while the official method has assay test on HPLC method.	Firm has submitted that they perform pharmaceutical equivalence studies using the same method provided in 3.2.P.5.1 & 3.2.P.5.2 and there was some typographical mistake while compiling dossier and by mistake some UV method was attached. *Submitted raw data in the originally submitted dossier is from UV method and no data of HPLC is submitted by the firm.*
		• No details of mfg. date, Exp. Date & batch numbers are provided in pharmaceutical equivalence studies.	Firm has submitted details of the innovator product as follows; Batch No. D1836, Mfg. date 06-2022, Exp. Date 05, 2024
7.	3.2.P.3.2.	Batch formula has mentioned Cefixime trihydrate 100 instead of Cefixime as trihydrate 100. Revised batch formula along with applicable fee shall be submitted.	Firm has submitted revised batch formula for the applied formulation without submission of applicable fee.

8.	3.2.P.5.3	• Method verification protocol shall be submitted.	Not submitted.
		• Sample and standard solution preparation used in method verification studies shall be submitted.	Firm has submitted that sample and standard preparation method used in verification studies are exactly same as defined in the analytical procedures of drug product. However, dilution prepared for the verification studies are not provided.
		• Provide justification for accuracy range i.e 90% - 110%.	Firm has submitted that accuracy range was mistakenly written as 90% - 110%, now we have corrected the range and our results were within the limit of ±2% as defined by ICH guidelines.
9.	3.2.P.8	• Official pharmacopoeia has mentioned that Adjust flow rate so that the retention time of Cefixime is about 10 min while all the submitted chromatograms has run time of 6 to 7 minutes and retention time is about 3 minutes.	Firm has submitted that they have performed verification studies and system suitability studies as defined by USP. During verifications studies they have performed HPLC analysis for run time greater than 10 minutes, but our analyte peak was observed from 3 to 4 minutes so as per USP recommendations they adjusted the HPLC run time to 07 minutes. Both standard as well as sample analysis show similar retention time which justify the identification as well as other analytical tests. Conditions applied are similar to USP however, retention time is not in line with USP.
		• Submitted chromatograms does not reveal system suitability parameters as required by the USP monograph. Justify. • Submitted chromatograms does not column efficiency as required by the USP monograph. Justify.	Firm has submitted that their default software for HPLC show limited options while printing HPLC chromatograms however, all parameters related to system suitability like number of theoretical plates, tailing factor, column efficiency etc. are recorded and saved within the system for each chromatograms.
		• API lot number is not mentioned in stability data sheets.	Firm has stated that API lot number is 00243/081/22. *However, the Purchase invoice has some other batch number of the raw material.*
		• Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	Firm has submitted copy of invoice No. 2645 dated 10-05-2022 mentioning Cefixime micronized with batch No. 00243-04/081/2022 with 2kg quantity.
		• Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Firm has submitted that their HPLC system is not 21 CFR compliant however they have maintained all relevant logs as per the GMP requirements.
		• Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Submitted.

• Complete six months stability study data shall be submitted.	Firm has submitted that they have recently been granted with manufacturing license and till date they have not received any approval of application with stability data. Submitted.

Decision of 326th meeting of Registration Board: Deferred for the following;

- Performance of Assay test in Pharmaceutical equivalence studies, as per USP monograph.
- Justification shall be submitted for retention time of Cefixime with respect to the USP which states that "Adjust flow rate so that the retention time of Cefixime is about 10 min" while all the submitted chromatograms has "run time" of 6 to 7 minutes and retention time is about 3 minutes.
- Justification shall be submitted for difference in the API lot number in stability summary data sheets and purchase invoice.
- Submission of Rs. 7,500/- fee for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.

Reply submitted by the firm:

Sr. No.	Reason for deferment	Reply submitted by the firm
1.	Performance of Assay test in Pharmaceutical equivalence studies, as per USP monograph.	Firm has submitted new results for Pharmaceutical equivalence studies wherein they have performed assay test as per USP monograph with HPLC.
2.	Justification shall be submitted for retention time of Cefixime with respect to the USP which states that "Adjust flow rate so that the retention time of Cefixime is about 10 min" while all the submitted chromatograms has "run time" of 6 to 7 minutes and retention time is about 3 minutes.	Firm has submitted next time point data wherein the chromatograms have retention time of about 7 to 8 minutes while the run time of the chromatograms is about 13 minutes. They further submitted that in future they will follow pharmacopoeial specifications.
3.	Justification shall be submitted for difference in the API lot number in stability summary data sheets and purchase invoice.	Firm has submitted that this was typo error. They also submitted revised stability data sheets wherein the API lot No. is as per purchase invoice.
4.	Submission of Rs. 7,500/- fee for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.	Not submitted.

Decision: Registration Board decided to defer the case for onsite inspection for verification and authenticity of the submitted stability data.

Case 03; Registration applications of deferred import cases (Human) drugs on Form 5F.

884.	Name, address of Applicant / Importer	M/s Pfizer Pakistan Limited, B-2, S.I.T.E. Karachi.
	Details of Drug Sale License of importer	License No: 030. Address: M/s Pfizer Pakistan Limited, B-2, S.I.T.E. Karachi. Address of Godown: (a) 12-Dockyard Road, West Wharf, Karachi. (b) C-II-D S.I.T.E. Karachi. Validity: 25-02-2023. Status: Drug License by way of Wholesale.
	Name and address of marketing authorization holder (abroad)	M/s Hospira UK Limited, Horizon, Honey Lane Hurley Maidenhead SL6 6RJ United Kingdom
	Name, address of manufacturer(s)	M/s Zydus Hospira Oncology Pvt., Ltd., Plot No. 3, Pharmez-Special Economic Zone, Sarkhej Bavla Highway, N.H. No. 8A Matoda, Taluka Sanand, District Ahmadabad, Gujrat, India.

	Name of exporting country	United Kingdom.
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted legalized & Notarized copy of CoPP certificate (No. PP10170759) dated 17-03-2021 issued by MHRA. Name of the product mentioned for Pakistan is Oxaliplatin 50mg/10ml Concentrate for Solution for Infusion. Certificate has mentioned M/s Hospira UK Limited, Horizon, Honey Lane Hurley Maidenhead SL6 6RJ United Kingdom as product License/marketing authorization holder with product license No. PL 04515/0215. Status of the product License/marketing authorization is "C" which means not involved in manufacturing, packaging or labelling the dosage form but is responsible for the quality and release of the product. Certificate has also mentioned the name of the manufacturer as M/s Zydus Hospira Oncology Pvt., Ltd., Plot No. 3, Pharmez-Special Economic Zone, Sarkhej Bavla Highway, N.H. No. 8A Matoda, Taluka Sanand, District Ahmadabad, Gujrat, India. GMP: Applicant has submitted copy of GMP certificate No. 2062066 dated 06-06-2020 issued by Food & Drug Control Administration, Gandhinagar, Gujrat State of India in the name of M/s Zydus Hospira Oncology Pvt., Ltd., Plot No. 3, Pharmez-Special Economic Zone, N.H. No. 8A Sarkhej-Bavla Road, Matoda, Tal- Sanand, District Ahmadabad, Gujrat, India having manufacturing License No. G/28/1267. The certificate is issued on the basis of inspection conducted on 03-04/10/2019 & 06/02/2020 and is valid till 05/06/2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of authorization from M/s Hospira UK Limited having its principal place of business at Horizon, Honey Lane Hurley Maidenhead SL6 6RJ United Kingdom wherein Hospira UK Limited authorizes M/s Pfizer Pakistan Limited, located at B-2, S.I.T.E. Karachi to be the marketing authorization holder in Pakistan for Oxaliplatin Hospira 50mg/10ml & 100mg/20ml concentrate for solution for infusion and be responsible for all matters pertaining to the regulation of this product in Pakistan. Authorization letter also confirms that these products are manufactured and released by Zydus Hospira Oncology Pvt., Ltd., Plot No. 3, Pharmez Special Economic Zone, Sarkhej Bavla Highway, N.H. No. 8A Matoda, Taluka Sanand, District Ahmadabad, Gujrat, India.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 10393 dated 23-04-2022.
	Details of fee submitted	PKR 150,000/- vide slip No. 60745999 Dated: 07-06-2021.
	The proposed proprietary name / brand name	Oxaliplatin 50mg/10ml, Concentrate for Solution for Infusion.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 10ml contains; Oxaliplatin ……. 50mg (5mg/ml)
	Pharmaceutical form of applied drug	Concentrate for Solution for Infusion.
	Pharmacotherapeutic Group of (API)	Antineoplastic Agents (L01)
	Reference to Finished product specifications	Not submitted.
	Proposed Pack size	1's.
	Proposed unit price	No information provided.
	The status in reference regulatory authorities	Eloxatin (Oxaliplatin 50mg/10ml (5mg/ml) USFDA Approved.
	For generic drugs (me-too status)	Oxitan 50/10ml, Reg. No. 110554, Atco pharma.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has also summarized information related to the drug substance and drug product both.
	Name, address of drug substance manufacturer	Heraeus Deutschland GmbH & Co. Address: Heraeusstr. 12-14. 63450 Hanau, Germany. UMICORE Argentina S.A. Address: 14 Street, Building # 229 - B1629MXA Pilar Industrial Park, Buenos Aires Province, Argentina.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, appearance, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of more than 03 batches for drug substance at accelerated as well as real time conditions. The real time stability data is conducted at 25ºC ± 2ºC & 60% ± 05% RH. The stability study data is till 60 months and accelerated stability study data is conducted at 40ºC ± 2ºC & 75% ± 5% RH for six months. Heraeus Deutschland GmbH & Co.

		Batch No. 10902, 11002 & 11102. UMICORE Argentina S.A. Batch No. OX12011, OX12012 & OX12013.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, batch formula, pharmaceutical development, manufacturer, manufacturing process and process control, process validation report, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis (OX11202, OX11203, OX11605, OX21202), justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not submitted.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type – I clear glass vial, with elastomeric closure, and aluminum seal with plastic flip-off top.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 03 batches of drug product. Accelerated stability study data is conducted at 40ºC ±2ºC & 75% ± 5% RH for 06 months. The real time stability study data is conducted at 30ºC ±2ºC & 75% ± 5% RH for 24 months. Batch No. OX11202, OX11203 & OX11605.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.		• Original, legalized copy of GMP certificate of the manufacturer shall be submitted.	Firm has once again submitted coloured copy of GMP certificate. *Legalized and notarized GMP certificate shall be submitted.*
		• Original/notarized authorization letter shall be submitted.	Firm has submitted notarized letter of authorization.
2.	1.4.1.1	Authorization letter has mentioned the territory of Pakistan only, while in module one section 1.4.1.1 has mentioned domestic and export sales. Clarification shall be submitted.	Firm has submitted revised Form 5F wherein they have made change in section 1.4.1.1 from domestic and export sales to domestic sales. *Fee required for pre-registration variation is not submitted.*
3.	1.5.6	Finished product specification for the finished product shall be mentioned.	*No specification is submitted for the finished drug product by the applicant.*
4.	3.2.S.4.1	Specification of the drug substance by the drug product manufacturer shall be submitted.	Firm has submitted two tables of specifications for both the drug substance manufacturers and stated that each lot of Oxaliplatin is tested and must meet the specifications listed in the provided table.
5.	3.2.S.4.2	Analytical method for drug substance by the finished product manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.3	Analytical method verification studies for the drug substance performed by the drug product manufacturer shall be submitted.	Firm has provided validation report completed at Mulgrave, Victoria, Australia (Mulgrave) site. They further submitted that they have provided the method transfer

			report demonstrating successful transfer of the determination of Identification and Assay by HPLC, Impurity B, Impurity E, Impurity C, Unspecified Impurities, residual solvents (for Heraeus API only) and silver contents of Oxaliplatin method from the Mulgrave to Zydus Hospira Oncology Private Limited (ZHOPL) manufacturing sites.
7.	3.2.P.2.2	The comparison of the developed formulation with innovator product with applied strength including the results of all the quality tests (pharmaceutical equivalence) shall be submitted and discussed.	Firm has submitted pharmaceutical equivalence of their product against the innovator product i.e Sanofi Synthelabo's Eloxatin™ Injection marketed in UK, Germany and Sweden for Appearance of Solution, pH, Assay and Related substance (impurity A, B, E, C, D and unknown impurities). Results providedhas shown that Mayne Pharma's Oxaliplatin Injection and the competitor product, Sanofi Synthelabo's Eloxatin™ Injection marketed in UK(50mg/10mL;100mg/20mL), Germany (50mg/10mL; 100mg/20mL) and Sweden (50mg/10mL) were similar with respect to Appearance of solution, pH, potency and related substances. Therefore, Mayne Pharma's Oxaliplatin Injection is considered equivalent to Sanofi Synthelabo's Eloxatin™ Injection marketed in UK, Germany and Sweden. *Pharmaceutical equivalence provided by the applicant is Mayne Pharma Limited Australia instead of M/s Zydus Hospira Oncology Pvt., Ltd., Plot No. 3, Pharmez-Special Economic Zone, Sarkhej Bavla Highway, N.H. No. 8A Matoda, Taluka Sanand, District Ahmadabad, Gujrat, India.*
8.	3.2.P.5.1	This section has mentioned In-house specifications for the Assay test of the drug product while official monograph is available in USP. Justify.	Firm has submitted that the specifications and acceptance criteria for Oxaliplatin Injection 5 mg/mL comply with the USP monograph for Oxaliplatin Injection requirements. The compendial analytical procedures have been verified suitable for their intended use and comply with compendia. Assay and Related Substances tests are performed according to validated in-house analytical procedures. Validation reports are provided in dossier section 3.2.P.5.3. Justification of specifications is provided in dossier section 3.2.P.5.6.

9.	3.2.P.5.3	Submitted Validation of analytical procedure is by Hospira Australia since the drug product manufacturer responsible for manufacture & quality control of drug product is in India. Clarification is required.	Firm has submitted that Validation of the in-house analytical procedures was performed by the Hospira Australia development site. As the product was subsequently transferred for commercial manufacture to the ZHOPL facility located in India, the method transfer study from Hospira Australia to ZHOPL was completed demonstrating the ability of the receiving site to perform testing. They also refer to Report QCC-008-TMR-005 submitted previously.

Decision of 324th meeting of Registration Board: Deferred for following;

- Valid, legalized and original GMP certificate of the finished product manufacturer shall be submitted.
- Justification shall be submitted for providing pharmaceutical equivalence of the product from M/s Mayne Pharma Limited Australia instead of M/s Zydus Hospira Oncology Pvt., Ltd., Plot No. 3, Pharmez-Special Economic Zone, Sarkhej Bavla Highway, N.H. No. 8A Matoda, Taluka Sanand, District Ahmadabad, Gujrat, India.
- Current regulatory status with respect to the market authorization and manufacturing sites for the applied formulation of both the firms i.e. M/s Mayne Pharma Limited Australia and M/s Hospira Australia shall be submitted from where the Pharmaceutical equivalence and Validation of analytical procedures are provided respectively.

Reply by the firm:

M/s Pfizer Pakistan Limited vide their reference No. PFZ-DRAP-2023-044 dated 31-03-2023 has submitted that registration application of the above mentioned product shall be considered as Withdrawn from their side.

Decision: Registration Board decided to acceded the request of M/s Pfizer Pakistan Limited, B-2, S.I.T.E. Karachi regarding withdrawal of their registration applications i.e., Oxaliplatin 50mg/10ml, Concentrate for Solution for Infusion and declared the application as disposed of.

885.	Name, address of Applicant / Importer	M/s Pfizer Pakistan Limited, B-2, S.I.T.E. Karachi.
	Details of Drug Sale License of importer	License No: 030. Address: M/s Pfizer Pakistan Limited, B-2, S.I.T.E. Karachi. Address of Godown: (a) 12-Dockyard Road, West Wharf, Karachi. (b) C-II-D S.I.T.E. Karachi. Validity: 25-02-2023. Status: Drug License by way of Wholesale.
	Name and address of marketing authorization holder (abroad)	M/s Hospira UK Limited, Horizon, Honey Lane Hurley Maidenhead SL6 6RJ United Kingdom
	Name, address of manufacturer(s)	M/s Zydus Hospira Oncology Pvt., Ltd., Plot No. 3, Pharmez-Special Economic Zone, Sarkhej Bavla Highway, N.H. No. 8A Matoda, Taluka Sanand, District Ahmadabad, Gujrat, India.
	Name of exporting country	United Kingdom.
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted legalized & Notarized copy of CoPP certificate (No. PP10170758) dated 17-03-2021 issued by MHRA. Name of the product mentioned for Pakistan is Oxaliplatin 100mg/20ml Concentrate for Solution for Infusion. Certificate has mentioned M/s Hospira UK Limited, Horizon, Honey Lane Hurley Maidenhead SL6 6RJ United Kingdom as product License/marketing

		authorization holder with product license No. PL 04515/0215. Status of the product License/marketing authorization is "C" which means not involved in manufacturing, packaging or labelling the dosage form but is responsible for the quality and release of the product. Certificate has also mentioned the name of the manufacturer as M/s Zydus Hospira Oncology Pvt., Ltd., Plot No. 3, Pharmez-Special Economic Zone, Sarkhej Bavla Highway, N.H. No. 8A Matoda, Taluka Sanand, District Ahmadabad, Gujrat, India. GMP: Applicant has submitted copy of GMP certificate No. 2062066 dated 06-06-2020 issued by Food & Drug Control Administration, Gandhinagar, Gujrat State of India in the name of M/s Zydus Hospira Oncology Pvt., Ltd., Plot No. 3, Pharmez-Special Economic Zone, N.H. No. 8A Sarkhej-Bavla Road, Matoda, Tal- Sanand, District Ahmadabad, Gujrat, India having manufacturing License No. G/28/1267. The certificate is issued on the basis of inspection conducted on 03-04/10/2019 & 06/02/2020 and is valid till 05/06/2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of authorization from M/s Hospira UK Limited having its principal place of business at Horizon, Honey Lane Hurley Maidenhead SL6 6RJ United Kingdom wherein Hospira UK Limited authorizes M/s Pfizer Pakistan Limited, located at B-2, S.I.T.E. Karachi to be the marketing authorization holder in Pakistan for Oxaliplatin Hospira 50mg/10ml & 100mg/20ml concentrate for solution for infusion and be responsible for all matters pertaining to the regulation of this product in Pakistan. Authorization letter also confirms that these products are manufactured and released by Zydus Hospira Oncology Pvt., Ltd., Plot No. 3, Pharmez Special Economic Zone, Sarkhej Bavla Highway, N.H. No. 8A Matoda, Taluka Sanand, District Ahmadabad, Gujrat, India.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 10394 dated 23-04-2022.

	Details of fee submitted	PKR 150,000/- vide slip No. 52026247959 Dated: 07-06-2021.
	The proposed proprietary name / brand name	Oxaliplatin 100mg/20ml, Concentrate for Solution for Infusion.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 20ml contains; Oxaliplatin ……. 100mg (5mg/ml)
	Pharmaceutical form of applied drug	Concentrate for Solution for Infusion.
	Pharmacotherapeutic Group of (API)	Antineoplastic Agents (L01)
	Reference to Finished product specifications	Not submitted.
	Proposed Pack size	1's.
	Proposed unit price	No information provided.
	The status in reference regulatory authorities	Eloxatin (Oxaliplatin 100mg/20ml (5mg/ml) USFDA Approved.
	For generic drugs (me-too status)	Oxitan 100/20ml, Reg. No. 110555, Atco pharma.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has also summarized information related to the drug substance and drug product both.
	Name, address of drug substance manufacturer	Heraeus Deutschland GmbH & Co. Address: Heraeusstr. 12-14. 63450 Hanau, Germany. UMICORE Argentina S.A. Address: 14 Street, Building # 229 - B1629MXA Pilar Industrial Park, Buenos Aires Province, Argentina.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, appearance, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of more than 03 batches for drug substance at accelerated as well as real time conditions. The real time stability data is conducted at 25ºC ± 2ºC & 60% ± 05% RH. The stability study data is till 60 months and accelerated stability study data is conducted at 40ºC ± 2ºC & 75% ± 5% RH for six months. Heraeus Deutschland GmbH & Co. Batch No. 10902, 11002 & 11102. UMICORE Argentina S.A. Batch No. OX12011, OX12012 & OX12013.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, batch formula, pharmaceutical development, manufacturer, manufacturing process and process control, process validation report, control of drug product, specifications, analytical procedures, validation of

		analytical procedures, batch analysis (OX21202, OX21203, OX21605), justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type – I clear glass vial, with elastomeric closure, and aluminum seal with plastic flip-off top.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 03 batches of drug product. Accelerated stability study data is conducted at 40ºC ±2ºC & 75% ± 5% RH for 06 months. The real time stability study data is conducted at 30ºC ±2º C & 75% ± 5% RH for 24 months. Batch No. OX21202, OX21203 & OX21605.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.		• Original, legalized copy of GMP certificate of the manufacturer shall be submitted. • Original/notarized authorization letter shall be submitted.	Firm has once again submitted coloured copy of GMP certificate. *Legalized and notarized GMP certificate shall be submitted.* Firm has submitted notarized letter of authorization.
2.	1.4.1.1	Authorization letter has mentioned the territory of Pakistan only, while in module one section 1.4.1.1 has mentioned domestic and export sales. Clarification shall be submitted.	Firm has submitted revised Form 5F wherein they have made change in section 1.4.1.1 from domestic and export sales to domestic sales. *Fee required for pre-registration variation is not submitted.*
3.	1.5.6	Finished product specification for the finished product shall be mentioned.	*No specification is submitted for the finished drug product by the applicant.*
4.	3.2.S.4.1	Specification of the drug substance by the drug product manufacturer shall be submitted.	Firm has submitted two tables of specifications for both the drug substance manufacturers and stated that each lot of Oxaliplatin is tested and must meet the specifications listed in the provided table.
5.	3.2.S.4.2	Analytical method for drug substance by the finished product manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.3	Analytical method verification studies for the drug substance performed by the drug product manufacturer shall be submitted.	Firm has provided validation report completed at Mulgrave, Victoria, Australia (Mulgrave) site. They further submitted that they have provided the method transfer report demonstrating successful transfer of the determination of Identification and Assay by HPLC, Impurity B, Impurity E, Impurity C, Unspecified Impurities, residual solvents (for Heraeus API only) and silver contents of Oxaliplatin method from the Mulgrave to Zydus Hospira Oncology Private Limited (ZHOPL) manufacturing sites.
7.	3.2.P.2.2	The comparison of the developed formulation with innovator product	Firm has submitted pharmaceutical equivalence of their product against the

		with applied strength including the results of all the quality tests (pharmaceutical equivalence) shall be submitted and discussed.	innovator product i.e Sanofi Synthelabo's Eloxatin™ Injection marketed in UK, Germany and Sweden for Appearance of Solution, pH, Assay and Related substance (impurity A, B, E, C, D and unknown impurities). Results provided has shown that Mayne Pharma's Oxaliplatin Injection and the competitor product, Sanofi Synthelabo's Eloxatin™ Injection marketed in UK(50mg/10mL;100mg/20mL), Germany (50mg/10mL; 100mg/20mL) and Sweden (50mg/10mL) were similar with respect to Appearance of solution, pH, potency and related substances. Therefore, Mayne Pharma's Oxaliplatin Injection is considered equivalent to Sanofi Synthelabo's Eloxatin™ Injection marketed in UK, Germany and Sweden. *Pharmaceutical equivalence provided by the applicant is Mayne Pharma Limited Australia instead of M/s Zydus Hospira Oncology Pvt., Ltd., Plot No. 3, Pharmez-Special Economic Zone, Sarkhej Bavla Highway, N.H. No. 8A Matoda, Taluka Sanand, District Ahmadabad, Gujrat, India.*
8.	3.2.P.5.1	This section has mentioned In-house specifications for the Assay test of the drug product while official monograph is available in USP. Justify.	Firm has submitted that the specifications and acceptance criteria for Oxaliplatin Injection 5 mg/mL comply with the USP monograph for Oxaliplatin Injection requirements. The compendial analytical procedures have been verified suitable for their intended use and comply with compendia. Assay and Related Substances tests are performed according to validated in-house analytical procedures. Validation reports are provided in dossier section 3.2.P.5.3. Justification of specifications is provided in dossier section 3.2.P.5.6.
9.	3.2.P.5.3	Submitted Validation of analytical procedure is by Hospira Australia since the drug product manufacturer responsible for manufacture & quality control of drug product is in India. Clarification is required.	Firm has submitted that Validation of the in-house analytical procedures was performed by the Hospira Australia development site. As the product was subsequently transferred for commercial manufacture to the ZHOPL facility located in India, the method transfer study from Hospira Australia to ZHOPL was completed demonstrating the ability of the receiving site to perform testing. They also refer to Report QCC-008-TMR-005 submitted previously.

Decision of 324th meeting of Registration Board: Deferred for following;

- Valid, legalized and original GMP certificate of the finished product manufacturer shall be submitted.
- Justification shall be submitted for providing pharmaceutical equivalence of the product from M/s Mayne Pharma Limited Australia instead of M/s Zydus Hospira Oncology Pvt., Ltd., Plot No. 3, Pharmez-Special Economic Zone, Sarkhej Bavla Highway, N.H. No. 8A Matoda, Taluka Sanand, District Ahmadabad, Gujrat, India.

• Current regulatory status with respect to the market authorization and manufacturing sites for the applied formulation of both the firms i.e. M/s Mayne Pharma Limited Australia and M/s Hospira Australia shall be submitted from where the Pharmaceutical equivalence and Validation of analytical procedures are provided respectively. Reply by the firm: *M/s Pfizer Pakistan Limited vide their reference No. PFZ-DRAP-2023-044 dated 31-03-2023 has submitted that registration application of the above mentioned product shall be considered as Withdrawn from their side.*		
Decision: Registration Board decided to acceded the request of M/s Pfizer Pakistan Limited, B-2, S.I.T.E. Karachi regarding withdrawal of their registration applications i.e., Oxaliplatin 100mg/20ml, Concentrate for Solution for Infusion and declared the application as disposed of.		
886.	Name, address of Applicant / Importer	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.
	Details of Drug Sale License of importer	License No: 521 Address: Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area, Karachi. Address of Godown: (a) 1st floor, Plot no. 211, Sector 23 Korangi Industrial Area, Karachi (b) Plot No 32, Sector 16, Korangi Industrial Area, Karachi Validity: 16-06-2022 Status: License to sell Drugs by way of Wholesale.
	Name and address of marketing authorization holder (abroad)	Nano Daru Pajuhan Pardis Address: No. 4&8, Northern Tak Ave., Attar St., Vanak Sq., Tehran, Iran.
	Name, address of manufacturer(s)	Nano Daru Pajuhan Pardis Address: Behnood Pharmed Incubation Center, No. 110, Bahman St., Karafarinan Blvd., Sepehr Industrial Zone, Nazarabad City, Alborz Province, Iran.
	Name of exporting country	Iran
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized CoPP certificate (No. 665/68759) dated 28-02-2022 issued by the Division of Pharmaceutical and Narcotic Affairs of Ministry of Health Food and Drug Adm. MOH. Name and dosage form on the CoPP certificate mentioned is "Exopio 380mg (Naltrexone extended release powder and diluent for suspension for injection)" and name of the product license holder is Nano Daru Pajuhan Pardis, No. 4&8, Northern Tak Ave., Attar St., Vanak Sq., Tehran, Iran. The certificate also confirms that the applied formulation is actually on the market in the exporting country. The name of importing country on CoPP is mentioned in Annexures as Pakistan. Furthermore, the CoPP is valid till 28-02-2023. GMP: Applicant has submitted legalized copy of GMP certificate No. 665/60857 dated 19-01-2022 issued by Iran Food and Drug Administration the name of

		M/s Nano Daru Pajuhan Pardis, No. 4&8, Northern Tak Ave., Attar St., Vanak Sq., Tehran, Iran having its manufacturing site at Behnood Pharmed Incubation Center, No. 110, Bahman St., Karafarinan Blvd., Sepehr Industrial Zone, Nazarabad City, Alborz Province, Iran and the certificate confirms that Hazardous aseptic injectable vials of the firm is in compliance with the cGMP/GMP standards and relevant principals and regulation and complies with the Good Manufacturing Practices requirements of the PIC/S Guidelines.
	Details of letter of authorization / sole agency agreement	Firm has submitted original and legalized sole agency agreement. The agreement specifies that product license holder i.e. M/s Nano Daru Pajuhan Pardis, No. 4&8, Northern Tak Ave., Attar St., Vanak Sq., Tehran, Iran appoints M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi to import below mentioned product. The document also emphasized that M/s Martin Dow Limited is the sole authorized importer of the below mentioned products in Pakistan; *Exopio 380mg (Powder and diluent for suspension for injection) Naltrexone extended-release 380mg.*
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 26860 dated 22-09-2022.
	Details of fee submitted	PKR 150,000/- vide slip No. 592742515 Dated: 31-12-2021
	The proposed proprietary name / brand name	EXOPIO 380 mg.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Naltrexone extended-release powder for suspension for injection ……..…380 mg Each vial of Diluent contains: Carboxy methylcellulose Sodium ……150mg Sodium Chloride……36mg Polysorbate……...……4mg Water for Injections…….…up to 4ml
	Pharmaceutical form of applied drug	Powder for suspension for injection.
	Pharmacotherapeutic Group of (API)	Drugs used in alcohol dependence.

	Reference to Finished product specifications	Innovator's Specifications.
	Proposed Pack size	1's.
	Proposed unit price	As per DPC.
	The status in reference regulatory authorities	VIVITROL (naltrexone for extended-release injectable suspension), USFDA Approved.
	For generic drugs (me-too status)	Not Available
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Temad Co. Active Pharmaceutical Ingredients Address: 28th km of Karaj Makhsous Road, Tehran, Iran.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, appearance, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches for drug substance at accelerated as well as real time conditions. The real time stability data is conducted at 30°C ± 2°C & 65% RH The stability study data is till 24 months and accelerated stability study data is conducted at 40°C ± 2°C & 75% ± 5% RH for six months. Batch No. NAB5058001, NAB5058002 & NAB5058003.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis (21002, 21003, 20003), justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence for the applied product against the reference product i.e. Vivitrol manufactured by Alkermes, Inc. by performing following tests; Appearance before preparation of suspension, Dispersion time, Appearance after preparation of

		suspension, pH, Osmolarity, Water content, Identification, Assay and In-vitro release.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type – I clear colourless glass vial with lyophilized bromobutyl rubber stopper.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 4 batches of drug product. The real time stability study data is conducted at 5°C ±3° C for 24 months. Batch No. 19003 24 months, 20001 18 months, 20002 18 months & 20003 12 months.
	Therapeutic indications in USFDA.	VIVITROL contains naltrexone, an opioid antagonist, and is indicated for the treatment of alcohol dependence in patients who are able to abstain from alcohol in an outpatient setting prior to initiation of treatment with VIVITROL. Patients should not be actively drinking at the time of initial VIVITROL administration (1.1). • VIVITROL is indicated for the prevention of relapse to opioid dependence, following opioid detoxification (1.2). • VIVITROL should be part of a comprehensive management program that includes psychosocial support (1).

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of Drug Sale License of the applicant shall be submitted.	Firm has submitted copy of DSL No. 565 dated 13-06-2022 in the name of M/s Martin Dow limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi valid till 16-06-2024.
2.	1.6.5	Valid copy of GMP certificate of drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. 665/18253 dated 17-05-2020 issued by Iran Food and Drug Administration in the name of Temad Co. Active Pharmaceutical Ingredients, 28th km of Karaj Makhsous Road, Tehran, Iran valid for three years.
3.	1.5.5	Pharmacotherapeutic Group of (API) shall be revised.	Firm has submitted that Pharmacotherapeutic group of Naltrexone is Narcotic/Opiate antagonist.
4.	3.2.S.4.1	Specification provided by the drug substance manufacturer has water content of NMT 2.0% while FPP has mentioned NMT 6.0%. Clarification shall be submitted.	Firm has submitted revised/corrected specification of the drug substance by providing a new COA for the drug substance from drug substance manufacturer. They also provided COA of the drug substance from both the drug substance and drug product manufacturer and both the COA's are having NMT 6% limit of water content.
5.	3.2.S.4.3	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.

6.	3.2.S.5	The submitted COA of the working standard used for analysis is of Naltrexone Hydrochloride. However, USP describes the reference standard for Naltrexone base (Cat. No. 1453504) only. Clarify.	Firm has submitted that same material was reported in section 3.2.S.5 as USP codes in drug substance and drug product. However, method of analysis which was reported in USP was for Naltrexone HCl. The method analysis of Naltrexone base was also the same. Because in the sample solution media & mobile phase, both forms become base form because of the pH conditions
7.	3.2.P.2.2	Justification of 12.9% of overage of naltrexone in the formulation shall be submitted.	Firm has submitted that Exopio has been prepared according to the data from originator product, Vivitrol, which applies 12.9% excess Naltrexone. Firm has also submitted a document confirming 12.9% of an excess quantity of naltrexone. *However, the authenticity of the document could not be confirmed.* *Furthermore, the review of the reference product in USFDA has also not mentioned any overage of the active substance.*
8.	3.2.P.8	• Complete real time stability data of the product shall be submitted.	Firm has submitted complete real time stability data for all the three batches i.e. 20001, 20002 & 20003 for which initially 18 months and 12-month data was submitted.
		• In use stability studies for the applied drug product shall be submitted.	Firm has submitted that the drug product should be used immediately after reconstitution process, and it should not remain unused after reconstitution. Also, it was mentioned in the booklet and guide card too.
		• Accelerated stability data for the applied drug product shall be submitted.	Firm has referred to the ICH Topic Q1A (R2) wherein for drug products intended for storage in a refrigerator, accelerated stability condition is 25°C ± 2° C / 60% ± 5% RH. Failure to meet the acceptance criteria for appearance, physical attributes, and functionality test (e.g. colour, phase separation, suspensibility, caking, hardness, dose delivery per actuation) If significant change occurs between 3 and 6 months' testing at the accelerated storage condition, the proposed re-test period should be based on the real time data available at the long term storage condition. If significant change occurs within the first 3 months' testing at the accelerated storage condition, a discussion should be provided to address the effect of short term excursions outside the label storage condition, e.g., during shipping or handling. Firm has further submitted that both Exopio and RLD samples had colour change and phenotype change after one in

	25ºC ± 2º C / 60% ± 5% RH. The accelerated studies were stopped and the storage condition (2 ºC - 8 ºC) noted on vial packaging of drug product.

Decision of 324th meeting of Registration Board: Deferred for following;

- Scientific justification of using 12.9% overage of drug substance i.e., Naltrexone in the applied formulation.
- Justification for use of Naltrexone Hydrochloride as working standard in the analysis while USP monograph recommends Naltrexone base as reference standard.

Submission by the firm;

Sr. No.	**Reason for deferment.**	**Reply by the firm**
1.	Scientific justification of using 12.9% overage of drug substance i.e., Naltrexone in the applied formulation.	Firm has submitted that Vivitrol is the originator brand available as NDA on USFDA, whereby the MA holder is Alkermes. Alkermes has entered into agreement for the same brand in Russia with Cilag GmBH international (Subsidiary of Johnson & Johnson) where the PIL shows that Naltrexone has been used 12.9% excess. Thus, it is evident that Vivitrol being the originator brand contains Naltrexone 12.9% excess. Therefore, Exopio has been developed according to the originator brand and thus, also contains 12.9% excess of Naltrexone.
2.	Justification for use of Naltrexone Hydrochloride as working standard in the analysis while USP monograph recommends Naltrexone base as reference standard.	Finished product manufacturer of the applied formulation clarify that Naltrexone HCl is not considered as the standard material in finished product's analysis. We only use Naltrexone base as a reference standard as per USP. They further submitted that their method of analysis for the finished product and details of the reference standard show that we are following Naltrexone USP standard only.

Decision: Deferred for following;

- **Scientific justification of using 12.9% overage of drug substance i.e., Naltrexone in the applied formulation.**
- **Justification for use of Naltrexone Hydrochloride as working standard in the analysis while USP monograph recommends Naltrexone base as reference standard.**

Case 04; Registration applications on the basis of Export facilitation of Locally manufactured (Human) drugs on Form 5D.

Deputy Director PRV/EFD vide letter No.F.1-6/2019-PR-I (EFD dated 28-02-2023 has informed that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical i.e. one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm i.e. **M/s Tabros Pharma (Pvt.) Ltd., Karachi** have achieved the benchmark of more than 100,000 USD **(575,683.20 USD)** during the fiscal Year 2021-2022 and submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.

Following products are presented before the Board in light of the decision of the 133rd meeting of DRAP Authority held on 13th April 2022 for consideration.

887.	Name and address of manufacturer / Applicant	Tabros Pharma, Essa House, 32-1/C, Block 6, P.E.C.H.S, Karachi.

	Brand Name +Dosage Form + Strength	Zontiv Tablets 40mg
	Diary No. Date of R& I & fee	Dy. No. 377, R&I dated 29.12.2014, Rs. 20,000.
	Composition	Each Tablet contains Azilsartan kamedoxomil eq.to azilsartan medoxomil.40mg
	Pharmacological Group	Anti-hypertensive/Angiotensin-II receptor blocker
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's.
	Pack size & Demanded Price	1x14's & Rs.264.2 per tablet
	Approval status of product in Reference Regulator Authorities	Edarbi 40mg Tablet (FDA Approved).
	Me-too status	Not Available
	GMP status	Last GMP Inspection 11.3.2014 (overall GMP rated as Good)
	Remarks of the Evaluator	The firm couldn't provide evidence of me-too status and replied to re-submit the application on form-5D with differential fees as me-too doesn't exist.
	Decision of 270th meeting of Registration Board.	Deferred for confirmation of evidence of me-too status and latest GMP inspection report conducted within one year.
	Copy of Form 5-D with 30,000/- fee vide slip No. 0275686 attested by statistical officer, DRAP dated 12-07-2017 is submitted.	

STABILITY STUDY DATA

Drug	Zontiv 40mg tablets.		
Manufacturer of API	M/s CTX Lifesciences, Block No. 251/P, 252/P, 253 to 255, 256/P, 258/P, 276/P, 277, 278/P, 279 to 282, 283/P, 284/P GIDC, City Sachin, Dist. Surat, Gujrat State India.		
API Lot No.	20AK00007.		
Description of Pack (Container closure system)	White, round, biconvex tablet plain on both sides.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TR001-1/ZON	TR002-1/ZON	TR003-1/ZON
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	17-11-2021	17-11-2021	17-11-2021
No. of Batches	03		
Date of Submission	Dy. No. 22722 dated 11-08-2022.		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status

<table>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm</td><td>Firm has referred last onsite panel inspection for instant dosage form conducted during last two years BAXIB (Apixaban) 2.5mg & 5mg Tablets on 5th January, 2021 by following panel:
1. Prof. Dr. Rafeeq Alam Khan, Dean, Faculty of Pharmacy, Zia Uddin University, Karachi. (Member Registration Board).
2. Dr. Saif-ur-Rehman Khattak, Director / FGA, CDL, DRAP, Karachi.</td></tr>
<tr><td>2.</td><td>Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Firm has submitted Copy of COA (Batch No. 20AK00007, Mfg. date 03-2020) of the drug substance (Azilsartan Medoxomil Potassium) from M/s CTX Lifesciences, India.
Finished product manufacturer has also submitted copy of COA for Azilsartan Medoxomil Potassium with same batch number and manufacturing date.</td></tr>
<tr><td>3.</td><td>Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer</td><td>Analytical procedures for the drug substance from both drug substance manufacturers and Finished Product Manufacturer are provided by the firm.</td></tr>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>Firm has submitted stability study data of drug substance. Stability study is conducted at Real time conditions; 25°C ± 2°C / 60% ± 5% RH for 18 months and at Accelerated conditions; 5°C ± 3°C for 6 months.
Batches: (AK180002, AK180003 & AK180004).</td></tr>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Firm has submitted copy of GMP certificate No. 22063346 dated 30-05-2022 in the name of M/s CTX Lifesciences, Block No. 251/P, 252/P, 253 to 255, 256/P, 258/P, 276/P, 277, 278/P, 279 to 282, 283/P, 284/P GIDC, City Sachin, Dist. Surat, Gujrat State India issued by Food & Drug Control Administration Gujrat State, India.
Valid till 29.05.2025.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Firm has submitted copy of invoice No. EI/3002100489 dated 13-11-2020 mentioning 2kg quantity of Azilsartan Medoxomil potassium with batch No. 20AK00007, Mfg. date 03-2020 attested by Assistant Director, DRAP, Karachi dated 25-11-2020.
Copy of Form 6 attested by Assistant Director, DRAP, Karachi is also submitted.</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted.</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted.</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Firm has used same ingredients as that of the innovator product, so compatibility studies with excipients are not required.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>TR001-1/ZON</td><td>1500 Tablets</td><td>04-10.2021</td></tr>
<tr><td>TR002-1/ZON</td><td>1500 Tablets</td><td>05-10.2021</td></tr>
<tr><td>TR003-1/ZON</td><td>1500 Tablets</td><td>06-10.2021</td></tr>
</table>
</td></tr>
</table>

11.	Record of comparative dissolution data (where applicable)	Firm has submitted comparative dissolution of their applied formulation i.e. Zontiv (Azilsartan Medoxomil potassium) 40mg Tablet against the innovator product Edarbi 40mg tablets, Batch No. 11701856, Mfg. date 07-2019 manufactured by M/s Takeda Pharmaceutical in Acid media (0.1N HCl), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The F2 values are found satisfactory.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr. No.	Observation	Reply by the firm
1.	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Copy of GMP certificate No. 22063346 dated 30-05-2022 in the name of M/s CTX Lifesciences, Block No. 251/P, 252/P, 253 to 255, 256/P, 258/P, 276/P, 277, 278/P, 279 to 282, 283/P, 284/P GIDC, City Sachin, Dist. Surat, Gujrat State India issued by Food & Drug Control Administration Gujrat State, India. Valid till 29.05.2025. *Firm has also submitted copy of GMP certificate No. 53/2022-DRAP (K) dated 15-04-2022 issued on the basis of inspection conducted on 07-04-2022.*
2.	Justification shall be submitted regarding the submitted stability study data for the drug substance at refrigerated conditions i.e. Real time conditions; 25˚C ± 2˚C / 60% ± 5% RH for 18 months and at Accelerated conditions; 5˚C ± 3˚C for 6 months while the innovator product has shown stability data of the drug substance at (up to 24 months at 25°C/60% RH and satisfactory 6 months results at 40°C/75% RH.	Firm has submitted that as per drug substance manufacturer storage condition is recommended, refrigerated i.e. 5˚C ± 3˚C. For refrigeration the real time storage condition is 5˚C ± 3˚C and accelerated condition is 25˚C ± 2˚C / 60% ± 5% RH. They further submitted they have submitted their stability as per ICH guidelines.
3.	Submitted BMR's for the trial batches have shown manufacturing date of 04 & 05 & 06 October while the stability data sheets have mentioned 17-11-2021 as date of initiation. Justification for this delay shall be submitted.	Firm has submitted that they acknowledge the comments of the competent authority that we have been delayed to charge the stability considering to its manufacturing date, due to huge load of routine stability samples testing. Therefore, we have little bit delayed to charge the stability, while 03rd and 06th month interval testing was done within the specified time.

Decision: Approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment**

submitted in the registration application.

- **Registration letter will be issued after submission of Rs. 7,500/- fee for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.**

888.	Name and address of manufacturer / Applicant	Tabros Pharma, Essa House, 32-1/C, Block 6, P.E.C.H.S, Karachi.
	Brand Name +Dosage Form + Strength	Zontiv Tablets 40mg
	Diary No. Date of R& I & fee	Dy. No. 376, R&I dated 29.12.2014, Rs. 20,000.
	Composition	Each Tablet contains Azilsartan kamedoxomil eq.to azilsartan Medoxomil …….. 80mg
	Pharmacological Group	Anti-hypertensive/Angiotensin-II receptor blocker
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's.
	Pack size & Demanded Price	1x14's & Rs. 478.57 per tablet
	Approval status of product in Reference Regulator Authorities	Edarbi 80mg Tablet (FDA Approved).
	Me-too status	Not Available
	GMP status	Last GMP Inspection 11.3.2014 (overall GMP rated as Good)
	Remarks of the Evaluator	The firm couldn't provide evidence of me-too status and replied to re-submit the application on form-5D with differential fees as me-too doesn't exist.
	Decision of 270th meeting of Registration Board.	Deferred for confirmation of evidence of me-too status and latest GMP inspection report conducted within one year.
	Copy of Form 5-D with 30,000/- fee vide slip No. 0275687 attested by statistical officer, DRAP dated 12-07-2017 is submitted.	

STABILITY STUDY DATA

Drug	Zontiv 80mg tablets.		
Manufacturer of API	M/s CTX Lifesciences, Block No. 251/P, 252/P, 253 to 255, 256/P, 258/P, 276/P, 277, 278/P, 279 to 282, 283/P, 284/P GIDC, City Sachin, Dist. Surat, Gujrat State India.		
API Lot No.	20AK00007.		
Description of Pack (Container closure system)	White, round, biconvex tablet plain on both sides.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (months) Real Time: 0, 3, 6 (months)		
Batch No.	TR001-2/ZON	TR002-2/ZON	TR003-1/ZON
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	17-11-2021	17-11-2021	17-11-2021

No. of Batches	03
Date of Submission	Dy. No. 22723 dated 11-08-2022.

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Firm has referred last onsite panel inspection for instant dosage form conducted during last two years BAXIB (Apixaban) 2.5mg & 5mg Tablets on 5th January, 2021 by following panel: 1. Prof. Dr. Rafeeq Alam Khan, Dean, Faculty of Pharmacy, Zia Uddin University, Karachi. (Member Registration Board). 2. Dr. Saif-ur-Rehman Khattak, Director / FGA, CDL, DRAP, Karachi.
2.	Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.	Firm has submitted Copy of COA (Batch No. 20AK00007, Mfg. date 03-2020) of the drug substance (Azilsartan Medoxomil Potassium) from M/s CTX Lifesciences, India. Finished product manufacturer has also submitted copy of COA for Azilsartan Medoxomil Potassium with same batch number and manufacturing date.
3.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer	Analytical procedures for the drug substance from both drug substance manufacturers and Finished Product Manufacturer are provided by the firm.
4.	Stability study data of API from API manufacturer	Firm has submitted stability study data of drug substance. Stability study is conducted at Real time conditions; 25°C ± 2°C / 60% ± 5% RH for 18 months and at Accelerated conditions; 5°C ± 3°C for 6 months. Batches: (AK180002, AK180003 & AK180004).
5.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. 22063346 dated 30-05-2022 in the name of M/s CTX Lifesciences, Block No. 251/P, 252/P, 253 to 255, 256/P, 258/P, 276/P, 277, 278/P, 279 to 282, 283/P, 284/P GIDC, City Sachin, Dist. Surat, Gujrat State India issued by Food & Drug Control Administration Gujrat State, India. Valid till 29.05.2025.
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. EI/3002100489 dated 13-11-2020 mentioning 2kg quantity of Azilsartan Medoxomil potassium with batch No. 20AK00007, Mfg. date 03-2020 attested by Assistant Director, DRAP, Karachi dated 25-11-2020. Copy of Form 6 attested by Assistant Director, DRAP, Karachi is also submitted.
7.	Protocols followed for conduction of stability study	Submitted.
8.	Method used for analysis of FPP	Submitted.
9.	Drug-excipients compatibility studies (where applicable)	Firm has used same ingredients as that of the innovator product, so compatibility studies with excipients are not required.

<table>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:<table><tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr><tr><td>TR001-2/ZON</td><td>1500 Tablets</td><td>14-10-2021</td></tr><tr><td>TR002-2/ZON</td><td>1500 Tablets</td><td>15-10.2021</td></tr><tr><td>TR003-2/ZON</td><td>1500 Tablets</td><td>16-10.2021</td></tr></table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>Firm has submitted comparative dissolution of their applied formulation i.e. Zontiv (Azilsartan Medoxomil potassium) 80mg Tablet against the innovator product Edarbi 80mg tablets, Batch No. 11665646, Mfg. date 03-2019 manufactured by M/s Takeda Pharmaceutical in Acid media (0.1N HCl), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The F2 values are found satisfactory.</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Submitted</td></tr>
<tr><td>14.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Submitted</td></tr>
<tr><td colspan="3">Remarks of Evaluator:<table><tr><th>Sr. No.</th><th>Observation</th><th>Reply by the firm</th></tr><tr><td>1.</td><td>Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.</td><td>Copy of GMP certificate No. 22063346 dated 30-05-2022 in the name of M/s CTX Lifesciences, Block No. 251/P, 252/P, 253 to 255, 256/P, 258/P, 276/P, 277, 278/P, 279 to 282, 283/P, 284/P GIDC, City Sachin, Dist. Surat, Gujrat State India issued by Food & Drug Control Administration Gujrat State, India.
Valid till 29.05.2025.
Firm has also submitted copy of GMP certificate No. 53/2022-DRAP (K) dated 15-04-2022 issued on the basis of inspection conducted on 07-04-2022.</td></tr><tr><td>2.</td><td>Justification shall be submitted regarding the submitted stability study data for the drug substance at refrigerated conditions i.e. Real time conditions; 25°C ± 2°C / 60% ± 5% RH for 18 months and at Accelerated conditions; 5°C ± 3°C for 6 months while the innovator product has shown stability data of the drug substance at (up to 24 months at 25°C/60% RH and satisfactory 6 months results at 40°C/75% RH.</td><td>Firm has submitted that as per drug substance manufacturer storage condition is recommended, refrigerated i.e. 5°C ± 3°C.
For refrigeration the real time storage condition is 5°C ± 3°C and accelerated condition is 25°C ± 2°C / 60% ± 5% RH.
They further submitted they have submitted their stability as per ICH guidelines.</td></tr><tr><td>3.</td><td>Submitted BMR’s for the trial batches have shown manufacturing date of 14 & 15 & 16 October while the stability data sheets have mentioned 17-11-2021 as date of initiation.</td><td>Firm has submitted that they acknowledge the comments of the competent authority that we have been delayed to charge the stability considering to its manufacturing date, due to huge load of routine stability samples testing. Therefore, we have little</td></tr></table></td></tr>
</table>

	Justification for this delay shall be submitted.	bit delayed to charge the stability, while 03rd and 06th month interval testing was done within the specified time.

Decision: Approved with innovator's specifications.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Registration letter will be issued after submission of Rs. 7,500/- fee for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.**

Case 05; Registration applications of Deferred Locally manufactured (Human) drugs on Form 5.

889.	Name and address of manufacturer / Applicant	M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore.
	Brand Name +Dosage Form + Strength	AZOLOD Tablets 500mg
	Composition	Each film coated tablet contains: Azithromycin as Dihydrate……..500mg
	Diary No. Date of R& I & fee	Dy.No.738, 8000/-, 29-12-2010, 12000/-, 28-10-2013
	Pharmacological Group	Macrolides
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO/ Pack of 20, 50,100, 250 and 500 tablets
	Approval status of product in Reference Regulatory Authorities.	Azithromycin 500 mg Film-Coated Tablets by TEVA UK Limited (MHRA Approved)
	Me-too status	Zetro 500mg Tablet by Getz Pharma (Reg # 053120)
	GMP status	The firm has submitted copy of letter from QA division vide letter No. F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for rectification f following: (M-250) a. Evidence of approval of section from Drug Licensing Division is not submitted. b. Methylene chloride is used in film coating which is class II solvent and its use has been restricted because of its inherent toxicity. c. Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection. Deferred for verification of R & I details of applied formulation (M-296).
	Evaluation by PEC-XIV	• The firm has submitted coating without methylene chloride. • The firm has been granted GMP certificate based on inspection dated 05-09-2019. • Dossier receiving has been verified from R & I section and R & I number has been updated.
	Decision of 297th meeting of Registration Board;	Deferred for verification of R & I details and confirmation that the applied formulation is not already registered with the firm.

	Submission by the firm;	Firm has submitted copy of receiving for Azolod-500mg tablets in DRAP dated 29-12-2010 and they also submitted an undertaking on stamp paper that this product is not registered with them.
	Evaluation by PEC	• Copy of the receiving is verified by the Incharge (R&I) Admin Division with same dairy number and date as mentioned above. • Current GMP status and section approval of the firm could not be confirmed.
	Decision: The Board after delibereation decided to defer the case for confirmation of approved section /manufacturing facility of the firm from Licensing Division.	
890.	Name and address of manufacturer / Applicant	M/s Caylex Pharmaceuticals, (Pvt.) Limited, 27-Km Raiwind road Lahore.
	Brand Name +Dosage Form + Strength	IROP Syrup
	Composition	Each 15ml contains: Iron protein succinylate 800mg equivalent to elemental Iron……..40mg
	Diary No. Date of R& I & fee	Dy.No.752, 8000/- dated 29-12-2010, 12000/- 28-10-2013
	Pharmacological Group	Hematinic
	Type of Form	Form-5
	Finished product Specification	Manufacturer specs
	Pack size & Demanded Price	As per SRO/ Pack of 30, 60,90, 120 and 450ml
	Approval status of product in Reference Regulatory Authorities.	Approved in Italy
	Me-too status	Wincuss Syrup 800mg/15 ml of Winthrox Karachi.
	GMP status	The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for rectification of following: (M-250) a. Evidence of approval of section from Drug Licensing Division is not submitted. b. Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection. Deferred for verification of R & I details of applied formulation (M-296).
	Evaluation by PEC-XIV	• The firm has been granted GMP certificate based on inspection dated 05-09-2019. • Dossier receiving has been verified from R & I section and R & I number has been updated.
	Decision of 297th meeting of Registration Board;	Deferred for verification of R & I details and confirmation that the applied formulation is not already registered with the firm.
	Submission by the firm;	Firm has submitted copy of receiving for Irop Syrup in DRAP dated 29-12-2010 and they also submitted an undertaking on stamp paper that this product is not registered with them.
	Evaluation by PEC	• Copy of the receiving is verified by the Incharge (R&I) Admin Division with same dairy number and date as mentioned above.

		• Current GMP status and section approval of the firm could not be confirmed.
	Decision: The Board after delibereation decided to defer the case for confirmation of approved section /manufacturing facility of the firm from Licensing Division.	
891.	Name and address of manufacturer / Applicant	M/s Caylex Pharmaceuticals, (Pvt.) Limited, 27-Km Raiwind road Lahore.
	Brand Name +Dosage Form + Strength	O-CIN Tablet 400mg
	Composition	Each film coated tablet contains: Ofloxacin……400mg
	Diary No. Date of R& I & fee	Dy. No. 733, 8000/- dated 29-12-2010, 12000/- 28-10-2013
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO/ Pack of 10, 20, 30, 50, 100, 250, and 500's
	Approval status of product in Reference Regulatory Authorities.	Tarivid 400 of MHRA approved
	Me-too status	Clamocid 400mg Tablets by M/s Rock Pharmaceuticals Laboratories
	GMP status	The firm has submitted copy of letter from QA division vide letter No. F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for rectification f following: (M-250) a. Evidence of approval of section from Drug Licensing Division is not submitted. b. Methylene chloride is used in film coating which is class II solvent and its use has been restricted because of its inherent toxicity. c. Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection. Deferred for verification of R & I details of applied formulation (M-296).
	Evaluation by PEC-XIV	• Diary No. is not mentioned. • The firm has submitted coating without methylene chloride. • The firm has been granted GMP certificate based on inspection dated 05-09-2019. • Dossier receiving has been verified from R & I section and R & I number has been updated.
	Decision of 297th meeting of Registration Board;	Deferred for verification of R & I details and confirmation that the applied formulation is not already registered with the firm.
	Submission by the firm;	Firm has submitted copy of receiving for O-Cin 400mg tablets in DRAP dated 29-12-2010 and they also submitted an undertaking on stamp paper that this product is not registered with them.
	Evaluation by PEC	• Copy of the receiving is verified by the Incharge (R&I) Admin Division with same dairy number and date as mentioned above.

		• Current GMP status and section approval of the firm could not be confirmed.
	Decision: The Board after delibereation decided to defer the case for confirmation of approved section /manufacturing facility of the firm from Licensing Division.	
892.	Name and address of manufacturer / Applicant	M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore.
	Brand Name +Dosage Form + Strength	BISUB Suspension
	Composition	Each 5ml contains: Bismuth subsalicylate…….88mg
	Diary No. Date of R& I & fee	Dy. No. 739, 8000/- dated 29-12-2010, 12000/- 28-10-2013
	Pharmacological Group	Anti-diarrhoeal
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO/ Pack of 30, 60, 90, 120 and 450ml
	Approval status of product in Reference Regulatory Authorities.	Gastro-Bismol 17.5mg/ml Oral Suspension of Procter & Gamble (MHRA approved)
	Me-too status	BISMOL Syrup of Macter International
	GMP status	The firm has submitted copy of letter from QA division vide letter No. F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for rectification of following: (M-250) a. Evidence of approval of section from Drug Licensing Division is required. b. Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection. Deferred for verification of R & I details of applied formulation (M-296).
	Evaluation by PEC-XIV	• The firm has been granted GMP certificate based on inspection dated 05-09-2019. • Dossier receiving has been verified from R & I section and R & I number has been updated.
	Decision of 297th meeting of Registration Board;	Deferred for verification of R & I details and confirmation that the applied formulation is not already registered with the firm.
	Submission by the firm;	Firm has submitted copy of receiving for Bisub Suspension 88mg/5ml in DRAP dated 29-12-2010 and they also submitted an undertaking on stamp paper that this product is not registered with them.
	Evaluation by PEC	• Copy of the receiving is verified by the Incharge (R&I) Admin Division with same dairy number and date as mentioned above. • Current GMP status of the firm could not be confirmed.
	Decision: The Board after delibereation decided to defer the case for confirmation of approved section /manufacturing facility of the firm from Licensing Division.	
893.	Name and address of manufacturer / Applicant	M/s Caylex Pharmaceuticals, (Pvt.) Limited, 27-Km Raiwind road Lahore.
	Brand Name +Dosage Form + Strength	K-ZIM Syrup 100mg/ 5ml

	Composition	Each 5ml contains: Cefixime as Trihydrate……....100mg
	Diary No. Date of R& I & fee	Dy. No. 731, 8000/- dated 29-12-2010, 12000/- 28-10-2013
	Pharmacological Group	Cephalosporin antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO/ Pack of 30, 60, 90, 120, 450ml
	Approval status of product in Reference Regulatory Authorities.	Cefixime 100 mg/5 ml Powder for Oral Suspension by M/s Generics Ltd (MHRA Approved)
	Me-too status	Cefim Suspension 100mg/5ml by M/s Hilton Pharma (Reg#022108)
	GMP status	The firm has submitted copy of letter from QA division vide letter No. F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for rectification of following: (M-250) a. Evidence of approval of section from Drug Licensing Division is not submitted. b. Master formulation of liquid oral dosage form is submitted. c. Precautions/controls submitted for liquid oral dosage form. d. Finished product specifications are not submitted. e. Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection. Moreover, the status of the section for applied formulation is not clear from the report. Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in its 275th meeting (M-296).
	Evaluation by PEC-XIV	• Reference formulation is Powder for oral suspension while applied formulation is syrup. • The firm has been granted GMP certificate based on inspection dated 05-09-2019. • Dossier receiving has been verified from R & I section and R & I number has been updated.
	Decision of 297th meeting of Registration Board;	Deferred for following: • Revision of dosage form as per reference product along with submission of requisite fee. • Verification of R & I details and confirmation that the applied formulation is not already registered with the firm.
	Submission by the firm;	Firm has submitted copy of receiving for K-Zim 100mg/5ml Dry, suspension in DRAP dated 29-12-2010 and they also submitted an undertaking on stamp paper that this product is not registered with them.
	Evaluation by PEC	• ***The firm has already been granted registration of Cefixime dry suspension 100mg/5ml vide reg. No. 064519 dated 07-06-2010 vide letter No. F. 15-4/2009/RRR-(M218).***

		• RRA status of the Syrup formulation could not be confirmed. • Copy of the receiving is verified by the Incharge (R&I) Admin Division with same dairy number and date as mentioned above. • Current GMP status of the firm could not be confirmed.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
894.	Name and address of manufacturer / Applicant	M/s Caylex Pharmaceuticals, (Pvt.) Limited, 27-Km Raiwind road Lahore.
	Brand Name +Dosage Form + Strength	CAYBION Capsules 50mg
	Composition	Each capsule contains: Diclofenac sodium enteric coated pellets (32%).....50mg
	Diary No. Date of R& I & fee	Dy. No. 737, 8000/- dated 29-12-2010, 12000/- 28-10-2013
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO/ Pack of 10, 20, 30, 50, 100, 250, and 500's
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Amfac Capsules of Ambrosia Pharma (Reg#056576)
	GMP status	The firm has submitted copy of letter from QA division vide letter No. F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for rectification of following: (M-250) a. Evidence of approval of section from Drug Licensing Division is not submitted. b. Evidence of approval of same generic, dosage form and strength in reference agencies is not submitted. c. Source of Diclofenac sodium pellets, their composition, certificate of analysis, stability studies as per zone IV and in case of import of pellets, legalized GMP certificate of the source along with the requisite fee prescribed under the rules is not submitted. d. Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection. Deferred for verification of R & I details of applied formulation (M-296).
	Evaluation by PEC-XIV	• Diary no. is missing • Source of Pellets: M/s Vision Pharma (Diclofenac sodium Enteric coated pellets 32%). • The firm has been granted GMP certificate based on inspection dated 05-09-2019. • Dossier receiving has been verified from R & I section and R & I number has been updated.

	Decision of 297th meeting of Registration Board;	Deferred for verification of R & I details and confirmation that the applied formulation is not already registered with the firm.
	Submission by the firm;	Firm has submitted copy of receiving for Caybion-50mg Capsules in DRAP dated 29-12-2010 and they also submitted an undertaking on stamp paper that this product is not registered with them.
	Evaluation by PEC	• Firm has submitted revised Form-5, wherein they have changed the label claim as under; **CAYBION 50mg DR Capsules** **Each DR Capsule contains:** **Enteric coated pellets of Diclofenac sodium** **eq. to Diclofenac sodium …….50mg** ***However, fee for change of label claim is not submitted.*** • Copy of the receiving is verified by the Incharge (R&I) Admin Division with same dairy number and date as mentioned above. • Current GMP status of the firm could not be confirmed.
	Decision: The Board after delibereation decided to defer the case for confirmation of approved section /manufacturing facility of the firm from Licensing Division. `Firm will also submit full fee for change of label claim as per reference product as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.	
895.	Name and address of manufacturer / Applicant	M/s Caylex Pharmaceuticals, (Pvt.) Limited, 27-Km Raiwind road Lahore.
	Brand Name +Dosage Form + Strength	CAYBION Capsules SR 100mg
	Composition	Each capsule contains: Diclofenac sodium SR pellets (32%)……..100mg
	Diary No. Date of R& I & fee	Dy. No. 734, 8000/- dated 29-12-2010, 12000/- 28-10-2013
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO/ Pack of 10, 20, 30, 50, 100, 250, and 500's
	Approval status of product in Reference Regulatory Authorities.	Diclomax Retard 100mg modified release capsules of Galen Ltd., UK (MHRA approved)
	Me-too status	Flamex SR capsules 100mg of M/s Werrick Pharma (Reg#020592)
	GMP status	The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for rectification of following: (M-250) a. Evidence of approval of section from Drug Licensing Division is not submitted. b. Evidence of approval of same generic, dosage form and strength in reference agencies is not submitted. c. Source of Diclofenac sodium pellets, their composition, certificate of analysis, stability studies as per zone IV and in case of import of pellets, legalized GMP certificate of the source along with the requisite fee prescribed under the rules is not submitted.

		d. Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection. Deferred for verification of R & I details of applied formulation (M-296).
	Evaluation by PEC-XIV	• Source of Pellets: M/s Vision Pharma (Diclofenac sodium SR pellets 32%) • The firm has been granted GMP certificate based on inspection dated 05-09-2019. • Dossier receiving has been verified from R & I section and R & I number has been updated.
	Decision of 297th meeting of Registration Board;	Deferred for verification of R & I details and confirmation that the applied formulation is not already registered with the firm.
	Submission by the firm;	Firm has submitted copy of receiving for Caybion-100mg SR Capsules in DRAP dated 29-12-2010 and they also submitted an undertaking on stamp paper that this product is not registered with them.
	Evaluation by PEC	• Copy of the receiving is verified by the Incharge (R&I) Admin Division with same dairy number and date as mentioned above. • Current GMP status and section approval of the firm could not be confirmed.
	Decision: The Board after delibereation decided to defer the case for confirmation of approved section /manufacturing facility of the firm from Licensing Division.	
896.	Name and address of manufacturer / Applicant	M/s Caylex Pharmaceuticals, (Pvt.) Limited, 27-Km Raiwind road Lahore.
	Brand Name +Dosage Form + Strength	C-PHOS Tablet 250mg
	Composition	Each film coated tablet contains: Chloroquine Phosphate ……...250mg
	Diary No. Date of R& I & fee	Dy. No. 760, 8000/- dated 29-12-2010, 12000/- 28-10-2013
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO/ Pack of 10, 20, 30, 50, 100, 250, and 500's
	Approval status of product in Reference Regulatory Authorities.	MHRA approved
	Me-too status	Cloroquin 250mg Tablet of klifton Pharma (Reg#058332)
	GMP status	The firm has submitted copy of letter from QA division vide letter No. F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for rectification of following: (M-250) a. Formulation is approved in reference drug agencies as uncoated tablet however applied formulation is film coated. b. Reference of finished product spec need to be submitted as it is included in official pharmacopeia.

		c. Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection. Deferred for verification of R & I details of applied formulation (M-296).
	Evaluation by PEC-XIV	• The firm has been granted GMP certificate based on inspection dated 05-09-2019. • Dossier receiving has been verified from R & I section and R & I number has been updated.
	Decision of 297th meeting of Registration Board;	Deferred for verification of R & I details and confirmation that the applied formulation is not already registered with the firm.
	Submission by the firm;	Firm has submitted copy of receiving for C-Phos-250mg Tablets in DRAP dated 29-12-2010 and they also submitted an undertaking on stamp paper that this product is not registered with them.
	Evaluation by PEC	• Copy of the receiving is verified by the Incharge (R&I) Admin Division with same dairy number and date as mentioned above. • Current GMP status of the firm could not be confirmed.
	Decision: The Board after delibereation decided to defer the case for confirmation of approved section /manufacturing facility of the firm from Licensing Division.	
897.	Name and address of manufacturer / Applicant	M/s Caylex Pharmaceuticals, (Pvt.) Limited, 27-Km Raiwind road Lahore.
	Brand Name +Dosage Form + Strength	BISUB Tablet 265mg
	Composition	Each film coated tablet contains: Bismuth Subsalicylate……...265mg
	Diary No. Date of R& I & fee	Dy. No., 8000/- dated 29-12-2010, 12000/- dated 28-10-2013
	Pharmacological Group	Mucosal protective.
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO/ Pack of 10, 20, 30, 50, 100, 250, and 500's
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Not confirmed
	GMP status	The firm has submitted copy of letter from QA division vide letter No. F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for rectification f following: (M-250) • Evidence of approval of section from Drug Licensing Division is not submitted. • Evidence of approval of same generic, dosage form in reference agencies is not submitted. • Applied drug is available locally as chewable tablet however firm has applied film coated. • Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/shortcomings pointed out during the inspection.

	Evaluation by PEC	The firm has been granted GMP certificate based on inspection dated 05-09-2019.
	Decision of 296th meeting of Registration Board;	Deferred for following: • Evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Submission by the firm;	Firm has submitted copy of receiving for Bisub 265mg Tablets in DRAP dated 29-12-2010 and they also submitted an undertaking on stamp paper that this product is not registered with them.
	Evaluation by PEC	• Copy of the receiving is verified by the Incharge (R&I) Admin Division with Dy. No. 742 dated 29-12-2010. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • However, approval status in RRA and me too are not provided by the firm. • Current GMP status and section approval of the firm could not be confirmed.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
898.	Name and address of manufacturer / Applicant	M/s Caylex Pharmaceuticals, (Pvt.) Limited, 27-Km Raiwind road Lahore.
	Brand Name +Dosage Form + Strength	CAYMOL Plus Tablet
	Composition	Each tablet contains: Paracetamol……...200mg Aspirin……..…300mg
	Diary No. Date of R& I & fee	Dy. No., 8000/- dated 29-12-2010, 12000/- dated 28-10-2013
	Pharmacological Group	NSAID.
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO/ Pack of 30, 60, 90, 120, 450ml
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Liskoprin of Lisko Pvt. Limited.
	GMP status	The firm has submitted copy of letter from QA division vide letter No. F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for rectification f following: (M-250)

		• Evidence of approval of section from Drug Licensing Division is not provided. • Evidence of approval of same generic, dosage form and strength in reference drug agencies need to be submitted. • Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/shortcomings pointed out during the inspection.
	Evaluation by PEC	• Approval status in reference agency is required to be submitted. • The firm has been granted GMP certificate based on inspection dated 05-09-2019.
	Decision of 296th meeting of Registration Board;	Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in its 275th meeting.
	Submission by the firm;	Firm has submitted copy of receiving for Caymol plus Tablets in DRAP dated 29-12-2010 and they also submitted an undertaking on stamp paper that this product is not registered with them.
	Evaluation by PEC	• Copy of the receiving is verified by the Incharge (R&I) Admin Division with Dy. No. 744 dated 29-12-2010. • However, approval status in RRA is not provided by the firm. • Current GMP status of the firm could not be confirmed.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	

Case 06; Registration applications of Deferred Locally manufactured (Veterinary) drugs on Form 5.

899.	Name and address of manufacturer/ Applicant	M/s Selmore Pharmaceuticals (Pvt.) Ltd., 36-Km, Multan Road Lahore.
	Brand Name + Dosage Form + Strength	Combigent Plus Injection 50ml.
	Composition	Each ml Contains: Gentamicin Sulphate ……..…60mg Tylosin Tartrate ……150mg Dexamethasone ……..…0.265mg Chlorpheniramine ……..…7.5mg
	Diary No. Date of R & I & fee	Dy. No 26562 dated 09-10-2020; Rs.20,000/- dated 08-10-2020.
	Pharmacological Group	Combination of antibiotic, corticosteroid & anti-histaminic drug.
	Type of Form	Form-5.
	Finished product Specification	Manufacturer specifications.
	Pack size & Demanded Price	Decontrolled.
	Approval status of product in Reference Regulatory Authorities	

	Me-too status	Genta Combisone Injection (10ml, 20ml, 50ml, 100ml, 250ml), Leads Pharma, Reg. No. 046696.
	GMP status	Same as above.
	Remarks of the Evaluator	Manufacturing facility/section approval could not be confirmed.
	Decision of 312th meeting of Registration Board.	Deferred for confirmation of required manufacturing facility / section from Licensing Division.
	Submission by the firm.	Firm has submitted copy of GMP certificate No. 10/2023-DRAP (AD-7613761776-5101) dated 27-02-2023 issued on the basis of inspection conducted on 24th & 25th January, 2023 wherein Injectable (Steroid) section is mentioned. Firm has also submitted Section approval letter wherein there in no steroidal injectable section is mentioned.
	Remarks of the Evaluator	***GMP certificate has mentioned separated Injectable (Steroid) section. However, no section approval from Licensing Division is provided by the firm.***
	Decision: The Board after delibereation decided to defer the case for confirmation of approved section /manufacturing facility of the firm from Licensing Division.	
900.	Name and address of manufacturer/ Applicant	M/s Selmore Pharmaceuticals (Pvt.) Ltd., 36-Km, Multan Road Lahore.
	Brand Name + Dosage Form + Strength	Combigent Plus Injection 100ml.
	Composition	Each ml Contains: Gentamicin Sulphate ……..…60mg Tylosin Tartrate ……150mg Dexamethasone ……..…0.265mg Chlorpheniramine ……..…7.5mg
	Diary No. Date of R & I & fee	Dy. No 26564 dated 09-10-2020; Rs.20,000/- dated 08-10-2020.
	Pharmacological Group	Combination of antibiotic, corticosteroid & anti-histaminic drug.
	Type of Form	Form-5.
	Finished product Specification	Manufacturer specifications.
	Pack size & Demanded Price	Decontrolled.
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	Genta Combisone Injection (10ml, 20ml, 50ml, 100ml, 250ml), Leads Pharma, Reg. No. 046696.
	GMP status	Same as above.
	Remarks of the Evaluator	Manufacturing facility/section approval could not be confirmed.
	Decision of 312th meeting of Registration Board.	Deferred for confirmation of required manufacturing facility / section from Licensing Division.
	Submission by the firm.	Firm has submitted copy of GMP certificate No. 10/2023-DRAP (AD-7613761776-5101) dated 27-02-2023 issued on the basis of inspection conducted on 24th & 25th January, 2023 wherein Injectable (Steroid) section is mentioned. Firm has also submitted Section approval letter wherein there in no steroidal injectable section is mentioned.
	Remarks of the Evaluator	***GMP certificate has mentioned separated Injectable (Steroid) section. However, no section approval from Licensing Division is provided by the firm.***
	Decision: The Board after delibereation decided to defer the case for confirmation of approved section /manufacturing facility of the firm from Licensing Division.	

901.	Name and address of manufacturer/ Applicant	M/s Selmore Pharmaceuticals (Pvt.) Ltd., 36-Km, Multan Road Lahore.
	Brand Name + Dosage Form + Strength	Tycosol Injection 50ml.
	Composition	Each ml Contains: Thiamphenicol ……200mg Tylosin Tartrate ……..…15.7mg Prednisolone ……5mg
	Diary No. Date of R & I & fee	Dy. No 26569 dated 09-10-2020; Rs.20,000/- dated 08-10-2020.
	Pharmacological Group	Antibiotic & steroid combination.
	Type of Form	Form-5.
	Finished product Specification	Manufacturer's specification.
	Pack size & Demanded Price	Decontrolled.
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	Triox-P Injection (20ml, 50ml & 100ml), S.J & G Fazul Ellahie, Reg. No. 069638.
	GMP status	
	Remarks of the Evaluator	• Firm has revised their formulation in line with available me too with submission of 30,000/- fee vide slip No. 01999823633 dated 06-09-2021. • Thipesin Injection, Reg. No. 099036, International pharma. Revised formulation is as under: Each ml Contains: Thiamphenicol ……200mg Tylosin Tartrate ……..…57.5mg Prednisolone acetate ..……5mg • Manufacturing facility/section approval could not be confirmed.
	Decision of 312th meeting of Registration Board.	Deferred for confirmation of required manufacturing facility / section from Licensing Division.
	Submission by the firm.	Firm has submitted copy of GMP certificate No. 10/2023-DRAP (AD-7613761776-5101) dated 27-02-2023 issued on the basis of inspection conducted on 24th & 25th January, 2023 wherein Injectable (Steroid) section is mentioned. Firm has also submitted Section approval letter wherein there in no steroidal injectable section is mentioned.
	Remarks of the Evaluator	***GMP certificate has mentioned separated Injectable (Steroid) section. However, no section approval from Licensing Division is provided by the firm.***
	Decision: The Board after delibereation decided to defer the case for confirmation of approved section /manufacturing facility of the firm from Licensing Division.	
902.	Name and address of manufacturer/ Applicant	M/s Selmore Pharmaceuticals (Pvt.) Ltd., 36-Km, Multan Road Lahore (Veterinary Hormone Liquid injection).
	Brand Name + Dosage Form + Strength	Bosol Injection 10ml.
	Composition	Each ml Contains: Buserelin Acetate 0.0042mg Eq. To Buserelin…0.004mg

	Diary No. Date of R & I & fee	Dy. No 26946 dated 13-10-2020; Rs.20,000/- dated 12-10-2020.
	Pharmacological Group	Gonadotropin releasing hormone analogue.
	Type of Form	Form-5.
	Finished product Specification	Manufacturer's specifications.
	Pack size & Demanded Price	Decontrolled.
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	Conceptal Injection (2.5ml, 5ml, 10ml), Star Laboratories, Reg. No. 058939.
	GMP status	Same as above.
	Remarks of the Evaluator	• Firm has Veterinary Hormone Liquid injection section. However, it is not cleared whether it is steroidal hormone section or only hormone section. • Manufacturing facility/section approval could not be confirmed.
	Decision of 312th meeting of Registration Board.	Deferred for confirmation of required manufacturing facility / section from Licensing Division.
	Submission by the firm.	Firm has submitted copy of GMP certificate No. 10/2023-DRAP (AD-7613761776-5101) dated 27-02-2023 issued on the basis of inspection conducted on 24th & 25th January, 2023 wherein Injectable (Hormone) section is mentioned. Firm has also submitted Section approval letter wherein Liquid Injectable (Hormone) Veterinary section is mentioned.
	Remarks of the Evaluator	***Firm has also submitted their registration letter for the same formulation in 5ml and 2.5ml packs with registration number 101516 & 083245 respectively.***
	Decision: The Board after delibereation decided to defer the case for confirmation of approved section /manufacturing facility of the firm from Licensing Division.	
903.	Name and address of manufacturer/ Applicant	M/s Selmore Pharmaceuticals (Pvt.) Ltd., 36-Km, Multan Road Lahore.
	Brand Name + Dosage Form + Strength	Bdex Liquid Injection 100ml.
	Composition	Each ml Contains: Benzathine Penicillin G ……125,000IU Benzyl Penicillin Procaine ……125,000IU Dihydro Streptomycin Sulphate ……0.25gm Dexamethasone Sodium Phosphate …0.20mg Dexamethasone 21 Isonicotinate ……0.20mg
	Diary No. Date of R & I & fee	Dy. No 10342 dated 02-07-2019; Rs.20,000/- dated 01-07-2019.
	Pharmacological Group	Natural penicillin/aminoglycosides/corticosteroids.
	Type of Form	Form-5.
	Finished product Specification	Manufacturer's specifications.
	Pack size & Demanded Price	Decontrolled.
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	Bicormicina L.A. Injection, Imported by Prix pharma from Italy, Reg. No. 027477.
	GMP status	
	Remarks of the Evaluator	• Reference product contain dihydrostreptomycin sulphate 0.25gm (equivalent to

		dihydrostreptomycin 0.20gm) while the applied formulation contains dihydrostreptomycin sulphate 0.25gm. • Manufacturing facility/section approval could not be confirmed.
	Decision of 312th meeting of Registration Board.	Deferred for confirmation of required manufacturing facility / section from Licensing Division.
	Submission by the firm.	Firm has submitted copy of GMP certificate No. 10/2023-DRAP (AD-7613761776-5101) dated 27-02-2023 issued on the basis of inspection conducted on 24th & 25th January, 2023 wherein Injectable (Steroid) section is mentioned. Firm has also submitted their registration letter for the same formulation in 50ml packs with registration number 080952. Firm has also submitted Section approval letter wherein there in no steroidal injectable section is mentioned.
	Remarks of the Evaluator	***GMP certificate has mentioned separated Injectable (Steroid) section. However, no section approval from Licensing Division is provided by the firm.***
	Decision: The Board after delibereation decided to defer the case for confirmation of approved section /manufacturing facility of the firm from Licensing Division.	

Agenda of Evaluator PEC-XV

NEW CASES OF FORM 5-F:

904.	Name, address of Applicant / Marketing Authorization Holder	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205 Industrial Triangle, kahuta Road, Islamabad-25000, Pakistan
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot # 204-205 Industrial Triangle, kahuta Road, Islamabad-25000, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3729 date of submission: 09-02-2022

	Details of fee submitted	PKR 75,000/-: dated 01/02/2022
	The proposed proprietary name / brand name	Segana XR 10mg/5mg/1000mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Empagliflozin…….10mg Linagliptin……5mg Metformin HCL……...1000mg (as extended release)
	Pharmaceutical form of applied drug	Tablet, Extended Release
	Pharmacotherapeutic Group of (API)	Metformin HCL biguanide class of antidiabetics Empagliflozin: Sodium-glucose co-transporter 2 (SGLT2) inhibitors. Linagliptin: dipeptidyl peptidase-4 (DPP-4) inhibitors.
	Reference to Finished product specifications	Innovator specs
	Proposed Pack size	30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TRIJARDY XR Tablet of BOEHRINGER INGELHEIM (FDA approved)
	For generic drugs (me-too status)	N/A
	GMP status of the Finished product manufacturer	The firm is granted GMP certificate based on inspection conducted on 03-01-2022 and it is valid till 02-01-2024.
	Name and address of API manufacturer.	<u>EMPAGLIFLOZIN:</u> • FUXIN LONG RUI PHARMACEUTICAL Co., Ltd. <u>METFORMIN HCL:</u> • AARTI DRUGS LIMITED <u>LINAGLIPTIN:</u> • M/s. Venkata Narayana Active Ingredients
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 66 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months

		EMPAGLIFLOZIN Batches: (20160606, 20161017, 20161219) METFORMIN HCL Batches: (MEF/1410027 MEF/1410028, MEF/1410029) LINAGLIPTIN batches: (LNG20131220 LNG20141220, LNG20151220)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	The Firm has performed pharmaceutical equivalence profile of their developed formulation Segana XR 10mg/5mg/1000mg tablet (B #ST21J011) with innovator product Trijardy XR Tablets (B # 3185605) of M/s Boehringer Ingelheim Pharma, USA. The results showed that release profile of both test and comparator products were comparable.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	EMPAGLIFLOZIN: • Manufacturer: FUXIN LONG RUI PHARMACEUTICAL Co., Ltd. METFORMIN HCL: • Manufacturer: AARTI DRUGS LIMITED LINAGLIPTIN: • Manufacturer: M/s. Venkata Narayana Active Ingredients		
API Lot No.	(Empagliflozin): E-20190920-D02-E06-01 (Metformin HCL): MEF/10030953 (Linagliptin): LG0131220		
Description of Pack (Container closure system)	HDPE bottles (30's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 36 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9,12,18, 24 & 36 (Months)		
Batch No.	ST21J011	ST21J012	ST21J013
Batch Size	3000 tablets	3000 tablets	3000 tablets
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	05-10-2021	06-10-2021	06-10-2021
No. of Batches	03		

Administrative Portion		
37.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has referred to previous inspection of stability data of the same dosage form on the basis of which Registration Board in 289th meeting decided to approve registration of Promig Plus 500mg/20mg Tablet and

		Promig Plus 375mg/20mg Tablet. Inspection date: 14th March, 2019 The report shows that: The HPLC software is 21 CFR compliant.The firm has provided data loggers with stability chambers.
38.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	EMPAGLIFLOZIN: Copy of GMP issued by Food & drug authority china valid till 23/08/2023. METFORMIN HCL: Copy of GMP certificate No. 20031933 issued by Food & drug Control Administration valid till 19/03/2023. LINAGLIPTIN: Copy of GMP certificate issued by drug Control Administration Andhra Pradesh valid till 07/12/2024.
39.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice for the import of EMPAGLIFLOZIN (1.5 Kg, Invoice # HN19120501-H) and attested copy of form 6 (I&E) DRAP, Islamabad dated 10-01-2020. The firm has submitted copy of invoice for the import of METFORMIN HCL (1000 Kg, Invoice # EXP/302/20-21) and attested copy of form 6 (I&E) DRAP, Islamabad dated 05-08-2020. The firm has submitted copy of invoice for the import of LINAGLIPTIN (0.350 Kg, Invoice # 202110329) and attested copy of form 6 (I&E) DRAP, Islamabad dated 08-03-2021.
40.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
41.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Compliance Record of HPLC software 21CFR & Audit trail on testing reports of product submitted.
42.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	3.2.S.4.2 Metformin HCl	Justify for performance of assay via potentiometric titration, since the USP recommended HPLC method for assay testing of metformin HCl.	Firm replied that they have now performed the assay of metformin HCl via HPLC method as per USP 43 and accordingly performed the verification studies of assay procedure on HPLC.
2.	3.2.S.4.2 Linagliptin	Justify for using different method for performing the enantiomeric purity test from that specified by the drug substance manufacturer. Further, submit the evidence of availability of chiral HPLC (chiral Pak AD column) as you have mentioned in the procedure of enantiomeric purity test.	Firm again submitted the procedure of enantiomeric purity test which is different from the procedure followed by the drug substance manufacturer.

3.	3.2.S.7	Please confirm the claimed re-test period of empagliflozin and linagliptin, accordingly provide the stability data of long term till the claimed re-test date.	Firm submitted the stability data of both drug substance.
4.	3.2.P.1	Justify the double film coating on the core of metformin comparing the formulation of innovator product in which single film coating has been done on the core of metformin.	Firm replied that " we have performed drug coating of empagliflozin and Lina gliptin in single step as performed by innovator and then finish coat (film coating) is done in order to protect the drug coating and smoothen the final tablets.
5.	3.2.P.5.1	Justify for not including the arginine content test and water content in the finished product specification since these test are included in the specification of finished product of innovator product.	Firm replied that they now included the arginine content test and water content in the finished product specification since these tests are included in the specification of finished product of innovator product. Firm submitted the procedure of arginine content and water content test.
6.	3.2.P.8	Submit the remaining stability data of drug product ,since you have submitted only three month stability data.	Firm submitted the stability data performed at long term stability condition till 12 months.
7.	3.2.R.1.1	Scientific justification is required for using 10% excess quantity of linagliptin and empagliflozin in the trail batches as evident from the submitted Batch manufacturing record comparing the review literature of innovator brand in which the composition did not mentioned the excess amount of said active ingredients.	Firm replied that to compensate the machine loss in coating they use 10% excess quantity of linagliptin and empagliflozin.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

PREVIOUSLY DEFERRED CASES OF FORM 5-F

a. IMPORTED PRODUCT:

905.	Name, address of Applicant / Importer	M/s. Hospital Supply Corporation
	Details of Drug Sale License of importer	License No:0013 Address: 42, Darul Aman Housing Society, Karachi Address of Godown: 46-E-2, Block-6, PECHS, Karachi Validity: 29-06-2022 Status: License to sell drugs as distributor Renewal: NA
	Name and address of marketing authorization holder (abroad)	BIEM ILac Sanayi ve Ticaret A.S., Anittepe Mah, Turgut Reis Cad. No.: 21 Tandogan Cnkaya, Ankara Turkey
	Name, address of manufacturer(s)	Mefar Ilac San A.S. Ramazanoglu Mahalles Ensar

		Caddesi No.2 Istanbul Turkey
	Name of exporting country	Turkey
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized copy of CoPP certificate (No.2021/3007) dated 01-10-2021 issued by Turkish Medicines and Medical Devices Agency. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 3 years. The name of importing country on CoPP is mentioned as Pakistan. Furthermore the CoPP was valid till 01-10-2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from BIEM ILac Sanayi ve Ticaret A.S., Anittepe Mah, Turgut Reis Cad. No.: 21 Tandogan Cnkaya, Ankara Turkey. The letter species that the manufacturer appoints M/s. Hospital Supply Corporation to register their products in Pakistan. The authorization letter is valid till 31-12-2024.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.795 : 10-01-2022
	Details of fee submitted	PKR 150,030/-: 26-10-2021
	The proposed proprietary name / brand name	Biemexol 350mgI/ml vial (50ml)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Iohexol……755mg/ml (755mg Iohexol equivalent to 350mg I)
	Pharmaceutical form of applied drug	Injectable
	Pharmacotherapeutic Group of (API)	X-Ray Contrast Media
	Reference to Finished product specifications	In-house specification/USP
	Proposed Pack size	50ml vial
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Monopague 350mg/ml Injection (063945) of M/s. Graton Pharma, Karachi.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.

		Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Zhejiang Taizhou Hisyn Pharmaceutical Co. Ltd. Chemical and Medical Raw Materials Base, Linhai Park Zhejian Province Zhejiang Starry Pharmaceutical Co. Ltd. No.1 Starry Road of Xianju Zhejiang Province, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25°C±2, 60% RH±5%. The stability study data is till 36 months. Zhejiang Taizhou Hisyn Pharmaceutical Co. Ltd. Chemical and Medical Raw Materials Base, Linhai Park Zhejian Province Batch no. H18920080501, H18920080502, H18920080503 Zhejiang Starry Pharmaceutical Co. Ltd. No.1 Starry Road of Xianju Zhejiang Province, China Batch no. C006-0802003, C006-0802004, C006-0802005
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence established against Omnipaque 350mgI/ML Vial (Batch no. 14778967)
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Colorless type I Glass vial (50ml), bromobutyl closure, blue tear off cap
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 2 batches The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 65% ± 5% RH. The real time stability study data of 24 month has submitted.

INDICATIONS AND USAGE:
OMNIPAQUE (iohexol) injection is a radiographic contrast agent indicated for intrathecal, intravascular, oral, rectal, intraarticular and body cavity use. OMNIPAQUE oral solution is indicated for oral use only in conjunction with OMNIPAQUE injection administered intravenously for computed tomography (CT) of the abdomen.
DOSAGE AND ADMINISTRATION:
The concentration and volume required will depend on the indication, size and condition of the patient, and the equipment and imaging technique used. For CT of the head and body, OMNIPAQUE may be used with an automated contrast injection system or contrast media management system cleared for use with OMNIPAQUE. See full prescribing information for complete dosing information.
Evaluation by PEC:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	Submit valid drug sale license of importer Hospital supply corporation ,since the submitted DSL was expired on 29-06-2022.	
2.	According to the composition table associated with CoPP of drug product, API iohexol comply USP specification while the submitted COA of both API vendors claimed that their material complies EP specification, so clarification is required in this regard.	
3.	3.2.S.4	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by the drug product manufacturer as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required".
4.	3.2.S.4.3	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".* Since you have submitted the validation report of drug substance manufacturer.
5.	3.2.S.7	Justify for not performing the test of sterility, bacterial endotoxin test, ionic compound test, free iodide test, ionic compound test, heavy metal test, residual solvent test and color of solution test during the stability studies of drug substance as evident from the data of both API suppliers.
6.	3.2.P.2.2.1	Justify for not performing the test of free iodine, particulate matter, sterility and bacterial endotoxin test while establishing the pharmaceutical equivalence against the reference product.
7.	3.2.P.5.1	Justify for not adopting the USP or BP specification for finished product, since the official monograph of iohexol injection is present in both BP and USP Pharmacopeia. Justify for adapting the wider assay limits i.e. from 90-110% comparing the assay limit recommended in USP monograph of iohexol injection i.e. 95-105%.
8.	3.2.P.8	Submit the batch size details of batches whose stability data has been submitted in section 3.2. P.8. Submit the complete data of long term stability studies performed at zone IV-a conditions, since you have claimed shelf life of 36months and provide the data of 24 months.

Decision of 326th meeting of Registration Board:
Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response of the Firm:

S.no.	Sections	Observations/Deficiencies/ Short-comings along with Response of the Firm
1.	Submit valid drug sale license of importer Hospital supply corporation, since the submitted DSL was expired on 29-06-2022.	

	Firm submitted the copy of valid DSL issued in the name of M/s. Hospital Supply Corporation 42, Darul Aman Housing Society, Karachi (DSL no. 0237) and validity granted till 29/06/2024.	
2.	According to the composition table associated with CoPP of drug product, API iohexol comply USP specification while the submitted COA of both API vendors claimed that their material complies EP specification, so clarification is required in this regard. Firm submit the explanation letter from Product License holder i.e. BIEM ILac Sanayi ve Ticaret A.S., Anittepe Mah, Turgut Reis Cad. No.: 21 Tandogan Cnkaya, Ankara Turkey, in which it is stated that "during pharmaceutical development and first application in country of origin, first DMF of API supplier Zhejiang Starry Pharmaceutical Co. Ltd. No.1 Starry Road of Xianju Zhejiang Province, China was in compliance of USP. Accordingly, batch formula was established according to USP specifications. Lately, starry pharmaceutical has update their specifications according to EP specifications and get approval for CEP. Biem has applied for CEP submission variation in 03-08-2016 and get approval for variation in 10.10.2016. Firm submitted the copy of variation letter issued from Turkish Medicines and Medical Agency for the approval of updated European Pharmacopeia certificate of conformity.	
3.	3.2.S.4	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by the drug product manufacturer as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required". Not submitted the requisite information.
4.	3.2.S.4.3	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".* Since you have submitted the validation report of drug substance manufacturer. Not submitted the requisite information.
5.	3.2.S.7	Justify for not performing the test of sterility, bacterial endotoxin test, ionic compound test, free iodide test, ionic compound test, heavy metal test, residual solvent test and color of solution test during the stability studies of drug substance as evident from the data of both API suppliers. Not submitted as the API supplier was on leave and commit to submit as soon as received.
6.	3.2.P.2.2.1	Justify for not performing the test of free iodine, particulate matter, sterility and bacterial endotoxin test while establishing the pharmaceutical equivalence against the reference product. • Product license holder replied that Product was developmental batches manufactured in non-sterile R&D Laboratory, because of this sterility test and bacterial endotoxin test was not performed. • Further, excipients used for manufacturing of Biemexol are standard excipient used in injectable solutions. Iohexol is very soluble in water. Trometamine dissolves in water and it is used for increasing solubility in our formulation. Therefore, particulate matter test was not performed in the developmental phase. • In the formulation of the drug product, the only source for free iodine is the API Iohexol. According to the analysis results (lower than 10 PPM) obtained from CoA of API, the free iodine was evaluated as low risk for effecting of product quality. Therefore, free iodine was not performed during the development phase. Also, it is confirmed by stability data that active ingredient has not got negative effects on free iodine and stability.

7.	3.2.P.5.1	Justify for not adopting the USP or BP specification for finished product, since the official monograph of iohexol injection is present in both BP and USP Pharmacopeia. Firm replied that for specifications which limits given In-house methods as related substances, assay and density-analysis methods are established following the USP monographs.
8.	3.2.P.5.1	Justify for adapting the wider assay limits i.e. from 90-110% comparing the assay limit recommended in USP monograph of iohexol injection i.e. 95-105%. Firm replied that the assay release and shelf life specifications of Biemexol 350mgI/ml vial containing solution for IA, IV Injection are proposed as 90.0%-110% according to the results obtained from analytical results of developmental batches, validation batches and reference product. However, the assay limit recommended in USP monograph of iohexol injection is 95-105%.
9.	3.2.P.8	Submit the batch size details of batches whose stability data has been submitted in section 3.2. P.8. Firm submitted the following details: Batch no. / Batch size (Litre) / Batch size (vials) 711001 (50ml) / 80L / 1,584 712002 (50ml) / 80L / 1,584 However, as per the CTD guidance document for selection of number and size of batches applicant may follow, any of the following options: a) ICH/WHO guidelines. b) At least 2 batches having the following minimum batch size considering the scientific reliability • OSDs: 5000 Units • Oral Liquid/Suspension: 2000 • Injectable: 2000 • Aerosol and any other specialized preparations: 500 c) At least 3 batches having scientifically rational batch size, sufficient enough to perform complete testing till the claimed shelf life.
10	3.2.P.8	Submit the complete data of long term stability studies performed at zone IV-a conditions, since you have claimed shelf life of 36 months and provide the data of 24 months. Firm submitted the stability data of two batches of 50ml till the claimed shelf life of 36months.

Decision: Deferred for the submission of following shortcomings/justifications:

- **Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by the drug product manufacturer.**
- **Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 by the Drug Product manufacturer for drug substance.**
- **Justification for not performing the test of sterility, bacterial endotoxin test, ionic compound test, free iodide test, ionic compound test, heavy metal test, residual solvent test and color of solution test during the stability studies of drug substance as evident from the data of both API suppliers.**
- **Justification for not performing the test of free iodine, particulate matter, sterility and bacterial endotoxin test while establishing the pharmaceutical equivalence against the reference product.**
- **Justify for not adopting the USP or BP specification for finished product, since the official monograph of iohexol injection is present in both BP and USP Pharmacopeia.**
- **Justify for adapting the wider assay limits i.e. from 90-110% comparing the assay limit recommended in USP monograph of iohexol injection i.e. 95-105%.**

• **Submit stability data of batch sizes in accordance with the CTD guidance document approved by Registration Board.Since you have submitted the stability data of drug product of batch sizes consist of 1584 vials while minimum requirement 2000 vials per batch.**		
906.	Name, address of Applicant / Importer	M/s. Sohail Corporation Plot no.7, SR-5,Serai Quarters (Techno City) WH-42, Ware House No.42, Karachi.
	Details of Drug Sale License of importer	License No:041 Address: Plot no.7, SR-5, Serai Quarters (Techno City) WH-42, Ware House No.42, Karachi. Address of Go down: Same as above Validity: 19-11-2022 Status: License to sell drugs as distributor Renewal: NA
	Name and address of marketing authorization holder (abroad)	M/s. Reyoung Pharmaceutical Co. Ltd. No.1 Ruiyang Road, Yiyuan County, Shandong Province, P.R. China.
	Name, address of manufacturer(s)	M/s. Reyoung Pharmaceutical Co. Ltd. No.1 Ruiyang Road, Yiyuan County, Shandong Province, P.R. China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized of CoPP certificate (No. 2105062) dated 27-05-2021 by the issuing authority Yiyuan Market Supervision and Administration of P.R. China. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every year. <u>The name of importing country on CoPP is mentioned as Pakistan. Furthermore, the CoPP valid till 26-05-2023.</u> GMP certificate issued by China Food and Drug Administration to M/s. Reyoung Pharmaceutical Co. Ltd. No.1 Ruiyang Road, Yiyuan County, Shandong Province, P.R. China. dated 13-06-2018 and valid till 12-06-2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted agent & distributor agreement between M/s. Qingdao JidaBarr International Trade Co., Ltd., No.-2, B-1-4, Heilongjiang South Road, Qingdao City, China (Exporter), M/s. Reyoung Pharmaceutical Co. Ltd. No.1 Ruiyang Road, Yiyuan County, Shandong Province, P.R. China. and Sohail corporation business situated at plot no. 474 Siraj Colony Moosa Lane Karachi. The letter specifies that the manufacturer appoints Sohail corporation business situated at plot no. 474 Siraj Colony Moosa Lane Karachi desire to agent of products.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☒ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only

	Dy. No. and date of submission	Dy. No.1740 dated 19-01-2022
	Details of fee submitted	PKR 150,030/-: DATED 03-01-2022
	The proposed proprietary name / brand name	BenzylPenicillin Sodium for injection 1 mega
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Benzylpenicillin Sodium eq. to Benzyl penicillin…1 mega
	Pharmaceutical form of applied drug	Powder for Injection
	Pharmacotherapeutic Group of (API)	Beta-lactamase sensitive penicillin
	Reference to Finished product specifications	BP specification
	Proposed Pack size	10 vials/box
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Benzyl penicillin sodium injection 1000,000 IU OF IMPORTER United international (Reg.no. 043024)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s. CSPC Zhongnuo Pharmaceutical (Shijiazhuang) Co. Ltd. No.88 Yangzi Road Economic & Technological Development Zone Shijiazhuang City Hebei Province China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25°C±2, 60% RH±5%. The stability study data is till 24 months. Batch no. 891805901, 891805901, 891805901 Claimed 48 months but provided data of 24 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or

		materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	submitted. Pharmaceutical Equivalence established against the product of M/s. Shandong Lukang Pharmaceuticals Co. Ltd., China Benzyl penicillin Sodium for Injection (1mega)
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	7ml Type-II glass vial rubber stopper flip off cap.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30ºC ±2ºC / 65% ± 5% RH. The real time stability study data of 36 months has submitted.

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	Submit evidence of approval status of applied formulation in the approved reference regulatory agencies in the same strength i.e. 1,000,000 IU.	
2.	Clarify the strength of applied formulation, since you have applied for benzyl penicillin sodium injection 1,000,000 IU while the CoPP is of benzyl penicillin sodium for injection 1 mega. Please submit the conversion/equivalent calculation from 1,000,000 IU to 1 mega.	
3.	3.2.S.4.1-3.2.S.4.2	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by the drug product manufacturer as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required". Analytical procedure of drug substance by drug substance manufacturer is different from the procedure specified in EP monogragh,Justify how the raw material comply EP specification as claimed in the batch analysis report.
4.	3.2.S.4.3	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".* Since you have submitted the validation report of drug substance manufacturer.
5.	3.2.P.1	According to the composition of finished product given in section 3.2.P.1 599mg equivalent to benzyl penicillin 1mega powder for injection is filled per vial while the reference product approved in MHRA claimed that Each vial contains Benzylpenicillin sodium 600 mg (1 mega unit). Comparing the label claim/ strength justify how the applied product is similar to the reference product.
6.	3.2.P.1 (c)	Provide details of type and quantity of diluents used for reconstitution for of applied product.
7.	3.2.P.2.2.1	According to the pharmaceutical equivalence report content of penicillin has calculated while the BP recommends quantification of benzypenicillin content, justification is required in this regard.
8.	3.2.P.5.1	Clarify the content of penicillin in term of benzyl penicillin as recommended by BP monograph.
9.	3.2.P.5.3	Assay procedure followed while performing the validation studies is different from the recommended assay procedure given in BP monograph of benzypenicillin sodium injection, justification is required in this regard.
10.	3.2.P.8	Justify for not including the bacterial endotoxin test in the stability studies of drug product since the BET is recommended in BP monograph.

Decision of 326th meeting of Registration Board:
Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Evaluation by PEC:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	Submit evidence of approval status of applied formulation in the approved reference regulatory agencies in the same strength i.e. 1,000,000 IU. Firm submitted the reply in which they stated "As a generic drug product with many years of production experience, Benzyl penicillin sodium for injection has been registered in many countries and obtained registration qualification, which is consistent with the formulation registered in Pakistan this time". (As a reference they attached registration certificate of Ghana and Nigeria) However, the reference product approved in MHRA Benzylpenicillin Sodium 600 mg powder for solution for injection / infusion contains: Benzyl penicillin Sodium 600 mg powder for solution for injection / infusion: Each vial contains 600 mg benzylpenicillin as sodium salt. Each vial contains 38.6 mg of sodium. Further the conversion details are mentioned in the SmPC of reference formulation is For international units (IU) and mass values, the following ratios apply: 1 mg benzylpenicillin sodium is equivalent to 1670 IU benzylpenicillin. 1 million IU benzylpenicillin is equivalent to 598.9 mg benzylpenicillin sodium. In general, 600 mg benzylpenicillin sodium is considered to be equivalent to 1 million IU benzylpenicillin.	
2.	Clarify the strength of applied formulation, since you have applied for benzyl penicillin sodium injection 1,000,000 IU while the CoPP is of benzyl penicillin sodium for injection 1 mega. Please submit the conversion/equivalent calculation from 1,000,000 IU to 1 mega. Firm replied that 1,000,000 IU is equivalent to 1Mega.	
3.	3.2.S.4.1	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by the drug product manufacturer as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required". Firm submitted the specification of drug substance by drug product manufacturer which is in accordance with BP.
4.	3.2.S.4.2	Analytical procedure of drug substance by drug substance manufacturer is different from the procedure specified in EP monograph, justify how the raw material comply EP specification as claimed in the batch analysis report. Firm submitted the analytical procedure of drug substance by drug product manufacturer which is inaccordance with EP monograph.
5.	3.2.S.4.3	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".* Since you have submitted the validation report of drug substance manufacturer. Firm replied that we will submit later.
6.	3.2.P.1	According to the composition of finished product given in section 3.2.P.1 599mg equivalent to benzyl penicillin 1mega powder for injection is filled per vial while the reference product approved in MHRA claimed that Each vial contains Benzyl penicillin sodium 600 mg (1 mega unit). Comparing the label claim/ strength justify how the applied product is similar to the reference product.

		Firm submitted the calculation as followings: Potency of Benzyl Penicillin Sodium= 1670 IU/mg (Each 1mg of C16H17N2NaO4S is equivalent to 1670 penicillin units, prescribed in pharmacopeia. Quantity per vial= 1,000,000IU/1670 IU/mg =598.8mg=599mg Fill weight may vary based on potency of active ingredient. The difference between the "599mg" in our product with "600mg" in the reference product may be because of rounding.
7.	3.2.P.1 (c)	Provide details of type and quantity of diluents used for reconstitution for of applied product. Firm replied that the reconstitution diluent are water for injection and 0.9% sodium chloride.
8.	3.2.P.2.2.1	According to the pharmaceutical equivalence report content of penicillin has calculated while the BP recommends quantification of benzyl penicillin content, justification is required in this regard. Firm did not submit the relevant reply.
9.	3.2.P.5.1	Clarify that either the content of penicillin is calculated in the assay of drug product comparing the assay criteria BP monograph in which the assay results are based on the quantity of benzyl penicillin. Firm did not submit the relevant reply.
10.	3.2.P.5.3	Assay procedure followed while performing the validation studies is different from the recommended assay procedure given in BP monograph of benzyl penicillin sodium injection, justification is required in this regard. Firm submitted the reply that it was a writing error and they have submitted the revised analytical procedure in accordance with BP. However, the revised analytical procedure was also not in accordance with BP as evident from the submitted report.
11.	3.2.P.8	Justify for not including the bacterial endotoxin test in the stability studies of drug product since the BET is recommended in BP monograph. Firm submitted the revised stability summary sheets in which Bacterial endotoxin test were included and the assay results are related to quantification of penicillin instead of Benzylpenicillin.

Decision: Deferred for the submission of following shortcomings/justifications:

- **Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".* Since you have submitted the validation report of drug substance by drug substance manufacturer.**
- **Justify the assay testing of drug product comparing the assay test in BP monograph, wherein the assay of benzypenicillin is recommended while the firm performed the assay of penicillin.**

907.	Name, address of Applicant / Importer	M/s. Sohail Corporation Plot no.7, SR-5,Serai Quarters (Techno City) WH-42, Ware House No.42, Karachi.
	Details of Drug Sale License of importer	License No:041 Address: Plot no.7, SR-5, Serai Quarters (Techno City) WH-42, Ware House No.42, Karachi. Address of Go down: Same as above Validity: 19-11-2022 Status: License to sell drugs as distributor Renewal: NA

	Name and address of marketing authorization holder (abroad)	M/s. Anhui Chengshi Pharmaceuticals Co. Ltd. No. 5068 Huaishang Road, Bengbu, Anhui Province, China
	Name, address of manufacturer(s)	M/s. Anhui Chengshi Pharmaceuticals Co. Ltd. No. 5068 Huaishang Road, Bengbu, Anhui Province, China
	Name of exporting country	China
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized of CoPP certificate (No. nil) dated 29-07-2021 without the name of issuing authority. The CoPP confirms free sale status of the product in exporting country as well as GMP status of the manufacturing site through periodic inspection every 3 years. The name of importing country on CoPP is mentioned as Pakistan. Furthermore, the CoPP valid for 5 years. GMP certificate issued by China Food and Drug Administration to M/s. Anhui Chengshi Pharmaceuticals Co. Ltd. No. 5068 Huaishang Road, Bengbu, Anhui Province, China dated 08-03-2021 and valid till 08-03-2021.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of agency agreement between Anhui Chengshi Pharmaceuticals Co. Ltd. and Sohail corporation business situated at plot no. 474 Siraj Colony Moosa Lane Karachi. The letter species that the manufacturer appoints Sohail corporation business situated at plot no. 474 Siraj Colony Moosa Lane Karachi desire to agent of products including atropine sulphate 1mg/1ml in Pakistan. The agreement letter will be terminated if the registration of the product is failed until 1 july,2022 and the term of agreement will be 5 years from 1 july,2022.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.667 dated 07-01-2022
	Details of fee submitted	PKR 100,030/-: dated 07-04-2021 and differential fee of Rs.50,000/- vide slip no. 0114822752 dated 07th June,2021 submitted
	The proposed proprietary name / brand name	Atropine Sulphate Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ampoule (1ml) contains: Atropine Sulphate….1mg

	Pharmaceutical form of applied drug	Injectable
	Pharmacotherapeutic Group of (API)	cholinergic muscarinic antagonist
	Reference to Finished product specifications	BP specification
	Proposed Pack size	1mg/1ml Injection
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TGA approved
	For generic drugs (me-too status)	Atrosol injection 1mg/ml of M/s. Indus Pharma (Pvt.) Ltd. Korangi Industrial Area Karachi
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	M/s. Henan Purui Pharmaceutical Co. Ltd. Yezhuangqiao Village, Xinhua County, Zhoukou City, Henan Province, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 25℃±2, 60% RH±5%. The stability study data is till 36 months. Batch no. 20040301,20040302,20040303
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	submitted. Pharmaceutical Equivalence established against the products of M/s.Aspen Pharma Trading Limited, M/s. Xinxiang Changle Pharmaceutical Co. Ltd., M/s. Zhejiang Xianju Pharmaceutical Co. Ltd.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Glass ampoule low borosilicate glass volume of 1.5ml.

	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40°C ±2°C / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30°C ±2°C / 65% ± 5% RH. The real time stability study data of 24 month has submitted.

Evaluation by PEC:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	1.4.1	Provide clarification, whether the applied product (drug product) is intended for sale in domestic market or both for domestic and export market.
2.	3.2.P.1	Justify for using 8.5 mg /ml sodium chloride comparing the composition of innovator brand in which 9mg/ml sodium chloride is used. Further, the composition of innovator brand includes sodium hydroxide and/or sulfuric acid for pH adjustment, while you have not been using any of the pH adjustment agent in the composition of applied product.
3.	3.2.P.3.1	Can you please co-relate the manufacturing procedure given in section 3.2.P.3 with the composition of applied injection because neither the procedure includes any of the active ingredient or excipients nor the pH measurement/adjustment is the part of solution preparation.
4.	3.2.P.3.5	Justify for keeping the pH limit of injection between 3.0-4.0 while the process validation ,since the recommended pH limit as per BP is 2.8-4.5.
5.	3.2.P.5.3	Justify for not complying the BP monograph while performing the analytical method verification studies of drug product.
6.	3.2.P.6	Submit COA of reference/working standard used in the analysis of drug product.
7.	3.2.P.8	Please clarify the designation of signing authority ,who correct the storage condition on the stability data sheet of Batch no. W170419 along with documented evidence.

Decision of 326th meeting of Registration Board:

Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response of the Firm:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	1.4.1	Provide clarification, whether the applied product (drug product) is intended for sale in domestic market or both for domestic and export market.	We (the manufacturer: Anhui Chengshi Pharmaceutical Co., Ltd) clarity that the applied product (Atropine Sulphate Injection) is intended for sale in domestic market (note: the domestic market is considered as China) and export market (note: the export market is considered as Pakistan).
2.	3.2.P.1	Justify for using 8.5 mg /ml sodium chloride comparing the composition of innovator brand in which 9mg/ml sodium chloride is used. Further, the composition of innovator brand includes sodium hydroxide and/or sulfuric acid for pH adjustment, while you have not been using any of the pH adjustment agent in the composition of applied product.	Firm replied that Physiological saline, also known as sterile saline, refers to the sodium chloride solution in physiological experiments or clinical common osmotic pressure is basically equal to the osmotic pressure of animal or human plasma. The concentration of sterile saline used in amphibians was 0.67% to 0.70%. When sterile saline is used in mammals and humans, the concentration is 0.85% to 0.9%. Considering the influence of the drug combination and excipients on the osmotic pressure, the sodium chloride concentration of the product is 0.85% (the concentration of

			NaCl in Atropine Sulfate Injection 1mg/1ml is 8.5mg/1ml). In the actual production, our company added sulfuric acid to adjust the product pH, and also specified in the product production process procedures. At the initial registration of the drug approval number, our MOH requires that all components of the product should be marked quantitatively. Because sulfuric acid is used to regulate the pH of atropine sulfate injection, it cannot be written quantitatively into the formula, so it is not reflected in the product formula.
3.	3.2.P.3.1	Can you please co-relate the manufacturing procedure given in section 3.2.P.3 with the composition of applied injection because neither the procedure includes any of the active ingredient or excipients nor the pH measurement/adjustment is the part of solution preparation.	Firm replied that for the protection of the process technology, our company just briefly introduced the production process. Please see the submitted documents of Atropine Sulfate Injection Production Process Procedure C-STP-SC-SC01026A" for details.
4.	3.2.P.3.5	Justify for keeping the pH limit of injection between 3.0-4.0 while the process validation ,since the recommended pH limit as per BP is 2.8-4.5.	Firm in their reply stated that "In the manufacturing process validation, the pH standard of semi-product is 3.0-4.0 and the pH standard of final product is 2.8-4.5. The semi-product is produced in the solution preparation process. After the solution preparation process, there are solution filling/sealing and sterilizing process. In order to ensure the pH of the final product comply with the BP standard (2.8-4.5) after experiencing the subsequent manufacturing process, the pH standard of semi-product should be stricter than the pH standard of final product."
5.	3.2.P.5.3	Justify for not complying the BP monograph while performing the analytical method verification studies of drug product.	Firm replied that The analytical procedure of the Atropine Sulphate Injection 1mg/1ml is according to the BP. So we only do the assay validation. In order comply with the requirement of the Drug Regulatory Authority of Pakistan, we do an overall analysis method validation according to the BP and ICH. Revised documents submitted.
6.	3.2.P.6	Submit COA of reference/working standard used in the analysis of drug product.	Submitted.

Decision: Deferred for submission of following shortcomings/justifucation:

- **Justify for performing the verification studies on assay procedure different from the assay method recommended in BP monograph of "atropine Sulphate Injection".**
- **Submit the manufacturing procedure of drug product specific to the applied formulation in relevant section.**

908.	Name, address of Applicant / Importer	M/s Himmel Pharmaceuticals (Pvt.) Ltd. 793-D, Block ''C'', Faisal Town Lahore.
	Details of Drug Sale License of	License No: 05-352-0065-016174-D

	importer	Address:793-D, Block-C, Faisal Town Lahore Address of Godown: NA Validity: 06. Feb.2022 Status: License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali, Bhaluka, Mymensingh Bangladesh Office address: 9/B/2, Toyenbee Circular Road, Motijheel Dhaka, Bangladesh
	Name, address of manufacturer(s)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali, Bhaluka, Mymensingh Bangladesh Office address: 9/B/2, Toyenbee Circular Road, Motijheel Dhaka, Bangladesh
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Original legalized COPP (Certificate# DA/6-110/2016/3303 issued on 01-06-2020 by Government of the people's republic of Bangladesh, Ministry of Health & Family welfare, Directorate General of Drug Administration, Oushad Bhaban, Mohkhali Dhaka-1212, Bangladesh. GMP: Firm has submitted Legalized GMP certificate (Certificate No. DA/6-110/06/10002) issued by M/s Beacon Pharmaceuticals limited. Also Renewal certificate is submitted (Certificate No. DA/6-110/06/4950).
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from Beacon Pharmaceuticals limited. The letter specifies that the manufacturer appoints M/s Himmel Pharmaceuticals Pvt. Ltd. to register their products in Pakistan. The authorization letter is valid till June, 2025.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy.No. 16109 :Date10.06.2021
	Details of fee submitted	PKR.100,030/- Date: 29-01-2021
	The proposed proprietary name / brand name	Sunitix 12.5mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains Sunitinib Malate INN…….12.5mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Anti-cancer

	Reference to Finished product specifications	In house
	Proposed Pack size	28's
	Proposed unit price	As per current pricing policy of DRAP
	The status in reference regulatory authorities	Sutent 12.5mg capsule USFDA approved
	For generic drugs (me-too status)	Sutent capsule 12.5mg (Pfizer Laboratories) Reg.no.052225
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Nanjing First Pharmaceuticals Co. Ltd. China Room No.2303,Technical Garden B Place Industrial University No.5 Xinmofang Road, Nanjing, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 36 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analysis Studies against the reference product Sutent 12.5mg capsule (Pfizer Laboratories) has been submitted
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE bottle (each contains 28 capsules)
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 65% ± 5% for 24 months
Evaluation by PEC:		

Sr. no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit data of analytical Method verification studies under section 3.2.S.4 including specificity, accuracy and repeatability (method precision) since you have submitted validation studies GC method for determination of residual solvent of Sunitinib Malate.	Firm has submitted the reply of this query.
2.	Scientific justification is required that how the applied product will be pharmaceutically equivalent to the innovator product i.e. sutent in which the granules are filled in capsules, while in the applied product dry powder mixture of active material and excipient are filled in capsules.	Firm has not submitted the reply of this query.
3.	All quality test which have been included in the finished product specification was not performed during pharmaceutical equivalence studies, clarification is required in this regard.	Firm has not submitted the reply of this query.
4.	Assay limits mentioned in the pharmaceutical equivalence data is in percentage without the clarification that either it is the quantification of salt or its base form. While the acceptance criteria specified in the finished product specification was content of sunitinib per capsule :22.50mg to 27. 50mg.Justification is required regarding the disparity in acceptance criteria of assay of drug product.	Firm has not submitted the reply of this query.
5.	As per the chromatographic condition specified in the procedure of dissolution testing under section 3.2.P.2: wavelength of UV detector was 230nm, column temperature 25°C and retention time is 2 min (as per chromatograms) while the chromatographic condition specified under section 3.2.P.5.2: wavelength of UV detector is 430nm, column temperature 30°C and retention time is approx.6.0 minutes. Justification is required regarding the variation in chromatographic condition despite using the same dissolution medium i.e.0.1M HCl +0.5% sodium lauryl sulphate.	Firm has not submitted the reply of this query.
6.	According to the FDA's Dissolution guidance document 2018 (same document has been referred for innovator product) the standard dissolution testing condition for sunitinib malate capsule should be *"Paddle Method (USP apparatus 2) • Stirring rate = 50 RPM • 500 mL of 0.1N HCl in aqueous medium • No surfactant in medium • 37±0.5°C"*. While the dissolution condition specified by the drug product manufacturer under section 3.2.P.2 and 3.2.P.5.2 was different from the said FDA's guidance document. Scientific justification is required in this regard.	Firm has not submitted the reply of this query.
7.	Justify the dissolution specification NLT 70% of the labelled amount of sunitinib is dissolved	Firm has not submitted the reply of this query.

	in 60 minutes since the acceptance criteria as per the FDA dissolution database for the innovator product is "*for immediate release solid oral drug products containing a high solubility drug substance the dissolution criterion is Q=80% in 30 minutes".*	
8.	Same comparative dissolution profile data has been submitted for sunitix 25 capsule and sunitix 12.5 capsule, clarification is required in this regard.	Firm has not submitted the reply of this query.
9.	Detailed analytical method validation report is required mentioning the concentration of test solutions and their individual results along with the results of mean value. Analytical method validation protocol specified assay method for capsule containing granules while the manufacturing process of drug product evident that capsule containing dry powder mixture of active material and excipient has been prepared. Justification is required that how the validation studies performed on assay method of capsule containing granules be applied on capsule containing dry powder mixture of active and excipients.	Firm has submitted the revised analytical method validation for drug product.
10.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product under section 2.3.R.1.1, for which stability studies data is provided in Module 3 section 3.2. P.8.	Firm submitted BMR, according to which 269.19 gm of sunitinib Malate having potency of 99.3% has been for manufacturing of 8,000 capsule.
11.	Firm has already had registration of sunitinib Malate Capsule imported from Germany and details are as follows: Product License Holder: Aqvida GmbH Kaiser-Wilhelm-Strabe 89 20355 Hamburg Germany. Manufacturer: M/s Combino Pharm (Malta) Ltd. HF 60, Hal Far Industrial Estate, Hal Far, Birzebbugia, BBG3000, Malta. Sunitinib Aqvida 12.5mg hard capsule (Reg.no.103778) Sunitinib Aqvida 25mg hard capsule (Reg.no.103779) Sunitinib Aqvida 50mg hard capsule (Reg.no.103780)	

Decision of 322nd meeting of Registration Board:
Deferred for submission of following:

- *Scientific justification is required that how the applied product will be pharmaceutically equivalent to the innovator product i.e. sutent in which the granules are filled in capsules, while in the applied product dry powder mixture of active material and excipient were filled in capsules.*
- *Submission of pharmaceutical equivalence report in which all the quality parameters of drug product specification should be included.*
- *Justification is required regarding the disparity in acceptance criteria of assay of drug product, assay limits mentioned in the pharmaceutical equivalence data is in percentage without the clarification that either it is the quantification of salt or its base form. While the acceptance criteria specified in the finished product specification was content of sunitinib per capsule :22.50mg to 27. 50mg.*
- *Scientific justification is required for using dissolution condition different from the dissolution parameters recommended in USFDA's innovator brand review report.*
- *Justify the dissolution specification NLT 70% of the labelled amount of sunitinib is dissolved in 60 minutes since the acceptance criteria as per the FDA dissolution database for the innovator product*

is "for immediate release solid oral drug products containing a high solubility drug substance the dissolution criterion is Q=80% in 30 minutes".

- *Same comparative dissolution profile data has been submitted for sunitix 25 capsule and sunitix 12.5 capsule, clarification is required in this regard.*

Response of the Firm:
Scientific justification is required that how the applied product will be pharmaceutically equivalent to the innovator product i.e. sutent in which the granules are filled in capsules, while in the applied product dry powder mixture of active material and excipient were filled in capsules.

Firm replied that as per *GUIDELINE THE INVESTIGATION OF BIOEQUIVALENCE* (Doc. Ref.: CPMP/EWP /QWP/1 401/98 Rev. 1/ Corr**) (EMA guidelines) Medicinal products are pharmaceutically equivalent if they contain the same amount of the same active substance(s) in the same dosage forms that meet the same or comparable standards.
We have manufactured Sunitix Capsule is identical as oral capsule dosage form as reference product (Sutent Capsule). Sunitix Capsule contains Sunitinib Malate equivalent Sunitinib which is identical Sutent Capsule which contains Sunitinib Malate equivalent Sunitinib.
An open label, balanced, randomized, two-treatment, two-sequence, two- period, crossover oral bioequivalence study of single dose of Sunitix Capsule (Each capsule contains Sunitinib Malate equivalent Sunitinib) of Beacon Pharmaceuticals Limited with Sutent Capsule (Each capsule contains Sunitinib Malate equivalent Sunitinib) of Pfizer Limited already performed. There was no serious adverse effect reported during study period & clinically safe as a single oral dose administration. Based on Pharmacokinetic Variables & statistical evaluation, it was observed that for both the test & reference product are bioequivalent.

Submission of pharmaceutical equivalence report in which all the quality parameters of drug product specification should be included.

Firm submitted the revised pharmaceutical equivalence report in which all the quality test was included in line with drug product specification.

Justification is required regarding the disparity in acceptance criteria of assay of drug product, assay limits mentioned in the pharmaceutical equivalence data is in percentage without the clarification that either it is the quantification of salt or its base form. While the acceptance criteria specified in the finished product specification was content of sunitinib per capsule :22.50mg to 27. 50mg.

Firm submitted the revised pharmaceutical equivalence report in which the assay limit is specified both in percentage and in mg.

As per the chromatographic condition specified in the procedure of dissolution testing under section 3.2.P.2: wavelength of UV detector was 230nm, column temperature 25°C and retention time is 2 min (as per chromatograms) while the chromatographic condition specified under section 3.2.P.5.2: wavelength of UV detector is 430nm, column temperature 30°C and retention time is approx.6.0 minutes. Justification is required regarding the variation in chromatographic condition despite using the same dissolution medium i.e.0.1M HCl +0.5% sodium lauryl sulphate.

Firm replied that "We have four (04) strength of Sunitinib Capsule and developed in different time as in-house method. In that time the molecule was not available in FDA and till now not available in pharmacopoeia. Recently we observed that assay, dissolution, impurity chromatographic conditions are not harmonized. We take initiative and harmonized these methods and solved the different chromatographic conditions. So there have some variations in previous condition with current condition. In future it will be inline."
Scientific justification is required for using dissolution condition different from the dissolution parameters recommended in USFDA's innovator brand review report.

Justify the dissolution specification NLT 70% of the labelled amount of sunitinib is dissolved in 60 minutes since the acceptance criteria as per the FDA dissolution database for the innovator product is "for

immediate release solid oral drug products containing a high solubility drug substance the dissolution criterion is Q=80% in 30 minutes".

Firm submitted the revised dissolution with the claimed of in line to innovator product sutent capsule of USFDA, but the revised dissolution conditions and acceptance criteria is still not in accordance with innovator product.

Dissolution condition of applied product	**Dissolution condition of Innovator's Formulation**
Apparatus USP II (Paddle System)	Apparatus USP II (Paddle System)
Dissolution medium: 0.1N HCl	Dissolution medium: 0.1M HCl
Volume: 500ml	Volume: 900ml
RPM: 50	Temperature: 37°C ± 0.5°C
Temperature: 37°C ± 0.5°C	Dissolution acceptance criteria : NLT Q in 30 minutes.
Dissolution Time: 60 minutes	
Acceptance Criteria: NLT 70% of the labeled amount of sunitinib is dissolved in 60 minutes.	

Same comparative dissolution profile data has been submitted for sunitix 25 capsule and sunitix 12.5 capsule, clarification is required in this regard.
Firm replied that This is referring to Bioequivalence study completed for product with higher strength, bio waiver for bioequivalence is acceptable for lower strength based on bioequivalence study on higher strength, dissolution testing of both higher and lower strength and proportional similarity of the formulations between lower strength and higher strength.

Decision: Deferred for the submission of following shortcomings:

- **Submit the revised dissolution conditions along with dissolution acceptance criteria in line with innovator product. Further the dissolution performance report of stability batches which are in accordance with revised acceptance criteria.**
- **Submit separate comparative dissolution profile data of both strength of sunitix 25mg and 12.5mg capsules.**

909.	Name, address of Applicant / Importer	M/s Himmel Pharmaceuticals (Pvt.) Ltd. 793-D, Block ''C'', Faisal Town Lahore.
	Details of Drug Sale License of importer	License No: 05-352-0065-016174-D Address:793-D, Block-C, Faisal Town Lahore Address of Godown: NA Validity: 06. Feb.2022 Status: License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s BEACON Pharmaceuticals Limited Plant address: Kathali, Bhaluka, Mymensingh Bangladesh Office address: 9/B/2, Toynbee Circular Road, Motijheel Dhaka, Bangladesh
	Name, address of manufacturer(s)	M/s BEACON Pharmaceuticals Limited Plant address: Kathali, Bhaluka, Mymensingh Bangladesh Office address: 9/B/2, Toynbee Circular Road, Motijheel Dhaka, Bangladesh
	Name of exporting country	Bangladesh

	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Original legalized COPP (Certificate# DA/6-110/2016/3304 issued on 01-06-2020 by Government of the people's republic of Bangladesh, Ministry of Health & Family welfare, Directorate General of Drug Administration, Oushad Bhaban, Mohkhali Dhaka-1212, Bangladesh. GMP: Firm has submitted Legalized GMP certificate (Certificate No. DA/6-110/06/10002) issued by M/s Beacon Pharmaceuticals limited. Also Renewal certificate is submitted (Certificate No. DA/6-110/06/4950).
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from Beacon Pharmaceuticals limited. The letter specifies that the manufacturer appoints M/s Himmel Pharmaceuticals Pvt. Ltd. to register their products in Pakistan. The authorization letter is valid till June, 2025.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.16108 , Date: 10.06.2021
	Details of fee submitted	PKR.100,030/- Date: 29-01-2021
	The proposed proprietary name / brand name	Sunitix 25mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains Sunitinib Malate INN …….25mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	Anti-cancer
	Reference to Finished product specifications	In house
	Proposed Pack size	28's
	Proposed unit price	As per current pricing policy of DRAP
	The status in reference regulatory authorities	Sutent 25mg capsule USFDA approved
	For generic drugs (me-too status)	Sutent (Pfizer Laboratories) Reg.no. 052226
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form,

		manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Nanjing First Pharmaceuticals Co. Ltd. China Room No.2303,Technical Garden B Place Industrial University No.5 Xinmofang Road, Nanjing, China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 36 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analysis Studies against the reference product Sutent 25mg capsule (Pfizer Laboratories) has been submitted
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	HDPE bottle (each contains 28 capsules)
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months. Real time stability studies conducted at 30°C±2°C and 65% ± 5% for 24 months

Evaluation by PEC:

Sr. no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit data of analytical Method verification studies under section 3.2.S.4 including specificity, accuracy and repeatability (method precision) since you have submitted validation studies GC method for determination of residual solvent of Sunitinib Malate.	Firm has submitted the reply of this query.
2.	Scientific justification is required that how the applied product will be pharmaceutically equivalent to the innovator product i.e. sutent in which the granules are filled in capsules, while in the applied product dry powder mixture of active material and excipient are filled in capsules.	Firm has not submitted the reply of this query.
3.	All quality test which have been included in the finished product specification was not performed during pharmaceutical equivalence studies, clarification is required in this regard.	Firm has not submitted the reply of this query.
4.	Assay limits mentioned in the pharmaceutical equivalence data is in percentage without the clarification that either it is the quantification of salt or its base form. While the acceptance criteria specified in the finished product specification was content of sunitinib per capsule :22.50mg to 27. 50mg.Justification is required regarding the disparity in acceptance criteria of assay of drug product.	Firm has not submitted the reply of this query.
5.	As per the chromatographic condition specified in the procedure of dissolution testing under section 3.2.P.2: wavelength of UV detector was 230nm, column temperature 25°C and retention time is 2 min (as per chromatograms) while the chromatographic condition specified under section 3.2.P.5.2: wavelength of UV detector is 430nm, column temperature 30°C and retention time is approx.6.0 minutes. Justification is required regarding the variation in chromatographic condition despite using the same dissolution medium i.e.0.1M HCl +0.5% sodium lauryl sulphate.	Firm has not submitted the reply of this query.
6.	According to the FDA's Dissolution guidance document 2018 (same document has been referred for innovator product) the standard dissolution testing condition for sunitinib malate capsule should be *"Paddle Method (USP apparatus 2) • Stirring rate = 50 RPM • 500 mL of 0.1N HCl in aqueous medium • No surfactant in*	Firm has not submitted the reply of this query.

	medium • 37±0.5°C". While the dissolution condition specified by the drug product manufacturer under section 3.2.P.2 and 3.2.P.5.2 was different from the said FDA's guidance document. Scientific justification is required in this regard.	
7.	Justify the dissolution specification NLT 70% of the labelled amount of sunitinib is dissolved in 60 minutes since the acceptance criteria as per the FDA dissolution database for the innovator product is "*for immediate release solid oral drug products containing a high solubility drug substance the dissolution criterion is Q=80% in 30 minutes".*	Firm has not submitted the reply of this query.
8.	Same comparative dissolution profile data has been submitted for sunitix 25 capsule and sunitix 12.5 capsule, clarification is required in this regard.	Firm has not submitted the reply of this query.
9.	• Detailed analytical method validation report is required mentioning the concentration of test solutions and their individual results along with the results of mean value. • Analytical method validation protocol specified assay method for capsule containing granules while the manufacturing process of drug product evident that capsule containing dry powder mixture of active material and excipient has been prepared. Justification is required that how the validation studies performed on assay method of capsule containing granules be applied on capsule containing dry powder mixture of active and excipients.	Firm has submitted the revised analytical method validation for drug product.
10.	Provide copy of Batch Manufacturing Record (BMR) for all the batches of drug product under section 2.3.R.1.1, for which stability studies data is provided in Module 3 section 3.2. P.8.	Firm submitted BMR, according to which 269.19 gm of sunitinib Malate having potency of 99.3% has been for manufacturing of 8,000 capsule.
11.	Firm has already had registration of sunitinib Malate Capsule imported from Germany and details are as follows: Product License Holder: Aqvida GmbH Kaiser-Wilhelm-Strabe 89 20355 Hamburg Germany. Manufacturer: M/s Combino Pharm (Malta) Ltd. HF 60, Hal Far Industrial Estate, Hal Far, Birzebbugia, BBG3000, Malta. Sunitinib Aqvida 12.5mg hard capsule (Reg.no.103778) Sunitinib Aqvida 25mg hard capsule (Reg.no.103779) Sunitinib Aqvida 50mg hard capsule (Reg.no.103780)	

Decision of 322nd meeting of Registration Board:
Deferred for submission of following:

- *Scientific justification is required that how the applied product will be pharmaceutically equivalent to the innovator product i.e. sutent in which the granules are filled in capsules, while in the applied product dry powder mixture of active material and excipient were filled in capsules.*
- *Submission of pharmaceutical equivalence report in which all the quality parameters of drug product specification should be included.*
- *Justification is required regarding the disparity in acceptance criteria of assay of drug product, assay limits mentioned in the pharmaceutical equivalence data is in percentage without the clarification that either it is the quantification of salt or its base form. While the acceptance criteria specified in the finished product specification was content of sunitinib per capsule :22.50mg to 27. 50mg.*
- *Scientific justification is required for using dissolution condition different from the dissolution parameters recommended in USFDA's innovator brand review report.*
- *Justify the dissolution specification NLT 70% of the labelled amount of sunitinib is dissolved in 60 minutes since the acceptance criteria as per the FDA dissolution database for the innovator product is "for immediate release solid oral drug products containing a high solubility drug substance the dissolution criterion is Q=80% in 30 minutes".*
- *Same comparative dissolution profile data has been submitted for sunitix 25 capsule and sunitix 12.5 capsule, clarification is required in this regard.*

Response of the Firm:

Scientific justification is required that how the applied product will be pharmaceutically equivalent to the innovator product i.e. sutent in which the granules are filled in capsules, while in the applied product dry powder mixture of active material and excipient were filled in capsules.

Firm replied that as per *GUIDELINE THE INVESTIGATION OF BIOEQUIVALENCE* (Doc. Ref.: CPMP/EWP /QWP/1 401/98 Rev. 1/ Corr**) (EMA guidelines) Medicinal products are pharmaceutically equivalent if they contain the same amount of the same active substance(s) in the same dosage forms that meet the same or comparable standards.

We have manufactured Sunitix Capsule is identical as oral capsule dosage form as reference product (Sutent Capsule). Sunitix Capsule contains Sunitinib Malate equivalent Sunitinib which is identical Sutent Capsule which contains Sunitinib Malate equivalent Sunitinib.

An open label, balanced, randomized, two-treatment, two-sequence, two- period, crossover oral bioequivalence study of single dose of Sunitix Capsule (Each capsule contains Sunitinib Malate equivalent Sunitinib) of Beacon Pharmaceuticals Limited with Sutent Capsule (Each capsule contains Sunitinib Malate equivalent Sunitinib) of Pfizer Limited already performed. There was no serious adverse effect reported during study period & clinically safe as a single oral dose administration. Based on Pharmacokinetic Variables & statistical evaluation, it was observed that for both the test & reference product are bioequivalent.

Submission of pharmaceutical equivalence report in which all the quality parameters of drug product specification should be included.

Firm submitted the revised pharmaceutical equivalence report in which all the quality test was included in line with drug product specification.

Justification is required regarding the disparity in acceptance criteria of assay of drug product, assay limits mentioned in the pharmaceutical equivalence data is in percentage without the clarification that either it is the quantification of salt or its base form. While the acceptance criteria specified in the finished product specification was content of sunitinib per capsule :22.50mg to 27. 50mg.

Firm submitted the revised pharmaceutical equivalence report in which the assay limit is specified both in percentage and in mg.

As per the chromatographic condition specified in the procedure of dissolution testing under section 3.2.P.2: wavelength of UV detector was 230nm, column temperature 25°C and retention time is 2 min (as per chromatograms) while the chromatographic condition specified under section 3.2.P.5.2: wavelength

of UV detector is 430nm, column temperature 30°C and retention time is approx.6.0 minutes. Justification is required regarding the variation in chromatographic condition despite using the same dissolution medium i.e.0.1M HCl +0.5% sodium lauryl sulphate.

Firm replied that "We have four (04) strength of Sunitinib Capsule and developed in different time as in-house method. In that time the molecule was not available in FDA and till now not available in pharmacopoeia. Recently we observed that assay, dissolution, impurity chromatographic conditions are not harmonized. We take initiative and harmonized these methods and solved the different chromatographic conditions. So there have some variations in previous condition with current condition. In future it will be inline."
Scientific justification is required for using dissolution condition different from the dissolution parameters recommended in USFDA's innovator brand review report.

Justify the dissolution specification NLT 70% of the labelled amount of sunitinib is dissolved in 60 minutes since the acceptance criteria as per the FDA dissolution database for the innovator product is "for immediate release solid oral drug products containing a high solubility drug substance the dissolution criterion is Q=80% in 30 minutes".

Firm submitted the revised dissolution with the claimed of in line to innovator product sutent capsule of USFDA, but the revised dissolution conditions and acceptance criteria is still not in accordance with innovator product.

Dissolution condition of applied product	**Dissolution condition of Innovator's Formulation**
Apparatus USP II (Paddle System)	Apparatus USP II (Paddle System)
Dissolution medium: 0.1N HCl	Dissolution medium: 0.1M HCl
Volume: 500ml	Volume: 900ml
RPM: 50	Temperature: 37°C ± 0.5°C
Temperature: 37°C ± 0.5°C	Dissolution acceptance criteria : NLT Q in 30 minutes.
Dissolution Time: 60 minutes	
Acceptance Criteria: NLT 70% of the labeled amount of sunitinib is dissolved in 60 minutes.	

Same comparative dissolution profile data has been submitted for sunitix 25 capsule and sunitix 12.5 capsule, clarification is required in this regard.
Firm replied that This is referring to Bioequivalence study completed for product with higher strength, bio waiver for bioequivalence is acceptable for lower strength based on bioequivalence study on higher strength, dissolution testing of both higher and lower strength and proportional similarity of the formulations between lower strength and higher strength.

Decision: Deferred for the submission of following shortcomings:

- **Submit the revised dissolution conditions along with dissolution acceptance criteria in line with innovator product. Further the dissolution performance report of stability batches which are in accordance with revised acceptance criteria.**
- **Submit separate comparative dissolution profile data of both strength of sunitix 25mg and 12.5mg capsules .**

b. EXPORT FACILITATION:

Export Facilitation: Applications was received through letter No.F.1-76/2019-PR-I (EFD)

"M/s Pharmedic Laboratories (Pvt.) Ltd. have achieved benchmark OF USD 1576776.335 as defined in the Board's decision during fiscal year 2020-2021. In this regard, please find the (1 molecule) 05 products applications submitted by the firm."		
910.	Name, address of Applicant / Marketing Authorization Holder	Name: Pharmedic Laboratories (Pvt.) Ltd. Address: 16km Multan Road, Lahore-Pakistan
	Name, address of Manufacturing site.	Name: Pharmedic Laboratories (Pvt.) Ltd. Address: 16km Multan Road, Lahore-Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.no.2629 dated 27/01/2022
	Details of fee submitted	PKR 30,000/-: dated 24/11/2021
	The proposed proprietary name / brand name	Nevol 2.5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Nebivolol HCl equivalent to Nebivolol…..2.5mg
	Pharmaceutical form of applied drug	White colored, round shaped, biconvex uncoated tablets with both sides plain.
	Pharmacotherapeutic Group of (API)	Beta blocking agent, selective
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	1×10's , 3x 10's and 2x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Bystolic tablets, Allergen, USA
	For generic drugs (me-too status)	Nabil 2.5mg Tablet by M/s Getz Pharma, Reg. No. 061344
	GMP status of the Finished product manufacturer	Last GMP was granted on 09/06/2020 GMP is in Renewal Process
	Name and address of API manufacturer.	Name: Jiangsu Weiqida Pharmaceutical Co., Ltd. Old Name: Shanghai Shyndec Pharmaceutical (Haimen) Co., Ltd Address: No.1, Linjiang Avenue, Nantong, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Nebivolol HCl is not present in any pharmacopeia. The firm has submitted detail of

		nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Test for Impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (NBB-1711001-1M, NBB-1711002-1M, NBB-1711003-1M)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Nebil 2.5mg tablet by Getz Pharma (Pvt) Ltd. by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Nebil 2.5mg tablet by Getz Pharma (Pvt) Ltd.in Acid media (pH 1.2), pH 4.5 & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including Specificity, linearity, accuracy, precision (repeatability and Intermediate), Limit of Detection, Limit of Quantification, Robustness.

STABILITY STUDY DATA			
Manufacturer of API	Jiangsu Weiqida Pharmaceutical Co., Ltd.		
API Lot No.	NBB-19070031M		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's , 3x 10's and 2x 7's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24, 36 (Months)		
Batch No.	NEB2.5-TR002	NEB2.5-TR003	NEB2.5-TR004
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	09-2020	09-2020	09-2020
No. of Batches	03		
Administrative Portion			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by DCA valid till 17/01/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No.759/2020DRAP-AD (I&E) dated 13/01/2020 is submitted wherein the permission to import Nebivolol HCl for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.2	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".* Since you have only submitted the requisite information provided by drug substance manufacturer.
2.	3.2.S.4.4	Justify how you have calculate the potency of nebivolol without HCl as mentioned in the COA of drug substance comparing the COA of drug substance by drug substance manufacturer calculated the assay on anhydrous basis only.
3.	3.2.P.2.2.1	• Justify for not performing the test of content uniformity by HPLC and water content test while establishing the pharmaceutical equivalence aginst the reference product, since these test are included in the specification of innovator brand of USFDA. • Justify for not performing the pharmaceutical equivalence and comparative dissolution against the innovator brand/brand leador approved in Pakistan.
4.	3.2.P.5.1	• Justify for not including the test of water content in the release specification of drug product, since these test are included in the specification of innovator brand. • Clarification is required that in assay either you have quantified the nebivolol or nebivolol HCl, since the calculated % is of nebivolol HCl, while the main peak in the chromatogram represent the nebivolol without HCl.

		• Sample preparation for assay is more general rather than specific, without the clarity that transfer quantity of the sample equivalent to 50mg represent either the quantity of nebivolol or nebivolol HCl. • Justify for adapting the acceptance criteria of dissolution NLT 80% within 45 minutes comparing the results of CDP in 0.01N HCl medium which was more than 80% within 15minutes and the acceptance criteria of innovator brand approved in USFDA.
5.	3.2.R.1.1	Justify for taking the strength of tablet with HCl factor for calculation of dispensed quantity of powder as revealed from the batch manufacturing record since you have taken the potency of drug substance without HCl on as is basis.

Decision of 324th meeting of Registration Board:

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response of the Firm:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	3.2.S.4.2	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".* Since you have only submitted the requisite information provided by drug substance manufacturer.	Firm submitted the analytical method verification report of drug substance performed by drug product manufacturer. However, the official monograph of drug substance is present in EP 11.0 and the applicant imported in-house complied drug substance.
2.	3.2.S.4.4	Justify how you have calculate the potency of nebivolol without HCl as mentioned in the COA of drug substance comparing the COA of drug substance by drug substance manufacturer calculated the assay on anhydrous basis only.	Firm replied it is an error which was rectified and correct COA of drug substance by drug product manufacturer has submitted.
3.	3.2.P.2.2.1	Justify for not performing the test of content uniformity by HPLC and water content test while establishing the pharmaceutical equivalence against the reference product, since these test are included in the specification of innovator brand of USFDA.	Firm submitted the analytical procedure instead of pharmaceutical equivalence report including the test of content uniformity by HPLC and water content test.
4.	3.2.P.5.1	Justify for not including the test of water content in the release specification of drug product, since these test are included in the specification of innovator brand.	Firm submitted the revised analytical procedure of drug along with specification.

5.	3.2.P.5.1	Sample preparation for assay is more general rather than specific, without the clarity that transfer quantity of the sample equivalent to 50mg represent either the quantity of nebivolol or nebivolol HCl.	Firm revised the sample preparation procedure in which 50mg is the quantity of nebivolol.
6.	3.2.P.5.1	Clarification is required that in assay either you have quantified the nebivolol or nebivolol HCl, since the calculated % is of nebivolol HCl, while the main peak in the chromatogram represent the nebivolol without HCl.	Firm replied that We have used Nebivolol HCl raw material in production of our trial batches as per Innovator's specifications not Nebivolol base as it is evident from our COA of raw material attached here but since international and our claim is Nebivolol as HCl (Nebivolol base) that's why we had used only Nebivolol in our chromatograms. The peak in chromatograms is of Nebivolol HCl but to justify our claim in product we write only Nebivolol on it which is also evident from the assay of standard which we use as 90.53%. The pictures of reference products to justify our claim are attached herewith along with some supporting data.
7.	3.2.P.5.2	Justify for adapting the acceptance criteria of dissolution NLT 80% within 45 minutes comparing the results of CDP in 0.01N HCl medium which was more than 80% within 15minutes and the acceptance criteria of innovator brand approved in USFDA.	Firm claimed that they submitted the updated documents but the submitted analytical procedure again specified the same acceptance i.e. criteria NLT 80% within 45 minutes.
8.	3.2.R.1.1	Justify for taking the strength of tablet with HCl factor for calculation of dispensed quantity of powder as revealed from the batch manufacturing record since you have taken the potency of drug substance without HCl on as is basis.	Firm replied that In trial BMR we have taken the potency of drug substance with HCl on as is basis, the potency given in COA is on as is basis with HCl.

Decision: Deferred for submission of following shortcomings:

- **Submit the revised acceptance criteria of dissolution in line with innovator product along with performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.**
- **Pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.**

911.	Name, address of Applicant / Marketing Authorization Holder	Name: Pharmedic Laboratories (Pvt.) Ltd. Address: 16km Multan Road, Lahore-Pakistan
	Name, address of Manufacturing site.	Name: Pharmedic Laboratories (Pvt.) Ltd. Address: 16km Multan Road, Lahore-Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale

		☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.no.2630 dated 27/01/2022
	Details of fee submitted	PKR 30,000/-: dated 24/11/2021
	The proposed proprietary name / brand name	Nevol 5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Nebivolol HCl equivalent to Nebivolol…..5mg
	Pharmaceutical form of applied drug	White colored, round shaped, biconvex uncoated tablets with both sides plain.
	Pharmacotherapeutic Group of (API)	Beta blocking agent, selective
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	1×10's , 3x 10's and 2x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Bystolic tablets, Allergen, USA
	For generic drugs (me-too status)	Nabil 5mg Tablet by M/s Getz Pharma, Reg. No. 061345
	GMP status of the Finished product manufacturer	Last GMP was granted on 09/06/2020 GMP is in Renewal Process
	Name and address of API manufacturer.	Name: Jiangsu Weiqida Pharmaceutical Co., Ltd. Old Name: Shanghai Shyndec Pharmaceutical (Haimen) Co., Ltd Address: No.1, Linjiang Avenue, Nantong, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Nebivolol HCl is not present in Pharmacopeia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Test for Impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 12 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (NEB5-TR002, NEB5-TR003, NEB5-TR004)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and

		justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Nebil 5mg tablet by Getz Pharma (Pvt) Ltd. by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Nebil 5mg tablet by Getz Pharma (Pvt) Ltd.in Acid media (pH 1.2), pH 4.5 & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including Specificity, linearity, accuracy, precision (repeatability and Intermediate), Limit of Detection, Limit of Quantification, Robustness.

STABILITY STUDY DATA			
Manufacturer of API	Jiangsu Weiqida Pharmaceutical Co., Ltd.		
API Lot No.	NBB-19070031M		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×10's3x 10's and 2x 7's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24, 36 (Months)		
Batch No.	NEB5-TR002	NEB5-TR003	NEB5-TR004
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	09-2020	09-2020	09-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by DCA valid till 17/01/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No.759/2020DRAP-AD (I&E) dated 13/01/2020 is submitted wherein the permission to import Nebivolol HCl for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.2	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".* Since you have only submitted the requisite information provided by drug substance manufacturer.
2.	3.2.S.4.4	Justify how you have calculate the potency of nebivolol without HCl as mentioned in the COA of drug substance comparing the COA of drug substance by drug substance manufacturer calculated the assay on anhydrous basis only.
3.	3.2.P.2.2.1	• Justify for not performing the test of content uniformity by HPLC and water content test while establishing the pharmaceutical equivalence against the reference product, since these test are included in the specification of innovator brand of USFDA. • Justify for not performing the pharmaceutical equivalence and comparative dissolution against the innovator brand/brand leador approved in Pakistan.
4.	3.2.P.5.1	• Justify for not including the test of water conent in the release specification of drug product, since these test are included in the specification of innovator brand. • Clarification is required that in assay either you have quantified the nebivolol or nebivolol HCl, since the calculated % is of nebivolol HCl, while the main peak in the chromatogram represent the nebivolol without HCl. • Sample preparation for assay is more general rather than specific, without the clarity that transfer quantity of the sample equivalent to 50mg represent either the quantity of nebivolol or nebivolol HCl. • Justify for adapting the acceptance criteria of dissolution NLT 80% within 45 minutes comparing the results of CDP in 0.01N HCl medium which was more than 80% within 15minutes and the acceptance criteria of innovator brand approved in USFDA.
5.	3.2.R.1.1	Justify for taking the strength of tablet with HCl factor for calculation of dispensed quantity of powder as revealed from the batch manufacturing record since you have taken the potency of drug substance without HCl on as is basis.

Decision of 324th meeting of Registration Board:

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response of the Firm:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	3.2.S.4.2	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including*	Firm submitted the analytical method verification report of drug substance performed by drug product manufacturer. However, the official monograph of drug substance is present in EP 11.0 and the applicant imported in-house complied drug substance.

		specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted". Since you have only submitted the requisite information provided by drug substance manufacturer.	
2.	3.2.S.4.4	Justify how you have calculate the potency of nebivolol without HCl as mentioned in the COA of drug substance comparing the COA of drug substance by drug substance manufacturer calculated the assay on anhydrous basis only.	Firm replied it is an error which was rectified and correct COA of drug substance by drug product manufacturer has submitted.
3.	3.2.P.2.2.1	Justify for not performing the test of content uniformity by HPLC and water content test while establishing the pharmaceutical equivalence against the reference product, since these test are included in the specification of innovator brand of USFDA.	Firm submitted the analytical procedure instead of pharmaceutical equivalence report including the test of content uniformity by HPLC and water content test.
4.	3.2.P.5.1	Justify for not including the test of water content in the release specification of drug product, since these test are included in the specification of innovator brand.	Firm submitted the revised analytical procedure of drug along with specification.
5.	3.2.P.5.1	Sample preparation for assay is more general rather than specific, without the clarity that transfer quantity of the sample equivalent to 50mg represent either the quantity of nebivolol or nebivolol HCl.	Firm revised the sample preparation procedure in which 50mg is the quantity of nebivolol.
6.	3.2.P.5.1	Clarification is required that in assay either you have quantified the nebivolol or nebivolol HCl, since the calculated % is of nebivolol HCl, while the main peak in the chromatogram represent the nebivolol without HCl.	Firm replied that We have used Nebivolol HCl raw material in production of our trial batches as per Innovator's specifications not Nebivolol base as it is evident from our COA of raw material attached here but since international and our claim is Nebivolol as HCl (Nebivolol base) that's why we had used only Nebivolol in our chromatograms. The peak in chromatograms is of Nebivolol HCl but to justify our claim in product we write only Nebivolol on it which is also evident from the assay of standard which we use as 90.53%. The pictures of reference products to justify our claim are attached herewith along with some supporting data.
7.	3.2.P.5.2	Justify for adapting the acceptance criteria of dissolution NLT 80% within 45 minutes comparing the results of CDP in 0.01N HCl medium which was more than 80% within 15minutes and the	Firm claimed that they submitted the updated documents but the submitted analytical procedure again specified the same acceptance i.e. criteria NLT 80% within 45 minutes.

		acceptance criteria of innovator brand approved in USFDA.	
8.	3.2.R.1.1	Justify for taking the strength of tablet with HCl factor for calculation of dispensed quantity of powder as revealed from the batch manufacturing record since you have taken the potency of drug substance without HCl on as is basis.	Firm replied that In trial BMR we have taken the potency of drug substance with HCl on as is basis, the potency given in COA is on as is basis with HCl.

Decision: Deferred for submission of following shortcomings:

- **Submit the revised acceptance criteria of dissolution in line with innovator product along with performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.**
- **Pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.**

912.	Name, address of Applicant / Marketing Authorization Holder	Name: Pharmedic Laboratories (Pvt.) Ltd. Address: 16km Multan Road, Lahore-Pakistan
	Name, address of Manufacturing site.	Name: Pharmedic Laboratories (Pvt.) Ltd. Address: 16km Multan Road, Lahore-Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.no.9330 dated 12/04-2022
	Details of fee submitted	PKR 30,000/-: dated 17/03/2022
	The proposed proprietary name / brand name	Nevol 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Nebivolol HCl equivalent to Nebivolol…..10mg
	Pharmaceutical form of applied drug	White colored, round shaped, biconvex uncoated tablets with both sides plain.
	Pharmacotherapeutic Group of (API)	Beta blocking agent, selective
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	1×10's , 3x 10's and 2x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Bystolic tablets, Allergen, USA
	For generic drugs (me-too status)	Bynevol 10mg Tablet by Atco Laboratories, Reg. No. 081562
	GMP status of the Finished product manufacturer	Last GMP was granted on 09/06/2020 GMP is in Renewal Process

	Name and address of API manufacturer.	Name: Jiangsu Weiqida Pharmaceutical Co., Ltd. Old Name: Shanghai Shyndec Pharmaceutical (Haimen) Co., Ltd Address: No.1, Linjiang Avenue, Nantong, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Nebivolol HCl is not present in any Pharmacoepia. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Test for Impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (NBB-1711001-1M, NBB-1711002-1M, NBB-1711003-1M)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Bynevol 10mg tablet by Atco Laboratories. by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Bynevol 10mg tablet by Atco Laboratories..…… in Acid media (pH 1.2), pH 4.5 & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including Specificity, linearity, accuracy, precision (repeatability and Intermediate), Limit of Detection, Limit of Quantification, Robustness.

STABILITY STUDY DATA	
Manufacturer of API	Jiangsu Weiqida Pharmaceutical Co., Ltd.
API Lot No.	NBB-19070031M
Description of Pack	Alu-Alu blister packed in unit carton (1×10's, 3x 10's and 2x 7's)

(Container closure system)			
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 12 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24, 36 (Months)		
Batch No.	NEB10-TR002	NEB10-TR003	NEB10-TR004
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	09-2020	09-2020	09-2020
Date of Initiation	09-2020	09-2020	09-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by DCA valid till 17/01/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of letter No.759/2020DRAP-AD (I&E) dated 13/01/2020 is submitted wherein the permission to import Nebivolol HCl for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.2	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".* Since you have only submitted the requisite information provided by drug substance manufacturer.
2.	3.2.S.4.4	Justify how you have calculate the potency of nebivolol without HCl as mentioned in the COA of drug substance comparing the COA of drug substance by drug substance manufacturer calculated the assay on anhydrous basis only.
3.	3.2.P.2.2.1	• Justify for not performing the test of content uniformity by HPLC and water content test while establishing the pharmaceutical equivalence aginst the reference product, since these test are included in the specification of innovator brand of USFDA.

		• Justify for not performing the pharmaceutical equivalence and comparative dissolution against the innovator brand/brand leador approved in Pakistan.
4.	3.2.P.5.1	• Justify for not including the test of water conent in the release specification of drug product, since these test are included in the specification of innovator brand. • Clarification is required that in assay either you have quantified the nebivolol or nebivolol HCl, since the calculated % is of nebivolol HCl, while the main peak in the chromatogram represent the nebivolol without HCl. • Sample preparation for assay is more general rather than specific, without the clarity that transfer quantity of the sample equivalent to 50mg represent either the quantity of nebivolol or nebivolol HCl. • Justify for adapting the acceptance criteria of dissolution NLT 80% within 45 minutes comparing the results of CDP in 0.01N HCl medium which was more than 80% within 15minutes and the acceptance criteria of innovator brand approved in USFDA.
5.	3.2.R.1.1	Justify for taking the strength of tablet with HCl factor for calculation of dispensed quantity of powder as revealed from the batch manufacturing record since you have taken the potency of drug substance without HCl on as is basis.

Decision of 324th meeting of Registration Board:
Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response of the Firm:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	3.2.S.4.2	Submit data of verification of analytical procedure of drug substance in section 3.2.S.4.3 as per the guidance document approved by Registration Board which specifies that *"Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as non-compendial drug substance(s) shall be submitted".* Since you have only submitted the requisite information provided by drug substance manufacturer.	Firm submitted the analytical method verification report of drug substance performed by drug product manufacturer. However, the official monograph of drug substance is present in EP 11.0 and the applicant imported in-house complied drug substance.
2.	3.2.S.4.4	Justify how you have calculate the potency of nebivolol without HCl as mentioned in the COA of drug substance comparing the COA of drug substance by drug substance manufacturer calculated the assay on anhydrous basis only.	Firm replied it is an error which was rectified and correct COA of drug substance by drug product manufacturer has submitted.
3.	3.2.P.2.2.1	Justify for not performing the test of content uniformity by HPLC and water content test while establishing the pharmaceutical equivalence against the reference product, since these test are included in the	Firm submitted the analytical procedure instead of pharmaceutical equivalence report including the test of content uniformity by HPLC and water content test.

		specification of innovator brand of USFDA.	
4.	3.2.P.5.1	Justify for not including the test of water content in the release specification of drug product, since these test are included in the specification of innovator brand.	Firm submitted the revised analytical procedure of drug along with specification.
5.	3.2.P.5.1	Sample preparation for assay is more general rather than specific, without the clarity that transfer quantity of the sample equivalent to 50mg represent either the quantity of nebivolol or nebivolol HCl.	Firm revised the sample preparation procedure in which 50mg is the quantity of nebivolol.
6.	3.2.P.5.1	Clarification is required that in assay either you have quantified the nebivolol or nebivolol HCl, since the calculated % is of nebivolol HCl, while the main peak in the chromatogram represent the nebivolol without HCl.	Firm replied that We have used Nebivolol HCl raw material in production of our trial batches as per Innovator's specifications not Nebivolol base as it is evident from our COA of raw material attached here but since international and our claim is Nebivolol as HCl (Nebivolol base) that's why we had used only Nebivolol in our chromatograms. The peak in chromatograms is of Nebivolol HCl but to justify our claim in product we write only Nebivolol on it which is also evident from the assay of standard which we use as 90.53%. The pictures of reference products to justify our claim are attached herewith along with some supporting data.
7.	3.2.P.5.2	Justify for adapting the acceptance criteria of dissolution NLT 80% within 45 minutes comparing the results of CDP in 0.01N HCl medium which was more than 80% within 15minutes and the acceptance criteria of innovator brand approved in USFDA.	Firm claimed that they submitted the updated documents but the submitted analytical procedure again specified the same acceptance i.e. criteria NLT 80% within 45 minutes.
8.	3.2.R.1.1	Justify for taking the strength of tablet with HCl factor for calculation of dispensed quantity of powder as revealed from the batch manufacturing record since you have taken the potency of drug substance without HCl on as is basis.	Firm replied that In trial BMR we have taken the potency of drug substance with HCl on as is basis, the potency given in COA is on as is basis with HCl.

Decision: Deferred for submission of following shortcomings:

- **Submit the revised acceptance criteria of dissolution in line with innovator product along with performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.**
- **Pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.**

913.	Export Facilitation: Applications was received through letter No.F.1-76/2019-PR-I (EFD) "M/s Pharmedic Laboratories (Pvt.) Ltd. have achieved benchmark OF USD 1576776.335 as defined in the Board's decision during fiscal year 2020-2021. In this regard, please find the (1 molecule) 02 products applications submitted by the firm."	
	Name, address of Applicant / Marketing Authorization Holder	Name: Pharmedic Laboratories (Pvt.) Ltd. Address: 16km Multan Road, Lahore-Pakistan
	Name, address of Manufacturing site.	Name: Pharmedic Laboratories (Pvt.) Ltd.

		Address: 16km Multan Road, Lahore-Pakistan Contact details: Tel: +92 42 37511861-65
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.no.11999 dated 17/05/2022
	Details of fee submitted	PKR 30,000/-: dated 07/04/2022
	The proposed proprietary name / brand name	Axaban 2.5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Apixaban……2.5mg
	Pharmaceutical form of applied drug	Pink colored, round shaped, biconvex film coated tablets with both sides plain.
	Pharmacotherapeutic Group of (API)	Antithrombotic agents, direct factor Xa inhibitors
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	10's , 14's and 20's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Bristol-Myers Squibb Company, USA (USFDA Approved) Bristol-Myers Squibb/Pfizer EEIG, Ireland
	For generic drugs (me-too status)	Elixaban Tablet 2.5mg (Reg.no. 105238) of M/s. Martin Dow Limited Karachi
	GMP status of the Finished product manufacturer	Last GMP was granted on 09/06/2020 GMP is in Renewal Process
	Name and address of API manufacturer.	Name: Jiangsu Yongan Pharmaceuticals Co., Ltd Address: No. 18, 237 Provincial Road, Economic Development zone, Huaian, Jiangsu, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Test for Impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies

		of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 18 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (23111001,2311102,23111101)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Eliquis 2.5mg Tablet by Pfizer Bristol-Myers Squibb/Pfizer EEIG Dublin Ireland. by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Eliquis 2.5mg Tablet by Bristol-Myers Squibb/Pfizer EEIG Dublin Ireland……. in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including Specificity, linearity, accuracy, precision (repeatability and Intermediate), Limit of Detection, Limit of Quantification, Robustness.

STABILITY STUDY DATA			
Manufacturer of API	Jiangsu Yongan Pharmaceuticals Co., Ltd		
API Lot No.	APB-202004002		
Description of Pack (Container closure system)	Alu-PVC blister packed in unit carton (10's , 14's and 20's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6(Months)		
Batch No.	Apx2.5-TR004	Apx2.5-TR005	Apx2.5-TR006
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	10-2021	10-2021	10-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. NIL issued by Huai'an Pharmaceutical Industry Association valid till 14/01/2024.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No.10927/2020DRAP-AD (I&E) dated 07/08/2020 is submitted wherein the permission to import Apixaban for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2. S.4.3	Provide analytical Method verification studies including specificity, accuracy and repeatability parameter of drug substance performed by the Drug Product manufacturer.
2.	3.2.P.2.2.1	In compliance of notification no. 14-1/2022-PEC dated 16th January,2023 issued by DRAP, submit the image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed.
3.	3.2.P.8	Submit the remaining stability data of drug product ,since you have submitted only three month stability data.

Decision of 326th meeting of Registration Board:

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
4.	3.2. S.4.3	Provide analytical Method verification studies including specificity, accuracy and repeatability parameter of drug substance performed by the Drug Product manufacturer.	Firm submit the analytical verification report of drug substance performed by drug product manufacturer.
5.	3.2.P.2.2.1	In compliance of notification no. 14-1/2022-PEC dated 16th January,2023 issued by DRAP, submit the image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed.	Firm submitted the snapshot of innovator product against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed.
6.	3.2.P.8	Submit the remaining stability data of drug product ,since you have submitted only three month stability data.	Submit the stability data till 12 month.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

• **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
914.	Name, address of Applicant / Marketing Authorization Holder	Name: Pharmedic Laboratories (Pvt.) Ltd. Address: 16km Multan Road, Lahore-Pakistan
	Name, address of Manufacturing site.	Name: Pharmedic Laboratories (Pvt.) Ltd. Address: 16km Multan Road, Lahore-Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy.no. 12000 dated 17/05/2022
	Details of fee submitted	PKR 30,000/-: dated 17/05/2022
	The proposed proprietary name / brand name	Axaban 5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Apixaban……5mg
	Pharmaceutical form of applied drug	Orange red colored, round shaped, biconvex film coated tablets with both sides plain.
	Pharmacotherapeutic Group of (API)	Antithrombotic agents, direct factor Xa inhibitors
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	10's , 14's and 20's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Bristol-Myers Squibb Company, USFDA Approved Bristol-Myers Squibb/Pfizer EEIG, Ireland
	For generic drugs (me-too status)	Elixaban Tablet 5mg (Reg.no. 105237) of M/s. Martin Dow Limited Karachi
	GMP status of the Finished product manufacturer	Last GMP was granted on 09/06/2020 GMP is in Renewal Process
	Name and address of API manufacturer.	Name: Jiangsu Yongan Pharmaceuticals Co., Ltd Address: No. 18, 237 Provincial Road, Economic Development zone, Huaian, Jiangsu, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature,

		structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, Test for Impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 12 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (23111001,2311102,23111101)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Eliquis 5mg Tablet by Pfizer Bristol-Myers Squibb/Pfizer EEIG Dublin Ireland. by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Eliquis 5mg Tablet by Bristol-Myers Squibb/Pfizer EEIG Dublin Ireland……. in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including Specificity, linearity, accuracy, precision (repeatability and Intermediate), Limit of Detection, Limit of Quantification, Robustness.

STABILITY STUDY DATA			
Manufacturer of API	Jiangsu Yongan Pharmaceuticals Co., Ltd		
API Lot No.	APB-202004002		
Description of Pack (Container closure system)	Alu-PVC blister packed in unit carton (10's , 14's and 20's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24, 36 (Months)		
Batch No.	Apx5-TR001	Apx5-TR002	Apx5-TR003
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	10-2021	10-2021	10-2021
No. of Batches	03		
Administrative Portion			

1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. NIL issued by Huai'an Pharmaceutical Industry Association valid till 14/01/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No.10927/2020DRAP-AD (I&E) dated 07/08/2020 is submitted wherein the permission to import Apixaban for the purpose of test/analysis and stability studies is granted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2. S.4.3	Provide analytical Method verification studies including specificity, accuracy and repeatability parameter of drug substance performed by the Drug Product manufacturer.
2.	3.2.P.2.2.1	In compliance of notification no. 14-1/2022-PEC dated 16th January,2023 issued by DRAP, submit the image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed.
3.	3.2.P.8	Submit the remaining stability data of drug product ,since you have submitted only three month stability data.

Decision of 326th meeting of Registration Board:

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	3.2. S.4.3	Provide analytical Method verification studies including specificity, accuracy and repeatability parameter of drug substance performed by the Drug Product manufacturer.	Firm submit the analytical verification report of drug substance performed by drug product manufacturer.
2.	3.2.P.2.2.1	In compliance of notification no. 14-1/2022-PEC dated 16th January,2023 issued by DRAP, submit the image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed.	Firm submitted the snapshot of innovator product against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed.
3.	3.2.P.8	Submit the remaining stability data of drug product ,since you have submitted only three month stability data.	Submit the stability data till 12 month.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

915.	Central Licensing Board in 272nd meeting held on 17th October,2019 has considered and approved additional section "Tablet II (General section)" of M/s Don Valley Pharmaceuticals Private Limited.	
	Name, address of Applicant / Marketing Authorization Holder	M/s Don Valley Pharmaceuticals Private Limited 31km Main Ferozepur Road Lahore
	Name, address of Manufacturing site.	M/s Don Valley Pharmaceuticals Private Limited 31km Main Ferozepur Road Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. -dated: 9th March 2023
	Details of fee submitted	PKR 30,000/-: dated 09/02/2023
	The proposed proprietary name / brand name	Ocalidon 5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Obeticholic Acid…….5mg
	Pharmaceutical form of applied drug	Yellow colored, Round biconvex shaped, without any score, Film coated oral tablet
	Pharmacotherapeutic Group of (API)	Farnesoid X receptor agonists
	Reference to Finished product specifications	In-house
	Proposed Pack size	3×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ocaliva 5mg tablet by M/s Intercept Pharma Limited EMA Approved.
	For generic drugs (me-too status)	Abeticholic 5mg Tablet by M/s Dyson Research Laboratories Pvt. Ltd., Reg. No. 109521
	GMP status of the Finished product manufacturer	Firm has submitted GMP certificate issued on dated 06-08-2019. Section approval letter issued on 05.11.2019
	Name and address of API manufacturer.	M/s Jari Pharmaceutical Co., Ltd. 18, Zhenhua Road, Lianyungang, Jiangsu Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of

		specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (20171001, 20171101, 20171102)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator product that is Ocaliva 5mg tablet by Intercept Pharma International Limited, Ireland (Batch no. CE00024E) by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Ocaliva 5mg tablet by Intercept Pharma International Limited, Ireland (Batch no. CE00024E) in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Jari Pharmaceutical Co., Ltd. 18, Zhenhua Road, Lianyungang, Jiangsu Province China.		
API Lot No.	20220802		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (3×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3(Months) Real Time: 0, 3(Months)		
Batch No.	KB-22-001	KB-22-002	KB-22-003
Batch Size	5000 tab	5000 tab	5000 tab
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	28-10-2022	28-10-2022	28-10-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Gutain 30 mg and Gutain 60 mg capsule approved in 324 DRB Meeting
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. JS20191190 issued by Jiangsu Drug Administration valid till 29/11/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No. K-1107632926281 dated 13/10/2022 is submitted wherein the permission to import different APIs including Obeticholic Acid for the purpose of test/analysis and stability studies is granted. • Invoice No. 22YX0049L dated 15/09/2022
4.	Data of stability batches will be supported by attested respective documents like chromatograms,Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2. S.4.1	Justify for not including the test of parcticle size distribution, palladium test and solid state form test in the specification of drug substance by drug substance manufacturer, since these tests are included in the specification of drug substance of innovator product.
2.	3.2.S.4.1-3.2.S.4.2	• Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by the drug product manufacturer as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required". Since you have only submitted the specification and analytical procedure by drug substance manufacturer. • Submit detailed analytical procedure of drug substance by drug substance manufacturer, since the submitted procedure seems incomplete or only refer the general chapters of USP.
3.	3.2.S.4.3	• Justify for performing validation study of assay procedure which is different from the assay method by drug substance manufacturer given in section 3.2.S.4.2. • Further drug substance manufacturer used RID detector in the HPLC system for assay while the submitted chromatogram of validation studies reflect that the assay has performed by setting the wavelength of detector at 210nm, Justify for using the different detector from that specified by drug substance manufacturer.
4.	3.2.S.5	COA of primary/secondary reference standard including source and lot no. is required.

5.	3.2.S.7	According to the review literature of innovator brand storage condition of drug substance is 5°C±3°C with the retest period of 36months then justify the testing condition of given stability data of drug substance i.e. 30±2°C RH 65±5% & 40±2°C RH 75±5%.
6.	3.2.P.2.2.1	• Clarification shall be submitted for the reported results of CDP studies without the aid of surfactant in the dissolution mediums while referring to the innovator drug product literature wherein the drug substances have been reported as BCS Class II drug substances and the recommended dissolution medium contains surfactant polysorbate 80. • In compliance of notification no. 14-1/2022-PEC dated 16th January,2023 issued by DRAP, submit the image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed.
7.	3.2.P.5.2	Clarification is required for not using reference standard/working standard for the preparation of standard solution as reflects from the given analytical procedures while performing the assay and dissolution of drug product.
8.	3.2.P.5.3	Justify for not performing the validation study on the same assay procedure which is given in section 3.2.P.5.2, specifically with reference to the preparation of both standard and sample preparation. Further , analytical method validation reports reflects that the assay procedure which has been validated is different from assay procedure given in section 3.2.P.5.2 and also not similar to the method specified in AMV protocol.
9.	3.2.P.5.4	Justify for not performing the content uniformity test while finished product analysis of drug product , since the test is included in the specification of finished drug product.
10.	3.2.P.8	• Submit the updated stability data of drug product, since you have submitted only three-month stability data. • Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
11.	2.3.R.1.1	Justify for not adjusting the water content in the dispensing weight of API since the assay results are achieved on anhydrous as evident from the COA of API.

Decision of 327th meeting of Registration Board:
Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	3.2. S.4.1	Justify for not including the test of particle size distribution, palladium test and solid state form test in the specification of drug substance by drug substance manufacturer, since these tests are included in the specification of drug substance of innovator product.	Firm forward the response of API supplier i.e. Reply from API Manufacturer: For PSD due to different customer has various requirements we did not include it in DMF. about palladium test or solid-state form test, it's not a regular item for an API supplier. We have no method and we did not study yet. Further the substance is of In-house standards and due to international patent rules, we can't use same innovator's specifications. However, Physicochemical characteristics of the active substance that impact the quality of the finished product are particle size distribution which plays a critical role in the content uniformity and dissolution of the tablets. https://www.ema.europa.eu/en/documents/assessmentreport/ocaliva-epar-public-assessment-report_en.pdf

			However, particle size distribution of active substance has not been controlled /performed either by Drug substance or Drug product manufacturer.
2.	3.2.S.4.1	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by the drug product manufacturer as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required". Since you have only submitted the specification and analytical procedure by drug substance manufacturer.	Firm submit the specifications and analytical procedure of drug substance by both drug substance manufacturer and drug product manufacturer.
3.	3.2.S.4.3	Justify for performing validation study of assay procedure which is different from the assay method by drug substance manufacturer given in section 3.2.S.4.2.	Firm has not submitted the reply of this response.
4.	3.2.S.4.3	Further drug substance manufacturer used RID detector in the HPLC system for assay while the submitted chromatogram of validation studies reflect that the assay has performed by setting the wavelength of detector at 210nm, Justify for using the different detector from that specified by drug substance manufacturer.	HPLC method used for the API is literature based and validated. UV detector is used as it is easily available. Method validation has been performed to justify the results.
5.	3.2.S.5	COA of primary/secondary reference standard including source and lot no. is required.	Submitted
6.	3.2.S.7	According to the review literature of innovator brand storage condition of drug substance is 5°C±3°C with the retest period of 36months then justify the	Firm submitted the real time stability data of drug substance performed at condition 5°C±3°C till 24 months.

		testing condition of given stability data of drug substance i.e. 30±2°C RH 65±5% & 40±2°C RH 75±5%.	
7.	3.2.P.2.2.1	Clarification shall be submitted for the reported results of CDP studies without the aid of surfactant in the dissolution mediums while referring to the innovator drug product literature wherein the drug substances have been reported as BCS Class II drug substances and the recommended dissolution medium contains surfactant polysorbate 80.	Firm replied that According to FDA recommended media for the CDP are pH 1.2, 4.5 and 6.8 buffer. These do not contain any surfactant. While testing the finished product, polysorbate 80 has been used as surfactant in the dissolution medium. As per USP and FDA, medium used for CDP should not contain any surfactant. Because CDP is in-vitro bioequivalence comparison and not a performance test of finished product. Given test method contains medium consist of polysorbate 80. Furthermore, the dissolution acceptance criteria of applied formulation is NLT 75% (Q) within 45 minutes while the innovator product approved in USFDA claimed NLT (Q) within 15 minutes. Firm further clarified that the dissolution time of their applied product is 15 minutes it was mentioned in testing method,however at one place it was erroneously mentioned 45 minutes but their all provided data is according to 15 minutes.
8.	3.2.P.2.2.1	In compliance of notification no. 14-1/2022-PEC dated 16th January,2023 issued by DRAP, submit the image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed.	Submitted
9.	3.2.P.5.3	Justify for not performing the validation study on the same assay procedure which is given in section 3.2.P.5.2, specifically with reference to the preparation of both standard and sample preparation. Further , analytical method validation reports reflects that the assay procedure which has been validated is different from assay procedure given in section 3.2.P.5.2 and also not similar to the method specified in AMV protocol.	Firm replied that Method used for the analysis for the finished product is same as AMV protocol. Test method has been revised as per actual performance method and attached.
10	3.2.P.5.4	Justify for not performing the content uniformity test while finished product	Firm replied that "Content uniformity has been performed as per finished test method and part of our record. Shared COA is of 0th month that's why we have not included Content

		analysis of drug product , since the test is included in the specification of finished drug product.	uniformity test. Now revised COA and already performed data of 0th month has been shared with you".
11	3.2.P.8	Submit the updated stability data of drug product, since you have submitted only three-month stability data.	
12	3.2.P.8	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP.	Firm submit the copy of Form-6 issued dated 13-oct-2022 and submit commercial invoice which is not attested by DRAP.
13	3.2.P.8	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm submitted the copy of GMP certificate of M/s. JARI Pharmaceutical co. Ltd. No.18 Zhenhua Road, Lianyungang, China which is valid till 29-11-2024.
14	2.3.R.1.1	Justify for not adjusting the water content in the dispensing weight of API since the assay results are achieved on anhydrous as evident from the COA of API.	Firm replied that the assay result of the API is achieved on anhydrous basis which indicated an assay result of 100.91%, in this case adjusting the dispensing weight of the API based on its water content would not be necessary, as the assay result is already indicative of the potency of the anhydrous material. Further Firm submit a commitment letter that they will adjust the water content in the dispensed quantity of API while manufacturing of commercial batches.

Decision: Approved with Innovator's Specifications. Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

916.	Name, address of Applicant / Marketing Authorization Holder	M/s Don Valley Pharmaceuticals Private Limited 31km Main Ferozepur Road Lahore
	Name, address of Manufacturing site.	M/s Don Valley Pharmaceuticals Private Limited 31km Main Ferozepur Road Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. -6676 dated: 9th March 2023
	Details of fee submitted	PKR 30,000/-: dated 09/02/2023
	The proposed proprietary name / brand	Ocalidon 10mg Tablet

	name	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Obeticholic Acid…….10mg
	Pharmaceutical form of applied drug	Red colored, Round biconvex shaped, without any score, Film coated oral tablet
	Pharmacotherapeutic Group of (API)	Farnesoid X receptor agonists
	Reference to Finished product specifications	In-house
	Proposed Pack size	3×10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ocaliva 10mg tablet by M/s Intercept Pharma Limited EMA Approved.
	For generic drugs (me-too status)	Abeticholic 10mg Tablet by M/s Dyson Research Laboratories Pvt. Ltd., Reg. No. 109522
	GMP status of the Finished product manufacturer	Firm has submitted GMP certificate issued on dated 06-08-2019. Section approval letter issued on 05.11.2019
	Name and address of API manufacturer.	M/s Jari Pharmaceutical Co., Ltd. 18, Zhenhua Road, Lianyungang, Jiangsu Province China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (20171001, 20171101, 20171102)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Brand Leader that is Ocaliva 10mg tablet by Intercept Pharma International Limited, Ireland (Batch no. CE00024E) by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form).

		CDP has been performed against the same brand that is Ocaliva 10mg tablet by Intercept Pharma International Limited, Ireland (Batch no. CE00024E) in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.		
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.		
STABILITY STUDY DATA				
Manufacturer of API		M/s Jari Pharmaceutical Co., Ltd. 18, Zhenhua Road, Lianyungang, Jiangsu Province China.		
API Lot No.		20220802		
Description of Pack (Container closure system)		Alu-Alu blister packed in unit carton (3×10's)		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		KA-22-001	KA-22-002	KA-22-003
Batch Size		5000 tab	5000 tab	5000 tab
Manufacturing Date		10-2022	10-2022	10-2022
Date of Initiation		28-10-2022	28-10-2022	28-10-2022
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Gutain 30 mg and Gutain 60 mg capsule approved in 324 DRB Meeting		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. JS20191190 issued by Jiangsu Drug Administration valid till 29/11/2024.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	• Copy of letter No. K-1107632926281 dated 13/10/2022 is submitted wherein the permission to import different APIs including Obeticholic Acid for the purpose of test/analysis and stability studies is granted. • Invoice No. 22YX0049L dated 15/09/2022		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted		
6.	Record of Digital data logger for temperature and humidity monitoring of	Submitted		

	stability chambers (real time and accelerated)	

Remarks OF Evaluator:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2. S.4.1	Justify for not including the test of parcticle size distribution, palladium test and solid state form test in the specification of drug substance by drug substance manufacturer, since these tests are included in the specification of drug substance of innovator product.
2.	3.2.S.4.1-3.2.S.4.2	• Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by the drug product manufacturer as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required". Since you have only submitted the specification and analytical procedure by drug substance manufacturer. • Submit detailed analytical procedure of drug substance by drug substance manufacturer, since the submitted procedure seems incomplete or only refer the general chapters of USP.
3.	3.2.S.4.3	• Justify for performing validation study of assay procedure which is different from the assay method by drug substance manufacturer given in section 3.2. S.4.2. • Further drug substance manufacturer used RID detector in the HPLC system for assay while the submitted chromatogram of validation studies reflect that the assay has performed by setting the wavelength of detector at 210nm, Justify for using the different detector from that specified by drug substance manufacturer.
4.	3.2.S.5	COA of primary/secondary reference standard including source and lot no. is required.
5.	3.2.S.7	According to the review literature of innovator brand storage condition of drug substance is 5°C±3°C with the retest period of 36months then justify the testing condition of given stability data of drug substance i.e. 30±2°C RH 65±5% & 40±2°C RH 75±5%.
6.	3.2.P.2.2.1	• Clarification shall be submitted for the reported results of CDP studies without the aid of surfactant in the dissolution mediums while referring to the innovator drug product literature wherein the drug substances have been reported as BCS Class II drug substances and the recommended dissolution medium contains surfactant polysorbate 80. • In compliance of notification no. 14-1/2022-PEC dated 16th January,2023 issued by DRAP, submit the image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed.
7.	3.2.P.5.2	Clarification is required for not using reference standard/working standard for the preparation of standard solution as reflects from the given analytical procedures while performing the assay and dissolution of drug product.
8.	3.2.P.5.3	Justify for not performing the validation study on the same assay procedure which is given in section 3.2.P.5.2, specifically with reference to the preparation of both standard and sample preparation. Further , analytical method validation reports reflects that the assay procedure which has been validated is different from assay procedure given in section 3.2.P.5.2 and also not similar to the method specified in AMV protocol.
9.	3.2.P.5.4	Justify for not performing the content uniformity test while finished product analysis of drug product , since the test is included in the specification of finished drug product.

10.	3.2.P.8	• Submit the updated stability data of drug product, since you have submitted only three-month stability data. • Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.
11.	2.3.R.1.1	Justify for not adjusting the water content in the dispensing weight of API since the assay results are achieved on anhydrous as evident from the COA of API.

Decision of 327th meeting of Registration Board:
Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	3.2. S.4.1	Justify for not including the test of particle size distribution, palladium test and solid state form test in the specification of drug substance by drug substance manufacturer, since these tests are included in the specification of drug substance of innovator product.	Firm forward the response of API supplier i.e. Reply from API Manufacturer: For PSD due to different customer has various requirements we did not include it in DMF. about palladium test or solid-state form test, it's not a regular item for an API supplier. We have no method and we did not study yet. Further the substance is of In-house standards and due to international patent rules, we can't use same innovator's specifications. However, Physicochemical characteristics of the active substance that impact the quality of the finished product are particle size distribution which plays a critical role in the content uniformity and dissolution of the tablets. https://www.ema.europa.eu/en/documents/assessmentreport/ocaliva-epar-public-assessment-report_en.pdf However, particle size distribution of active substance has not been controlled /performed either by Drug substance or Drug product manufacturer.
2.	3.2.S.4.1	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by the drug product manufacturer as per the guidance document approved by Registration Board which specifies that "Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by both Drug substance & Drug Product manufacturer is required". Since you have only submitted the specification and analytical procedure by drug substance manufacturer.	Firm submit the specifications and analytical procedure of drug substance by both drug substance manufacturer and drug product manufacturer.

3.	3.2.S.4.3	Justify for performing validation study of assay procedure which is different from the assay method by drug substance manufacturer given in section 3.2.S.4.2.	Firm has not submitted the reply of this response.
4.	3.2.S.4.3	Further drug substance manufacturer used RID detector in the HPLC system for assay while the submitted chromatogram of validation studies reflect that the assay has performed by setting the wavelength of detector at 210nm, Justify for using the different detector from that specified by drug substance manufacturer.	HPLC method used for the API is literature based and validated. UV detector is used as it is easily available. Method validation has been performed to justify the results.
5.	3.2.S.5	COA of primary/secondary reference standard including source and lot no. is required.	Submitted
6.	3.2.S.7	According to the review literature of innovator brand storage condition of drug substance is 5°C±3°C with the retest period of 36months then justify the testing condition of given stability data of drug substance i.e. 30±2°C RH 65±5% & 40±2°C RH 75±5%.	Firm submitted the real time stability data of drug substance performed at condition 5°C±3°C till 24 months.
7.	3.2.P.2.2.1	Clarification shall be submitted for the reported results of CDP studies without the aid of surfactant in the dissolution mediums while referring to the innovator drug product literature wherein the drug substances have been reported as BCS Class II drug substances and the recommended dissolution medium contains surfactant polysorbate 80.	Firm replied that According to FDA recommended media for the CDP are pH 1.2, 4.5 and 6.8 buffer. These do not contain any surfactant. While testing the finished product, polysorbate 80 has been used as surfactant in the dissolution medium. As per USP and FDA, medium used for CDP should not contain any surfactant. Because CDP is in-vitro bioequivalence comparison and not a performance test of finished product. Given test method contains medium consist of polysorbate 80. Furthermore, the dissolution acceptance criteria of applied formulation is NLT 75% (Q) within 45 minutes while the innovator product approved in USFDA claimed NLT (Q) within 15 minutes. Firm further clarified that the dissolution time of their applied product is 15 minutes it was mentioned in testing method,however at one place it was erroneously mentioned 45 minutes but their all provided data is according to 15 minutes.
8.	3.2.P.2.2.1	In compliance of notification no. 14-1/2022-	Submitted

		PEC dated 16th January,2023 issued by DRAP, submit the image/picture/snapshot of innovator /reference/comparator pack against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed.	
9.	3.2.P.5.3	Justify for not performing the validation study on the same assay procedure which is given in section 3.2.P.5.2, specifically with reference to the preparation of both standard and sample preparation. Further , analytical method validation reports reflects that the assay procedure which has been validated is different from assay procedure given in section 3.2.P.5.2 and also not similar to the method specified in AMV protocol.	Firm replied that Method used for the analysis for the finished product is same as AMV protocol. Test method has been revised as per actual performance method and attached.
10	3.2.P.5.4	Justify for not performing the content uniformity test while finished product analysis of drug product , since the test is included in the specification of finished drug product.	Firm replied that "Content uniformity has been performed as per finished test method and part of our record. Shared COA is of 0th month that's why we have not included Content uniformity test. Now revised COA and already performed data of 0th month has been shared with you".
11	3.2.P.8	Submit the updated stability data of drug product, since you have submitted only three-month stability data.	
12	3.2.P.8	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP.	Firm submit the copy of Form-6 issued dated 13-oct-2022 and submit commercial invoice which is not attested by DRAP.
13	3.2.P.8	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm submitted the copy of GMP certificate of M/s. JARI Pharmaceutical co. Ltd. No.18 Zhenhua Road, Lianyungang, China which is valid till 29-11-2024.
14	2.3.R.1.1	Justify for not adjusting the water content in the dispensing weight of API since the assay results are achieved on anhydrous as evident from the COA of API.	Firm replied that the assay result of the API is achieved on anhydrous basis which indicated an assay result of 100.91%, in this case adjusting the dispensing weight of the API based on its water content would not be necessary, as the assay result is already indicative of the potency of the anhydrous material.

			Further Firm submit a commitment letter that they will adjust the water content in the dispensed quantity of API while manufacturing of commercial batches.

Decision: Approved with Innovator's Specifications. Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

917.	Name, address of Applicant / Marketing Authorization Holder	M/s Curexa Health (Pvt.) Ltd. Plot 517, Sundar Industrial Estate, Raiwind Road, Lahore
	Name, address of Manufacturing site.	M/s Curexa Health (Pvt.) Ltd. Plot 517, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22724 dated 11/08/2022
	Details of fee submitted	PKR 75,000/-: (Rs. 25,000 dated 06/07/2022 (vide Slip No. 8570310414 & Differential Fee of Rs. 50,000 dated 02/08/2022 vide Slip No. 74476073709)
	The proposed proprietary name / brand name	Ceflaro 400mg Injection IV
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftaroline Fosamil monoacetate monohydrate eq. to Ceftaroline Fosamil……. 400mg (With Arginine)
	Pharmaceutical form of applied drug	Dry Powder for Injection
	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use. Fifth-generation cephalosporin
	Reference to Finished product specifications	Manufacturer's Specifications
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Teflaro 400mg Injection (US-FDA Approved) by M/s ALLERGAN Pharma
	For generic drugs (me-too status)	N/A
	GMP status of the Finished product manufacturer	The firm is granted GMP certificate based on inspection conducted on 24-05-2019, was valid till 24-05-2022. Request for GMP inspection R&1 date: 30-12-2021 is provided.

	Name and address of API manufacturer.	M/s Qilu Antibiotics Pharmaceutical Co., Ltd. No.849 Dongjia Town, Licheng District, Jinan, Shandong Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Monograph of Ceftaroline Fosamil is not present in any Pharmacopoeia. The firm has submitted details of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (60001EJ87Z-A, 60002EJ87Z-A, 60003EJ87Z-A)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence with Innovator Brand Teflaro Injection 400mg IV has been submitted Comparative Dissolution Profile - NA
	Analytical method validation/verification of product	Analytical Method Validation of the product is provided

STABILITY STUDY DATA			
Manufacturer of API	M/s Qilu Antibiotics Pharmaceutical Co., Ltd. No.849 Dongjia Town, Licheng District, Jinan, Shandong Province, China		
API Lot No.	1003DJ87ZA		
Description of Pack (Container closure system)	1's (Blister of 1 filled vial & 1 WFI 20mL, LDPE ampoule), securely packed in carton.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 (Months)		
Batch No.	RD-CH-22001	RD-CH-22002	RD-CH-22003
Batch Size	200 Vials	200 Vials	200 Vials

Manufacturing Date		Feb-2022	Feb-2022	Feb-2022
Date of Initiation		08-Feb-2022	08-Feb-2022	08-Feb-2022
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Fortez Injection 2g IV CTD Dossier approved in 317th DRB Meeting held on 16th-17th May-2022		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. SD20170569 issued by CFDA & Copy of DML certificate No. Lu 20160006 issued by CFDA valid till 03/11/2025 has been provided		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	DRAP Approved Commercial Invoice No. A21229J dated 14/10/2021 is enclosed (DRAP Approval Ref. No. 17934/2021-DRAP dated 24-11-2021) (Approval letter No. F.08-10/2021-I&E (QA&LT) is also provided)		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted		

Remarks of Evaluator:

- CAS NO. of starting material used in the applied product is 229016-73-3 i.e. sterile Ceftaroline fosamil monoacetate
- CAS no. of starting material used in the manufacturing of innovator brand is 866021-48-9 i.e. Ceftaroline Fosamil monoacetate monohydrate with the statement that Ceftaroline Fosamil is not stable in the anhydrous form

S.no.	Observations/Deficiencies/ Short-comings	Reply of the Firm
1.	According to the review literature of innovator brand salt form of drug substance is Ceftaroline fosamil acetic acid solvate monohydrate, while the drug substance used in the applied drug product is Ceftaroline fosamil monoacetate as per the information submitted in substance part. Justification is required for variation in the drug substance against the innovator product.	Firm replied that the drug substance used in the applied drug product is same as used by the innovator brand i.e. Ceftaroline fosamil monoacetate monohydrate. However, the CAS number of starting material mentioned in the documents of drug substance manufacturer is different from the CAS no. specified in the review documents of innovator brands.
2.	Please provide complete composition of drug product, specifiy the composition of ceftaroline fosamil monoacetone and L-arginine separately.	Firm replied that Ceftaroline fosamil and arginine are mixed in ratio of 1:0.66 so as per ratio quantity used for injection is Ceftaroline fosamil monoacetate monohydrate eq. to ceftaroline fosamil…400mg Arginine eq. to….264mg
3.	As per the assay results of pharmaceutical equivalence report ceftaroline is quantify instead of ceftaroline fosamil, justification is required in this regard.	Firm replied that it was a typographical error and in pharmaceutical equivalence report in assay ceftaroline fosamil was quantified.

4.	• Justify for not including the test of Constitution Time, Content Uniformity (by Assay) and extractable volume test in the release specification of drug product, since these test are included in the specification of innovator brand. • Elaborate the calculation formula for determination of potency of ceftaroline fosamil.	Firm replied that product is dry powder injection so extractable volume is not applicable and content uniformity test is applicable at the blending stage. However, the test of Constitution Time, Content Uniformity (by Assay) and extractable volume test is included in the release specification of innovator product. Firm submitted the following calculation formula: Assay = 99.2% (on anhydrous, acetic acid & arginine free basis) Potency = {(100-water-arginine-acetic acid)/100}x assay
5.	Submit the remaining stability data of drug product ,since you have submitted only three month stability data.	Submitted
6.	Justify the dispensed quantity of ceftaroline fosamil injection comparing the potency of active (ceftaroline fosamil).	Filled weight = (Label claim/Potency) x 100 Ceflaro 400mg Injection= (400/56.8416)x100= 703.7mg per vial.

Decision of 324th meeting of Registration Board:

Deferred for scientific justification for the drug substance used for the formulation of the applied product since as evident from the submitted data drug substance used in applied formulation i.e., Ceftaroline fosamil monoacetate (229016-73-3) is different from that used in the innovator drug product i.e., Ceftaroline fosamil monoacetate monohydrate (866021-48-9).

Response of the Firm:

Following points are submitted for your consideration please:

1. Ceftaroline fosamil as starting material:
    a. Ceftaroline fosamil monoacetate monohydrate is not a starting material rather it is formulated through chemical transformation of the starting material "Ceftaroline fosamil". The CAS number (229016-73-3) mentioned in the DMF attributes to the starting material i.e., "Ceftaroline fosamil" and the same has also been mentioned in the US FDA Chemistry review document for innovator product. While the CAS no. 866021-48-9 is for the intermediate product Ceftaroline fosamil monoacetate monohydrate, formulated subsequently.

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

A) CAS : 229016-73-3

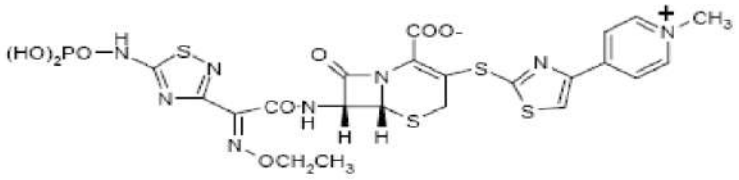
USAN: Ceftaroline Fosamil

(6R,7R)-7-{(2Z)-2-(ethoxyimino)-2-[5-(phosphonoamino)-1,2,4-thiadiazol-3-yl]acetamido}-3-{[4-(1-methylpyridin-1-ium-4-yl)-1,3-thiazol-2-yl]sulfanyl}-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate

Molecular weight 684.68

Formula $C_{26}H_{21}N_8O_8PS_4$

Structural Formula:



2. ~~Revised USAN nomenclature for the Ceftaroline fosamil monoacetate:~~

- Please refer to the attached extract (Annexure-I) from US FDA Chemistry review document for innovator product i.e., "Teflaro" Injection which states as under:
    - "The title of the USAN monograph for this drug substance is Ceftaroline fosamil according to the current USAN dictionary online (8/30/10). The USAN monograph currently lists as

the chemical name the monoacetate monohydrate (Structure B). The Ceftaroline Fosamil USAN monograph may be changed in the future to show instead the chemical name and Structure A".

- Structure A refers to the title and molecular structure of "Ceftaroline Fosamil" having CAS no. 229016-73-3.
- Also in the most recent editions of USAN (United State Adopted Name) the nomenclature for Ceftaroline fosamil acetate has been revised and is adopted as "Ceftaroline Fosamil" with CAS no. 229016-73-3.
- Based upon above cited facts the nomenclature and CAS number 229016-73-3 for Ceftaroline fosamil has been mentioned in the submitted DMF from Qilu antibiotics.

3. Monohydrate monoacetate form of Ceftaroline Fosamil:
   - As submitted in above points that Ceftaroline fosamil monoacetate monohydrate is formulated as intermediate between starting material "Ceftaroline fosamil" and "Sterile Ceftaroline fosamil with arginine". Qilu antibiotics also process the starting material in the same manner as per innovator product wherein Ceftaroline fosamil is converted to Ceftaroline Fosamil monoacetate solvate (hydrate form) through reaction with acetic acid and glacial WFI (extract of DMF presented below). It is pertinent to mention that the monoacetate form is a solvate hydrate wherein water molecule is available as water of crystallization and hence it was not separately mentioned in the nomenclature of the Intermediate form, whereas it is evident form the Manufacturing outline and Drug substance specifications that "Ceftaroline fosamil monoacetate" contains water.

   - The limit of water content of $\leq$ 3.0% also makes it evident that water content equivalent to about monohydrate form is available in the drug substance.

4. Approval of DMF of Qilu antibiotics by US FDA for the ANDA applications:
   a. It is pertinent to mention that the same DMF of same drug susbatcne titled as "STERILE CEFTAROLINE FOSAMIL WITH ARGININE" has been approved by US FDA as Type –II DMF that has passed the completeness assessment and are available for reference by ANDAs, meaning by that the submitted DMF is acceptable to be presented along with any ANDA (generic application) to be filed for the "Ceftaroline Fosamil Injection".
   DMF No.: 28245.
   Status: Active.
   Ref: Types of Drug Master Files (DMFs) | FDA

Decision: Approved with Innovator's Specifications. Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

918.	Name, address of Applicant / Marketing Authorization Holder	M/s High-Q Pharmaceuticals.
	Name, address of Manufacturing site.	M/s High-Q Pharmaceuticals. Plot No.224 & 225/1 Sector 23, Korangi Industrial Area, Karachi-Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 29842 dated 21-10-2022
	Details of fee submitted	PKR 30,000/-: dated 05-10-2022
	The proposed proprietary name / brand name	Daytef 400mg Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: 400mg Ceftaroline fosamil (equivalent to 466mg of ceftaroline fosamil monoacetate monohydrate) powder for intravenous infusion
	Pharmaceutical form of applied drug	Yellow white to light yellow powder for intravenous infusion
	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use
	Reference to Finished product specifications	Manufacturer's Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Teflaro 400mg/vial for Injection, USFDA Approved.
	For generic drugs (me-too status)	Not applicable since the product is New drug
	GMP status of the Finished product manufacturer	GMP issuance date: 21st Dec, 2021 Dry Powder Injectable (Cephalosporin) section is approved
	Name and address of API manufacturer.	M/s Qilu Antibiotics Pharmaceutical Co., Ltd. No.849 Dongjia Town, Licheng District, PC-250105 Jinan, Shandong Province, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Ceftaroline fosamil is not present in any monograph. The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities specifications, analytical procedures and its verification, batch analysis and justification of specification, working standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 25˚C ± 2˚C / 60% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (60001EJ87Z-A, 60002EJ87Z-A, 60003EJ87Z-A)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls,

		impurities, specifications, analytical procedure and its validation studies, force degradation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.		
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator that is Teflaro 400mg/vial for Injection by performing quality tests (Identification, Assay, completeness & clarity of solution, Particulate matter, pH, Water content, Fill weight variation, Related substances, bacterial endotoxin and Sterility test.) CDP is not applicable		
	Analytical method validation/verification of product	Method validation studies are submitted including linearity, accuracy, precision, LOD, LOQ, Robustness and Force degradation studies		
STABILITY STUDY DATA				
Manufacturer of API		M/s Qilu Antibiotics Pharmaceutical Co., Ltd. No.849 Dongjia Town, Licheng District, PC-250105 Jinan, Shandong Province, China		
API Lot No.		1002DJ87ZA		
Description of Pack (Container closure system)		Clear glass vial plugged with rubber stopper and secured with Aluminium seal (1's) packed in unit carton along with Water for Injection as diluent and leaflet		
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		4DTFPD01/22	4DTFPD02/22	4DTFPD03/22
Batch Size		470 vials	470 vials	470 vials
Manufacturing Date		02-2022	02-2022	02-2022
Date of Initiation		29-03-2022	29-03-2022	29-03-2022
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Inspection dated 12th July, 2018 for verification of authenticity of stability data of Vesoft 400mg/100mg tablet (Approved in 284th meeting minute of Registration Board)		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. SD20170569 issued by Shandong Food & Drug Administration valid till 25/06/2023. According to the latest Drug Administration Law of the People's Republic of China, GMP certification program for all the Chinese pharmaceutical manufacturers is cancelled and won't be issued since Dec 1st, 2019		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Form 6 license No. 2556/21, DRAP/K dated 13/8/2021 is submitted wherein the permission to import for the purpose of test/analysis and stability studies is granted.		

		Commercial Invoice No.A21176J attested by AD I&E DRAP, Karachi dated: 13th Aug, 2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms,Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

- CAS NO. of starting material used in the applied product is 229016-73-3 i.e. sterile ceftaroline fosamil monoacetate
- CAS no. of starting material used in the manufacturing of innovator brand is 866021-48-9 i.e. Ceftaroline Fosamil monoacetate monohydrate with the statement that Ceftaroline Fosamil is not stable in the anhydrous form

S.no.	Observations/Deficiencies/ Short-comings	Reply of the Firm
1.	Submit differential fee for the registration of applied new drug product as per the notification for revision of fee vide SRO No. F.7-11/2012-B&A/DRA dated 7th May 2021.	Firm submit Rs. 45,000/- differential fee vide Challan No.786519557 dated: 09-01-2023
2.	According to the review literature of innovator brand salt form of drug substance is ceftaroline fosamil acetic acid solvate monohydrate, while the drug substance used in the applied drug product is ceftaroline fosamil monoacetate as per the information submitted in substance part.Justification is required for variation in the drug substance against the innovator product.	Firm replied that "Molecular formula and structure submitted by the manufacturer (Qilu Antibiotics Pharmaceutical Co., Ltd. China) did not reflect the solvate hydrate. The reason being that they are using USAN (synonym) chemical name of the molecule as the title of the USAN monograph for this drug substance is Ceftaroline fosamil according to the current USAN dictionary. The USAN monograph currently lists this as monoacetate monohydrate as the chemical name. However, the CAS number of starting material mentioned in the documents of drug substance manufacturer is different from the CAS no. specified in the review documents of innovator brands.
3.	Submit stability data of drug substance as per zone-IV-A condition OR In case where the real time stability data of drug substance is not conducted at zone IV-A conditions (e.g 30°C ± 2°C/65% RH ± 5% RH), the drug product manufacturer shall have to submit long term stability studies data of the product for 6 months along with degradation studies in the finished pharmaceutical product.	Firm in their reply submit the validation report of forced degradation studies while the Registration Board in its decision stated that the drug product manufacturer shall have to submit long term stability studies data of the product for 6 months along with degradation studies in the finished pharmaceutical product.
4.	• Justify for not including the test of Constitution Time and extractable volume test in the release specification of drug product, since these test are	Firm replied that Since we do not have access to innovation's specification, therefore we have performed universal tests (related to dry powder injection) and some specific tests on the finished product. However, considering the importance of

	included in the specification of innovator brand. •	these two tests (constitution time & extractable volume), we have performed the tests on retention samples of trial batches of Daytef 400 mg Injection to know the compliance level of our product in comparison with the innovator's product. The results are attached. We have also included these tests in the following documents: Specification and Testing Methods of Daytef 400 mg Injection • Stability Protocol for Commercial batches • Certificate of Analysis format for Finished Product Copies of revised documents, as above, enclosed for your reference.
5.	Elaborate the calculation formula for determination of potency of ceftaroline fosamil.	Firm submitted the following calculation formula: Calculation formula as provided in Doc # API/STM-093 (Raw Material Specification and Control methods): % of Ceftaroline Fosamil in the sample=(ru/rs) x (Cs/Cu) x P Where: ru= Peak area of sample solution rs= Peak area of standard solution Cu= Concentration of sample solution in mg/ml = Weight of sample x 10 / Dilution (100 ml) 100 Cs= Concentration of working standard in mg/ml = Weight of standard (Ceftaroline fosamil) / Dilution (100 ml) P= Potency of Ceftaroline Fosamil working standard = Taken from the respective CoA from the supplier (ru/rs) = Peak area of Sample / Peak area of Standard
6.	Justify, how ceftaroline fosamil separately eluted using the reference standard of ceftaroline fosamil with arginine.	Firm replied that "Prior to analyzing API mix (Ceftaroline fosamil monoacetate monohydrate + L-arginine) we had run working standard of Ceftaroline fosamil and Reference standard of L-Arginine separately, following exactly the same method as to be used for API mix analysis, in order to identify the peaks and to ensure proper resolution (Certificate of Analysis of both these standards are enclosed in Annexure 3). As you would see from the chromatograms of API mix and the reference standard; the peak due to Ceftaroline fosamil and L-arginine are completely separate and reproducible.
7.	Submit the remaining stability data of drug product ,since you have submitted only three month stability data.	Firm submit the stability data of drug product till 6 month.
8.	Justify the dispensed quantity of ceftaroline fosamil injection with respect to the potency of active.	Firm replied that Ceftaroline fosamil with L-arginine is received as sterile powder, in ready to fill form, therefore the sealed container, of known

net weight, is dispensed as such to maintain the sterility. The potency of ceftaroline fosamil is adjusted while calculating the fill weight of powder in vials.

% Potency of Ceftaroline fosamil (as monoacetate, monohydrate) = _____%

Factor (Ceftaroline fosamil to Ceftaroline fosamil monoacetate monohydrate) = 1.114*

Label Claim = Ceftaroline fosamil 400 mg (as Ceftaroline fosamil monoacetate monohydrate) and 264 mg L-arginine per vial

Target Fill Weight (Ceftaroline fosamil monoacetate monohydrate)

$$= \frac{\text{Label claim x F x 100}}{\text{\% Potency of Ceftaroline fosamil}}$$

$$= \frac{400 \text{ x } 1.114 \text{ x } 100}{\text{\% Potency of Ceftaroline fosamil}}$$

$$= \_\_\_\_\_ \text{ mg/vial (A)}$$

Total Fill Weight (Ceftaroline fosamil monoacetate monohydrate + L-arginine)

= A + 264 mg

= _____ mg / vial

* calculated from the molecular weights of Ceftaroline fosamil and Ceftaroline fosamil monoacetate monohydrate:

Molecular weight of ceftaroline fosamil monoacetate monohydrate =762.8

Molecular weight of ceftaroline fosamil = 684.7

or

1 mg of ceftaroline fosamil = 1.114 mg of ceftaroline fosamil monoacetate monohydrate

Decision of 324th meeting of Registration Board:

Deferred for scientific justification for the drug substance used for the formulation of the applied product since as evident from the submitted data drug substance used in applied formulation i.e., Ceftaroline fosamil monoacetate (229016-73-3) is different from that used in the innovator drug product i.e., Ceftaroline fosamil monoacetate monohydrate (866021-48-9).

Response of the Firm:

Following points are submitted for your consideration please:

1. Ceftaroline fosamil as starting material:
    a. Ceftaroline fosamil monoacetate monohydrate is not a starting material rather it is formulated through chemical transformation of the starting material "Ceftaroline fosamil". The CAS number (229016-73-3) mentioned in the DMF attributes to the starting material i.e., "Ceftaroline fosamil" and the same has also been mentioned in the US FDA Chemistry review document for innovator product. While the CAS no. 866021-48-9 is for the intermediate product Ceftaroline fosamil monoacetate monohydrate, formulated subsequently.

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

A) CAS : 229016-73-3

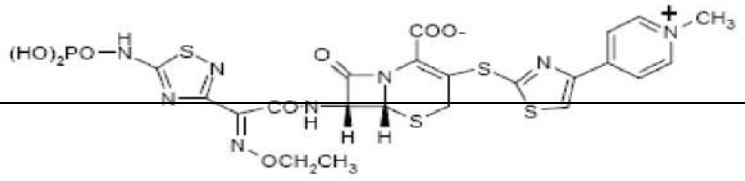
USAN: Ceftaroline Fosamil

(6R,7R)-7-{(2Z)-2-(ethoxyimino)-2-[5-(phosphonoamino)-1,2,4-thiadiazol-3-yl]acetamido}-3-{[4-(1-methylpyridin-1-ium-4-yl)-1,3-thiazol-2-yl]sulfanyl}-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate

Molecular weight 684.68

Formula $C_{26}H_{21}N_8O_8PS_4$

Structural Formula:



Minut

2. Revised USAN nomenclature for the Ceftaroline fosamil monoacetate:

- Please refer to the attached extract (Annexure-I) from US FDA Chemistry review document for innovator product i.e., "Teflaro" Injection which states as under:
    - "The title of the USAN monograph for this drug substance is Ceftaroline fosamil according to the current USAN dictionary online (8/30/10). The USAN monograph currently lists as the chemical name the monoacetate monohydrate (Structure B). The Ceftaroline Fosamil USAN monograph may be changed in the future to show instead the chemical name and Structure A".
- Structure A refers to the title and molecular structure of "Ceftaroline Fosamil" having CAS no. 229016-73-3.
- Also in the most recent editions of USAN (United State Adopted Name) the nomenclature for Ceftaroline fosamil acetate has been revised and is adopted as "Ceftaroline Fosamil" with CAS no. 229016-73-3.
- Based upon above cited facts the nomenclature and CAS number 229016-73-3 for Ceftaroline fosamil has been mentioned in the submitted DMF from Qilu antibiotics.

3. Monohydrate monoacetate form of Ceftaroline Fosamil:
    - As submitted in above points that Ceftaroline fosamil monoacetate monohydrate is formulated as intermediate between starting material "Ceftaroline fosamil" and "Sterile Ceftaroline fosamil with arginine". Qilu antibiotics also process the starting material in the same manner as per innovator product wherein Ceftaroline fosamil is converted to Ceftaroline Fosamil monoacetate solvate (hydrate form) through reaction with acetic acid and glacial WFI (extract of DMF presented below). It is pertinent to mention that the monoacetate form is a solvate hydrate wherein water molecule is available as water of crystallization and hence it was not separately mentioned in the nomenclature of the Intermediate form, whereas it is evident form the Manufacturing outline and Drug substance specifications that "Ceftaroline fosamil monoacetate" contains water.

    - The limit of water content of $\leq$ 3.0% also makes it evident that water content equivalent to about monohydrate form is available in the drug substance.

4. Approval of DMF of Qilu antibiotics by US FDA for the ANDA applications:
    a. It is pertinent to mention that the same DMF of same drug substance titled as "STERILE CEFTAROLINE FOSAMIL WITH ARGININE" has been approved by US FDA as Type –II DMF that has passed the completeness assessment and are available for reference by ANDAs, meaning by that the submitted DMF is acceptable to be presented along with any ANDA (generic application) to be filed for the "Ceftaroline Fosamil Injection".
    DMF No.: 28245.
    Status: Active.

Ref: Types of Drug Master Files (DMFs) | FDA

Decision: Approved with Innovator's Specifications. Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 before issuance of registration letter.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Withdrawal of Registration Applications by M/s. Al Habib Pharmaceuticals:

M/s. Al Habib Pharmaceuticals in its letter dated 20th March ,2023 informed that they would like to withdraw following registration application of their imported products due to discontinuation of their foreign beneficiary. Further, firm requested for re-shuffling and consideration of the paid fee vide slip no.

7575709392 dated 26-01-2022 of following product for registration of product kunyrin (Leucovorin Calcium) 100mg Injection submitted on 08-12-2022.

Sr.no.	Name and Address of Manufacturer & Importer	Brand name along with composition	Details of Registration Application
1.	M/s Al-Habib Pharmaceuticals. Plot No. 81, Block B, SMCHS, Karachi, Pakistan By M/s Naprod Life Sciences Pvt Ltd. Plot No. G-17/1, MIDC, Tarapur, Boisar, Thane 401506, Maharashtra State, India	Cafonate 300mg/30ml Lyophillized Powder for Injection Each Vial Contains: Leucovorin Calcium…300mg/30ml	Form-5F Dy.No 5223 dated 24-02-2022 Rs.150,000/- dated 26-01-2022

Decision: Registration Board acceded the request of withdrawal of firm and declared the above registration applications as disposed off. Further, the Board did not accept the request of re-consideration of already paid fee of the instant application for the registration of product "Kunyrin (Leucovorin Calcium) 100mg Injection."

CASES OF FORM-5 (NEW):

919.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Lanzopin 7.5mg Tablets
	Composition	Each Film coated tablet contains: Olanzapine…..7.5mg
	Diary No. Date of R & I & fee	Dy.No. 16912 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0705986 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specification	
	Pack size & Demanded Price	10's pack. As per SRO.
	Approval status of product in Reference Regulatory Authorities	USFDA Approved (Zyprexa Tablet 7.5mg)
	Me-too status	Psyclan Tablet 7.5mg of M/s. Pharm Evo Pvt. Ltd., Karachi Reg.no. 029170
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Reference of finished product specifications.
	Decision: Approved with USP specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
920.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar

	Brand Name + Dosage Form + Strength	Lanzopin 10 mg Tablets
	Composition	Each Film coated tablet contains: Olanzapine…..10 mg
	Diary No. Date of R & I & fee	Dy.No. 16913 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0777700 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specification	
	Pack size & Demanded Price	10's pack. As per SRO.
	Approval status of product in Reference Regulatory Authorities	USFDA Approved (Zyprexa Tablet 10mg)
	Me-too status	Psyclan Tablet 10mg of M/s. PharmEvo Pvt. Ltd., Karachi Reg.no. 029171
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Reference of finished product specifications.
	Decision: Approved with USP specifications. **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
921.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Lanxodex DR 30mg Capsule
	Composition	Each Capsule contains: Dexlansoprazole…..30 mg
	Diary No. Date of R & I & fee	Dy.No. 16900 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0777686 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Proton Pump Inhibitor (PPI)
	Type of Form	Form-5
	Finished product Specification	
	Pack size & Demanded Price	3X10's pack. As per SRO.
	Approval status of product in Reference Regulatory Authorities	DEXILANT 30mg Capsule of M/s TAKEDA PHARMS USA (USFDA approved)
	Me-too status	Razodex 30 mg Capsule of M/s GETZ Pharma (Reg no. 086976)
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Source of pellets and all requisite documents. In case of imported pellets requisite fee is required. • Reference of finished product specifications.
	Decision: Registration Board decided to reject the application since the firm has not submitted stability study data of 3 batches of the drug product before the lapse of agreed deadline decided by DRAP Authority i.e. till 31st December 2022.	
922.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Orfenamol Tablet
	Composition	Each Film coated tablet contains: Orphenadrine….35mg Paracetamol…..450mg
	Diary No. Date of R & I & fee	Dy.No. 16906 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0321950 dated 07.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Antipyretic & Analgesic / Muscle relaxant
	Type of Form	Form-5

	Finished product Specification	
	Pack size & Demanded Price	100's pack. As per SRO.
	Approval status of product in Reference Regulatory Authorities	NORGESIC (paracetamol Orphenadrine citrate) uncoated tablets, TGA approved.
	Me-too status	Nuberol tablet 450mg+35mg, Searle Pakistan Ltd, Reg. No. 020373.
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Clarification of salt form of orphenadrine, since the reference product contains orphenadrine citrate while the applied product contains orphenadrine. • Applied formulation is film coated tablet while the reference product approved in TGA Australia is uncoated tablet. • Reference of finished product specifications.
	Decision: Approved with Innovator's specification and following label claim: **Each Tablet Contains:** **Paracetamol…450mg** **Orphendrine Citrate…35mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
923.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Teverin 80mg Tablet
	Composition	Each tablet contains: Drotaverine…..80mg
	Diary No. Date of R & I & fee	Dy.No. 16899 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0777684 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Drugs for functional gastrointestinal disorders
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	20's pack. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Relispa Forte 80mg Tablet (Reg.no.039263) of M/s. The Searle Company Limited, Karachi.
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier, however the applied formulation is not present in any monograph. • Applied formulation is different from the reference product with reference to the salt form of drotaverine. • RRA status of applied formulation could not be confirmed.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	

924.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Matic Injection
	Composition	Each 3ml ampoule contains: Diclofenac sodium…..75mg
	Diary No. Date of R & I & fee	Dy.No. 16890 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0705995 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	NSAIDs
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Econac 75mg/3ml Solution for Injection MHRA Approved
	Me-too status	Difisal 75mg/3ml Injection by M/s Iqra Pharmaceuticals (Reg no. 097721)
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier, however the applied formulation is present in USP monograph. • Firm has not provided section approval letter of injectable section. •
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Liquid Injectable ampoule section" from CLB. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
925.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Libnax 0.25mg Tablet
	Composition	Each Tablet contains: Alprazolam…..0.25mg
	Diary No. Date of R & I & fee	Dy.No. 16908 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0705995 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Sedative and Hypnotic (Tranquilizer)
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	USFDA
	Me-too status	ALP 0.25mg Tablet of M/s. Hilton Pharma (Pvt.) Ltd. Karachi (Reg no. 015322)
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier, however the applied formulation is present in USP monograph. • Firm has not provided section approval letter of Psychotropic tablet section. •

	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Tablet (Psychotropic) section" from CLB. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
926.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Libnax 0.5mg Tablet
	Composition	Each Tablet contains: Alprazolam…..0.5mg
	Diary No. Date of R & I & fee	Dy.No. 16909 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0705995 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Sedative and Hypnotic (Tranquilizer)
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	USFDA
	Me-too status	ALP 0.5mg Tablet of M/s. Hilton Pharma (Pvt.) Ltd. Karachi (Reg no. 015045)
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier, however the applied formulation is present in USP monograph.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Tablet (Psychotropic) section" from CLB. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
927.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Libnax 1mg Tablet
	Composition	Each Tablet contains: Alprazolam…..1mg
	Diary No. Date of R & I & fee	Dy.No. 16910 dated 07-03-2019; Fee Rs.20,000 paid vide slip No. 0705995 dated 06.03.2019, endorsed on 07.03.2019
	Pharmacological Group	Sedative and Hypnotic (Tranquilizer)
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	USFDA
	Me-too status	ALP 1mg Tablet of M/s. Hilton Pharma (Pvt.) Ltd. Karachi (Reg no. 015046)
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier, however the applied formulation is present in USP monograph.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Tablet (Psychotropic) section" from CLB.	

	The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
928.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Temifen Injection 80mg/ml
	Composition	Each 1ml Ampoule Contains: Artemether…80mg
	Diary No. Date of R & I & fee	Dy.No 16894 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed in any RRA However its monograph is available in Ph. Int. and is also available in NEML
	Me-too status	Artem 80mg Injection of M/s. Hilton Pharma (Pvt.) Ltd., Karachi (Reg.no.015529)
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier, however the applied formulation is present in Intl. Pharmacopeia monograph. • Firm has not provided section approval letter of Injectable section. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
929.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Dexfen 400mg Tablet
	Composition	Each Tablet Contains: Dexibuprofen….400mg
	Diary No. Date of R & I & fee	Dy.No 16916 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Dexibuprofen 400 mg film-coated tablets MHRA Approved
	Me-too status	Tercica 400mg Tablet of M/s. Sami Pharmaceuticals (Pvt.) Ltd., Karachi (Reg.no.058446)
	GMP status	Follow-up inspection report dated 12-08-2020 with the

		remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier, however the applied formulation is not present in any Pharmacopeia. • Firm did not mentioned the coating details of tablet while the reference product is film coated tablet.
	Decision: Aprroved with Innovator's specification and with the following label claim: **Each Film Coated Tablet Contains:** **Dexibuprofen…400mg** • **Firm shall submit 7,500/- fee for pre-registration variation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
930.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Dexfen 300mg Tablet
	Composition	Each Tablet Contains: Dexibuprofen….300mg
	Diary No. Date of R & I & fee	Dy.No 16915 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Dexibuprofen 300 mg film-coated tablets MHRA Approved
	Me-too status	Tercica 300mg Tablet of M/s. Sami Pharmaceuticals (Pvt.) Ltd., Karachi (Reg.no.058445)
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier, however the applied formulation is not present in any Pharmacopeia. • Firm did not mentioned the coating details of tablet while the reference product is film coated tablet.
	Decision: Aprroved with Innovator's specification and with the following label claim: **Each Film Coated Tablet Contains:** **Dexibuprofen…300mg** • **Firm shall submit 7,500/- fee for pre-registration variation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
931.	**Deleted due to duplication of application at Sr. no. 930**	
932.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Dexfen 100mg/5ml Suspension
	Composition	Each 5ml Contains: Dexibuprofen….100mg
	Diary No. Date of R & I & fee	Dy.No 16914 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed

	Me-too status	Dexibu Suspension of M/s. Hiranis Pharmaceuticals Pvt. Ltd., Karachi (Reg.no. 067131)
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier, however the applied formulation is not present in any Pharmacopeia. • Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
933.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Teverin 40mg Tablet
	Composition	Each tablet contains: Drotaverine…..40mg
	Diary No. Date of R & I & fee	Dy.No 16898 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Drugs for functional gastrointestinal disorders
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	20's pack. As per SRO.
	Approval status of product in Reference Regulatory Authorities	Approved in three EMA states as un-coated tablets in Hungary (both coated and uncoated), Romania & Solvakia (both coated and uncoated).
	Me-too status	Spasmostar Tablets of M/s. Star Laboratories, Lahore Reg. No. 78711
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier, however the applied formulation is not present in any monograph. • Applied formulation is different from the reference product with reference to the salt form of drotaverine. Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Tablet Contains: Drotaverine HCL…40mg
	Decision: Approved with innovator's specification and with the following label claim: **Each Tablet Contains:** **Drotaverine HCL…40mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
934.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Libastin 10mg Tablet
	Composition	Each Film Coated Tablet Contains:

		Ebastine…10mg
	Diary No. Date of R & I & fee	Dy.No 16902 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Histamine H1 receptor antagonist
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	EBASTINE ARROW 10 mg film-coated tablets ANSM Approved
	Me-too status	Atmos Tablets 10mg of Scotmann Pharma (Reg# 056116)
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier, however the applied formulation is not present in any monograph. • Firm did not mentioned the coating details of tablet while the reference product is film coated tablet.
	Decision: Approved with JP specifications and with the following label claim: **Each Film Coated Tablet Contains:** **Ebastine…10mg** • **Firm shall submit 7,500/- fee for pre-registration variation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
935.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Libastin 5mg/5ml Liquid
	Composition	Each 5ml Contains: Ebastine…5mg
	Diary No. Date of R & I & fee	Dy.No 16903 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Histamine H_1-receptor antagonist, Anti allergic agent
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	USFDA Approved.
	Me-too status	Kestine 5mg/5ml oral liquid by M/s Highnoon Laboratories Ltd, Reg. No. 028369
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier, however the applied formulation is not present in any monograph. • Section approval letter of oral liquid section required.
	• **Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Oral Liquid section" from CLB.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
936.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Haemofer Injection

	Composition	Each 5ml Ampoule Contains: Iron Sucrose Eq. To Elemental Iron…100mg
	Diary No. Date of R & I & fee	Dy.No 16893 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Iron preparations
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	5ml ampoule; As per SRO
	Approval status of product in Reference Regulatory Authorities	VENOFER iron 100mg/5mL (as iron (III) hydroxide sucrose complex) injection ampoule. TGA approved
	Me-too status	Hemofer Injection IV (Reg.no. 030955) of M/s. Barrett & Hodgson Pakistan.
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier, however the applied formulation is not present in any monograph. • Section approval letter of injectable section.
	Decision: Deferred for submission of following: • **Submit finished product specification of applied formulation.** • **Section approval letter of Injectable section issued by Licensing Division.** • **Evidence of availability of atomic absorption spectrophotometer as required by the USP monograph of applied formulation.**	
937.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Lidocaine Injection 20mg
	Composition	Each 2ml Ampoule Contains: Lidocaine Hcl…20mg
	Diary No. Date of R & I & fee	Dy.No 16892 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anaesthetic
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	2ml ampoule; As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved (Lidocaine 2 % with preservative Injection, Lidocaine 2% w/v solution for injection
	Me-too status	Adcaine Injection (Each 1ml injection contains Lidocaine HCl….20mg) of M/s Ameer & Adnan pharmaceuticals, Lahore. Registration No. 078638
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Applied formulation is different from the reference formulation in terms of quantity of lidocaine HCl. Applied formulation contain lidocaine HCl 20mg in 2ml while the reference product contains Lidocaine HCl 20mg in 1ml. • Firm did not mention the finished product specification in the submitted dossier, however the applied formulation is not present in any monograph. • Section approval letter of injectable section.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	

	The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
938.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Orfenamol 35 Tablet
	Composition	Each Film Coated Tablet Contains: Orphenadrine…35mg
	Diary No. Date of R & I & fee	Dy.No 16892 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antimuscuranic agent
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Heligesic Tablet 35mg of M/s. Helicon Pharmaceutek, Pakistan (Reg.no. 030278)
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier, however the applied formulation is not present in any Pharmacopeia. • Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
939.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Alcobal 500mcg Tablet
	Composition	Each Tablet Contains: Mecobalamin…500mcg
	Diary No. Date of R & I & fee	Dy.No 16884 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Vitamin B12 (cyanocobalamin and analogues)
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	PMDA approved.
	Me-too status	Methycobal Tablet 500mcg (Reg.no. 010134) of M/s. Hilton Pharma (Pvt.) Ltd., Karachi
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier, however the applied formulation is not present in any Pharmacopeia.

		• Reference product is sugar coated while applied product is simple uncoated tablet.
	Decision: Approved with JP specifications and with following label claim: **Each Sugar Coated Tablet Contains:** **Mecobalamin…500mcg** • **Firm shall submit 7,500/- fee for revision of formulation from film coated tablet to sugar coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
940.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Zavad Gel
	Composition	Each applicator full of vaginal gel (5g) Contains: Metronidazole…..37.5mg
	Diary No. Date of R & I & fee	Dy.No 16887 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Provide proof of approval of me-too product (name registration number and name of company) with same composition same strength and same salt form(s) by DRAP. • Firm did not mention the finished product specification in the submitted dossier, however the applied formulation is not present in any Pharmacopeia.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board.	
941.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Enr G 200mg Tablet
	Composition	Each Tablet Contains: Sulbutiamine…200mg
	Diary No. Date of R & I & fee	Dy.No 16886 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Vitamin B1, unassociated – ATC code: A11DA02
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ANSM France (coated tablet ARCALION 200 mg, coated tablet
	Me-too status	Buten Tablet Sugar Coated of M/s. Standpharm Pakistan Pvt. Ltd. Lahore (Reg.no. 049941)

	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier. • Reference product is sugar coated while applied product is simple uncoated tablet.
	Decision: Approved with innovator's specifications and with the following label claim: **Each Sugar Coated Tablet Contains:** **Sulbutiamine…200mg** **Firm shall submit 7,500/- fee for pre-registration variation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
942.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Doxet 30mg Capsule
	Composition	Each Capsule Contains: Duloxetine…30mg
	Diary No. Date of R & I & fee	Dy.No 16883 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Serotonin and noradrenaline reuptake inhibitor
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cymbalta Capsules by Lilly (USFDA Approved)
	Me-too status	Lyta 30mg Capsules by GETZ Pharmaceuticals (Reg. # 066917)
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier. • Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets). • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Capsule Contains: • Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine…30mg
	Decision: Deferred for the submission of following: • **Revision of label claim as per the innovator product as per following:** **Each Capsule Contains:** **Duloxetine HCl Enteric Coated Pellets Eq. To Duloxetine…30mg** • **Submission of fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.** • **Submit details of source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets).** • **Submit finished product specification of applied product.**	
943.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Lanzopin 5mg Tablets
	Composition	Each Film coated tablet contains:

		Olanzapine…..5mg
	Diary No. Date of R & I & fee	Dy.No 16911 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	10's pack. As per SRO.
	Approval status of product in Reference Regulatory Authorities	USFDA Approved (Zyprexa Tablet 5mg)
	Me-too status	Psyclan Tablet 5mg of M/s. PharmEvo Pvt. Ltd., Karachi Reg.no. 029169
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Reference of finished product specifications.
	Decision: Approved with USP specifications. • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021**	
944.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Gravion 50mg/ml
	Composition	Each 1ml ampoule contains: Dimenhydrinate…..50mg
	Diary No. Date of R & I & fee	Dy.No 16888 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antiemetic
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Dimenhydrinate Injection of Fresenius Kabi, USFDA Approved.
	Me-too status	Corinate 50mg/ml Inj. of Asian continental (Reg. no. 057863)
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier. • Evidence of approval letter of injectable section from CLB.
	• **Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Liquid Injectable ampoule section" from CLB.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
945.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Omic-d Tablet
	Composition	Each Film Coated Tablet Contains: Ossein Mineral Complex…830mg Vitamin D…400IU
	Diary No. Date of R & I & fee	Dy.No 16885 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Minerals / Vitamin

	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Osam-D registered in the name of M/s. Getz Pharma, Karachi (Reg.no.061106).
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier. • Evidence of presence of Atomic Absorption Spectrophotometer verified by FID. • Provide complete composition of Ossein mineral complex as same has not provided in the submitted dossier.
	Decision: Deferred for the submission of following: • **Reference of finished product specification.** • **Submit evidence of presence of Atomic Absorption Spectrophotometer verified by FID.** • **Submit complete composition of Ossein mineral complex.**	
946.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Paroxit CR 25mg
	Composition	Each Controlled Release Tablet Contains: Paroxetine HCl…25mg
	Diary No. Date of R & I & fee	Dy.No 16924 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Selective serotonin-reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	PAXIL CR of (USFDA approved)
	Me-too status	Panox CR Tablet 25 mg M/s Regal Pharmaceuticals, (Reg.no.081954)
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each enteric, film coated, controlled release tablet contains: • Paroxetine (as HCl)….25mg
	Decision: Approved with USP specification and with the following label claim: **Each enteric, film coated, controlled release tablet contains:** **Paroxetine (as HCl) …25mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	

947.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Paroxit CR 12.5mg
	Composition	Each Controlled Release Tablet Contains: Paroxetine HCl…12.5mg
	Diary No. Date of R & I & fee	Dy.No 16923 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Selective serotonin-reuptake inhibitors
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	PAXIL CR of (USFDA approved)
	Me-too status	Panox CR Tablet 12.5 mg M/s Regal Pharmaceuticals, (Reg.no.081953)
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each enteric, film coated, controlled release tablet contains: • Paroxetine (as HCl)….25mg
	Decision: Approved with USP specification and with the following label claim: **Each enteric, film coated, controlled release tablet contains:** **Paroxetine (as HCl) …12.5mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
948.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Gabalim 75mg Capsule
	Composition	Each Capsule Contains: Pregabalin…75mg
	Diary No. Date of R & I & fee	Dy.No 16917 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lyrica of (USFDA approved)
	Me-too status	Gabica Capsule by M/s Getz Pharma (Reg.no.047365)
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier. • Evidence of approval of capsule section by CLB is required.
	Decision: Approved with BP Specifications.	

	The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
949.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Gabalim 300mg Capsule
	Composition	Each Capsule Contains: Pregabalin…300mg
	Diary No. Date of R & I & fee	Dy.No 16919 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lyrica of (USFDA approved)
	Me-too status	Gabica Capsule by M/s Getz Pharma (Reg.no.047368)
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier. • Evidence of approval of capsule section by CLB is required.
	Decision: Approved with BP Specifications. **The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
950.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Goban Capsule
	Composition	Each Capsule Contains: Ferrous Gluconate…250mg Manganese Sulfate Monohydrate...0.2mg Copper Sulfate…0.2mg Vitamin C…50mg Folic Acid…1mg Vitamin B12…7.5mg
	Diary No. Date of R & I & fee	Dy.No 16882 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Vitamin –Mineral Formulation
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Could not be confirmed
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier. • Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.

		• Provide proof of approval of me-too product (name registration number and name of company) with same composition same strength and same salt form(s) by DRAP.
	Decision:Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board.	
951.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Libion Injection
	Composition	Each 3ml Ampoule Contains: Thiamine…100mg Pyridoxine…100mg Cyanocobalamin…1000mcg
	Diary No. Date of R & I & fee	Dy.No 16891 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Vitamin Formulation
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Neurobion solution for Injection 3ml by M/s Merck Selbstmedikation GmbH (Germany Approved)
	Me-too status	Neurolina Injection 3ml by M/s Alina Combine (Reg.no.076143)
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier. • Provide evidence of approval of liquid injectable section by CLB.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Liquid Injectable ampoule section" from CLB. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
952.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Proxil 300mg Tablet
	Composition	Each Tablet Contains: Proglumetacin…300mg
	Diary No. Date of R & I & fee	Dy.No 16926 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Non-steroidal anti-inflammatory and anti-rheumatic
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.

	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier. • Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Provide proof of approval of me-too product (name registration number and name of company) with same composition same strength and same salt form(s) by DRAP.
	Decision:Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board.	
953.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Proxil 150mg Capsule
	Composition	Each Capsule Contains: Proglumetacin…150mg
	Diary No. Date of R & I & fee	Dy.No 16925 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Non-steroidal anti-inflammatory and anti-rheumatic
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Loglu Capsule 150mg of M/s. Lisko Pharma (Reg.no. 061800)
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier. • Provide evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision:Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board.	
954.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Quepin 100mg Tablet
	Composition	Each Tablet Contains: Quetiapine…100mg
	Diary No. Date of R & I & fee	Dy.No 16905 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Neuroleptic/dopamine receptor antagonist/antipsychotic
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Quetiapine film coated tablet (25mg,50mg 100mg, 200mg, 300mg, 400mg) by M/s Astrazeneca Pharms, USFDA Approved.

	Me-too status	Qusel Tablet 100mg (25mg, 100mg, 200mg) by M/s Hilton pharma, Reg No. 037685
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier. • Revise your formulation as per reference product i.e. Quetiapine fumarate and the label claim to film coated tablet along with submission of requisite fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Quetiapine as Fumarate…100mg
	Decision: Approved with USP specification and with the following label claim: **Each Film Coated Tablet Contains:** **Quetiapine (as fumarate) …. 100mg** • **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
955.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Quepin 25mg Tablet
	Composition	Each Tablet Contains: Quetiapine…25mg
	Diary No. Date of R & I & fee	Dy.No 16904 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Neuroleptic/dopamine receptor antagonist/antipsychotic
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Quetiapine film coated tablet (25mg,50mg 100mg, 200mg, 300mg, 400mg) by M/s Astrazeneca Pharms, USFDA Approved.
	Me-too status	Qusel Tablet 25mg (25mg, 100mg, 200mg) by M/s Hilton pharma, Reg No. 037684
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier. • Revise your formulation as per reference product i.e. Quetiapine fumarate and the label claim to film coated tablet along with submission of requisite fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Quetiapine as Fumarate…25mg
	Decision: Approved with USP specification and with the following label claim: **Each Film Coated Tablet Contains:** **Quetiapine (as fumarate) …. 100mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
956.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Water for Injection

	Composition	Each Ampoule Contains: Sterile Water…5ml
	Diary No. Date of R & I & fee	Dy.No 16895 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Water for injection
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Water for injection 5ml of M/s. Shaigan Pharmaceuticals (Reg.no. 035535)
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier. • Evidence of approval of liquid injectable section by CLB.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Liquid Injectable ampoule section" from CLB. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
957.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Topiramate 100mg Tablet
	Composition	Each Tablet Contains: Topiramate…100mg
	Diary No. Date of R & I & fee	Dy.No 16922 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antiepileptics
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Topiramate Aristo 100mg tablets MHRA Approved
	Me-too status	Neutop 100mg tablets by M/s Nabiqasim Industries (Reg#089056)
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier. • Revise your label claim to film coated tablet along with submission of 7,500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Topiramate …100mg
	Decision: Approved with USP specification and with the following label claim: **Each Film Coated Tablet Contains:** **Topiramate…100mg** • **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	

958.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Topiramate 50mg Tablet
	Composition	Each Tablet Contains: Topiramate…50mg
	Diary No. Date of R & I & fee	Dy.No 16921 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antiepileptics
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Topamax of (USFDA Approved)
	Me-too status	Lowseiz 50mg Tablets of M/S Helix Pharma
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier. • Revise your label claim to film coated tablet along with submission of 7,500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Topiramate …50mg
	Decision: Approved with USP specification and with the following label claim: **Each Film Coated Tablet Contains:** **Topiramate…50mg** **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
959.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Topiramate 25mg Tablet
	Composition	Each Tablet Contains: Topiramate…25mg
	Diary No. Date of R & I & fee	Dy.No 16920 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antiepileptics
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Topamax of (USFDA Approved)
	Me-too status	Lowseiz 25mg Tablets of M/S Helix Pharma
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier. • Revise your label claim to film coated tablet along with submission of 7,500 fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Topiramate …25mg
	Decision: Approved with USP specification and with the following label claim: **Each Film Coated Tablet Contains:**	

	Topiramate…25mg **Firm shall submit 7,500/- fee for revision of formulation from uncoated tablet to film coated tablet as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
960.	Name and address of manufacturer/ Applicant	M/s. Libra Pharmaceuticals Hayatabad Industrial Estate, Peshawar
	Brand Name + Dosage Form + Strength	Relieve Injection 100mg/2ml
	Composition	Each 2ml Ampoule Contains: Tramadol …100mg
	Diary No. Date of R & I & fee	Dy.No 16889 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Opioid Analgesic
	Type of Form	Form-5
	Finished product Specification	…
	Pack size & Demanded Price	2ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Tramadol hydrochloride 50mg/ml solution for Injection MHRA Approved
	Me-too status	Amadrol Injection 100mg/ 2 ml by M/s Amarant Pharmaceuticals (Reg#83042)
	GMP status	Follow-up inspection report dated 12-08-2020 with the remarks of compliant.
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier. • Revise the applied formulation as per reference product, since you have mentioned only tramadol without the hydrochloride salt factor. Revise your formulation and label as per the innovator's product along with requisite fee. • Approval of Small volume ampoule parenteral section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Liquid Injectable ampoule section" from CLB. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
961.	Name and address of manufacturer/ Applicant	M/s Innvotek Pharmaceuticals.35-Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Daspine 5/40 mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine Besylate Eq. To Amlodipine…5mg Atorvastatin Calcium Hydrate Eq. To Atorvastatin…40mg
	Diary No. Date of R & I & fee	Dy.No 16440 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	HMG CoA reductase inhibitors, other combinations
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	CADUET® (amlodipine besylate and atorvastatin calcium) tablets, film-coated (5mg/10mg, 5mg/20mg, 5mg/40mg, 5mg/80mg; 10mg/10mg, 10mg/20mg, 10mg/40mg,

		10mg/80mg; 2.5mg/10mg, 2.5mg/20mg, 2.5mg/40mg). USFDA Approved
	Me-too status	Co-Atorap 10/40 Tablet. Reg. No. 050589 (does not reveal film-coating)
	GMP status	GMP Certificate issued dated 11th January,2021 vide certificate no. F.3-64/2021-Addl.Dit. (QA&LT-I).
	Remarks of the Evaluator	• Firm claimed manufacturer's specification while the official monograph of applied formulation is present in USP.
	Decision: Approved with USP Specifications. **The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
962.	Name and address of manufacturer/ Applicant	M/s Innvotek Pharmaceuticals.35-Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Asez-E 10/10 mg Tablet
	Composition	Each Film Coated Tablet Contains: Atorvastatin as Calcium…10mg Ezetimibe…10mg
	Diary No. Date of R & I & fee	Dy.No 16442 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Cholesterol absorption inhibitors/ HMG-CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Liptruzet Tablet (10/10,20/10,40/10,80/10) of USFDA approved
	Me-too status	Atozet 10/10 Tablet of M/s Hilton Pharma (Pvt.)Limited 055148
	GMP status	GMP Certificate issued dated 11th January,2021 vide certificate no. F.3-64/2021-Addl.Dit. (QA&LT-I).
	Remarks of the Evaluator	
	Decision: Approved	
963.	Name and address of manufacturer/ Applicant	M/s Innvotek Pharmaceuticals.35-Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Asez-E 40/10 mg Tablet
	Composition	Each Film Coated Tablet Contains: Atorvastatin as Calcium…40mg Ezetimibe…10mg
	Diary No. Date of R & I & fee	Dy.No 16444 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Cholesterol absorption inhibitors/ HMG-CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Liptruzet Tablet (10/10,20/10,40/10,80/10) of USFDA approved
	Me-too status	Atozet 10/40 Tablet of M/s Hilton Pharma (Pvt.)Limited 061217
	GMP status	GMP Certificate issued dated 11th January,2021 vide certificate no. F.3-64/2021-Addl.Dit. (QA&LT-I).

	Remarks of the Evaluator	
	Decision: Approved	
964.	Name and address of manufacturer/ Applicant	M/s Innvotek Pharmaceuticals.35-Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Asez-E 80/10 mg Tablet
	Composition	Each Film Coated Tablet Contains: Atorvastatin as Calcium…80mg Ezetimibe…10mg
	Diary No. Date of R & I & fee	Dy.No 16443 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Cholesterol absorption inhibitors/ HMG-CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Liptruzet Tablet (10/10,20/10,40/10,80/10) of USFDA approved
	Me-too status	Could not be confirmed
	GMP status	GMP Certificate issued dated 11th January,2021 vide certificate no. F.3-64/2021-Addl.Dit. (QA&LT-I).
	Remarks of the Evaluator	Provide proof of approval of me-too product (name registration number and name of company) with same composition same strength and same salt form(s) by DRAP.
	Decision: Approved	
965.	Name and address of manufacturer/ Applicant	M/s Innvotek Pharmaceuticals.35-Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Natilol 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Carvedilol…25mg
	Diary No. Date of R & I & fee	Dy.No 16448 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Alpha and beta blocking agents
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Carvedilol 25 mg Film-coated Tablets by Generics [UK] Limited t/a Mylan. MHRA approved
	Me-too status	Carlol 25mg Tablets by Nabiqasim Industries. Reg. No. 39405
	GMP status	GMP Certificate issued dated 11th January,2021 vide certificate no. F.3-64/2021-Addl.Dit. (QA&LT-I).
	Remarks of the Evaluator	
	Decision: Approved	
966.	Name and address of manufacturer/ Applicant	M/s Innvotek Pharmaceuticals.35-Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Natilol 6.25mg Tablet
	Composition	Each Film Coated Tablet Contains: Carvedilol…6.25mg
	Diary No. Date of R & I & fee	Dy.No 16446 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Alpha and beta blocking agents
	Type of Form	Form-5

	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Carvedilol 6.25 mg Film-coated Tablets by Generics [UK] Limited t/a Mylan. MHRA approved
	Me-too status	Carlol 6.25mg Tablets by Nabiqasim Industries. Reg. No. 039707
	GMP status	GMP Certificate issued dated 11th January,2021 vide certificate no. F.3-64/2021-Addl.Dit. (QA&LT-I).
	Remarks of the Evaluator	
	Decision: Approved	
967.	Name and address of manufacturer/ Applicant	M/s Innvotek Pharmaceuticals.35-Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Natilol 12.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Carvedilol…12.5mg
	Diary No. Date of R & I & fee	Dy.No 16447 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Alpha and beta blocking agents
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Carvedilol 12.5 mg Film-coated Tablets by Generics [UK] Limited t/a Mylan. MHRA approved
	Me-too status	Carlol 12.5mg Tablets by Nabiqasim Industries. Reg. No. 39708
	GMP status	GMP Certificate issued dated 11th January,2021 vide certificate no. F.3-64/2021-Addl.Dit. (QA&LT-I).
	Remarks of the Evaluator	
	Decision: Approved	
968.	Name and address of manufacturer/ Applicant	M/s Innvotek Pharmaceuticals.35-Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Rostek 40mg Tablet
	Composition	Each Film Coated Tablet Contains: Rosuvastatin Calcium Eq. To Rosuvastatin…40mg
	Diary No. Date of R & I & fee	Dy.No 16441 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	HMG-CoA reductase inhibitor
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Crestor 40mg film-coated tablets. MHRA approved
	Me-too status	Crestat Tablet 40mg. Reg. No. 042692 of M/s. CCL Pharmaceuticals, Lahore.
	GMP status	GMP Certificate issued dated 11th January,2021 vide certificate no. F.3-64/2021-Addl.Dit. (QA&LT-I).
	Remarks of the Evaluator	Firm claimed Manufacturer's Specification while the official monograph of applied formulation is present in USP/BP Pharmacoepia.
	Decision: Approved with USP Specifications. **The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	

969.	Name and address of manufacturer/ Applicant	M/s Innvotek Pharmaceuticals.35-Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Rostek 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Rosuvastatin Calcium Eq. To Rosuvastatin…5mg
	Diary No. Date of R & I & fee	Dy.No 16445 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	HMG-CoA reductase inhibitor
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Crestor 5mg film-coated tablets. MHRA approved
	Me-too status	Rovista Tablet 5mg of M/s. Getz Pharma, Karachi, (Reg.no.044043)
	GMP status	GMP Certificate issued dated 11th January,2021 vide certificate no. F.3-64/2021-Addl.Dit. (QA&LT-I).
	Remarks of the Evaluator	Firm claimed Manufacturer's Specification while the official monograph of applied formulation is present in USP/BP Pharmacopeia.
	Decision: Approved with USP Specifications. **The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
970.	Name and address of manufacturer/ Applicant	M/s Innvotek Pharmaceuticals.35-Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Esipram 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Escitalopram Oxalate Eq. To Escitalopram…20mg
	Diary No. Date of R & I & fee	Dy.No 16439 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anti- depressant
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Escital Tablet Helix Pharma (Pvt.) Ltd; Reg.no. 061635
	GMP status	GMP Certificate issued dated 11th January,2021 vide certificate no. F.3-64/2021-Addl.Dit. (QA&LT-I).
	Remarks of the Evaluator	Firm claimed Manufacturer's Specification while the official monograph of applied formulation is present in USP/BP Pharmacopeia.
	Decision: Approved with USP Specifications. **The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
971.	Name and address of manufacturer/ Applicant	M/s. Hamaz Pharmaceuticals (Pvt.) Ltd. 13 KM, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form + Strength	Phonac Capsule 100mg SR
	Composition	Each Capsule Contains: Diclofenac Sodium…100mg
	Diary No. Date of R & I & fee	Dy.No 15723 dated 07-03-2019 Rs.20,000/- dated 07-03-

		2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	….
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	DICLOMAX RETARD® (Diclofenac Sodium) 100mg Capsules MHRA APPROVED. Manufacturers: Almac Pharma Services Limited Almac House 20, Seagoe Industrial Estate, Craigavon, BT63, 5QD, UK Mipharm SpA Via Bernardo Quaranta, 12 20141-Milan, Italy.
	Me-too status	Visodic SR 100mg Capsules Vision Pharmaceuticals (Pvt.) Ltd. (Reg.# 078171)
	GMP status	GMP certificate issued to Hamaz pharmaceuticals on dated 25-05-2021 based on inspection conducted on 13-04-2021. Further, firm submitted the panel inspection report conducted for grant of renewal of DML dated 21-02-2022,22-02-2022 and 04-08-2022 concluded with the remarks that the panel is of the opinion to recommend the renewal of M/s. Hamaz Pharmaceuticals Pvt. Ltd., Multan.
	Remarks of the Evaluator	• Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets). • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Capsule Contains: Diclofenac sodium (as SR pellets) …100mg • Firm did not mention the finished product specification the submitted dossier.
	Decision: Deferred for the submission of following: • **Submit details about source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets).** • **Revision of label claim of applied formulation along with submission of full fee as per the innovator's product as per following:** **Each Capsule Contains:** **Diclofenac sodium (as SR pellets) …100mg** • **Reference of finished product specification.**	
972.	Name and address of manufacturer/ Applicant	M/s. Hamaz Pharmaceuticals (Pvt.) Ltd. 13 KM, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form + Strength	Phonac Capsule 50mg SR
	Composition	Each Capsule Contains: Diclofenac Sodium…50mg
	Diary No. Date of R & I & fee	Dy.No 15724 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	….
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Ayanac 50mg SR Capsule
	GMP status	GMP certificate issued to Hamaz pharmaceuticals on dated 25-05-2021 based on inspection conducted on 13-04-2021. Further, firm submitted the panel inspection report conducted for grant of renewal of DML dated 21-02-2022,22-02-2022 and 04-08-2022 concluded with the remarks that the panel is of the opinion to recommend the renewal of M/s. Hamaz Pharmaceuticals Pvt. Ltd., Multan.
	Remarks of the Evaluator	• Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets). • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Firm did not mention the finished product specification in the submitted dossier.
	Decision: Deferred for the submission of following: • **Submit details about source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets).** • **Revision of label claim of applied formulation along with submission of full fee as per the innovator's product as per following:** **Each Capsule Contains:** **Diclofenac sodium (as SR pellets) …50mg** **Reference of finished product specification.**	
973.	Name and address of manufacturer/ Applicant	M/s. Hamaz Pharmaceuticals (Pvt.) Ltd. 13 KM, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form + Strength	Itapro Tablet 50mg
	Composition	Each Film Coated Tablet Contains: Itopride Hcl…50mg
	Diary No. Date of R & I & fee	Dy.No 15717 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antiemetics
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	PMDA Japan Approved
	Me-too status	Ganaton Tablet 50mg by Abbott (Reg.no. 028429)
	GMP status	GMP certificate issued to Hamaz pharmaceuticals on dated 25-05-2021 based on inspection conducted on 13-04-2021
	Remarks of the Evaluator	
	Decision: Approved	
974.	Name and address of manufacturer/ Applicant	M/s. Hamaz Pharmaceuticals (Pvt.) Ltd. 13 KM, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form + Strength	Rifamin Tablet 550mg
	Composition	Each Film Coated Tablet Contains: Rifaximin…550mg
	Diary No. Date of R & I & fee	Dy.No 15714 dated 07-03-2019 Rs.20,000/- dated 07-03-2019

	Pharmacological Group	Antibiotics (A07AA11)
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TARGAXAN 550 mg film-coated tablets by M/s Norgine Pharmaceuticals Ltd, MHRA Approved.
	Me-too status	Xifaxa 550mg Tablet by M/s Brookes Pharma, Reg. No. 070438
	GMP status	GMP certificate issued to Hamaz pharmaceuticals on dated 25-05-2021 based on inspection conducted on 13-04-2021. Further, firm submitted the panel inspection report conducted for grant of renewal of DML dated 21-02-2022,22-02-2022 and 04-08-2022 concluded with the remarks that the panel is of the opinion to recommend the renewal of M/s. Hamaz Pharmaceuticals Pvt. Ltd., Multan.
	Remarks of the Evaluator	
	Decision: Approved	
975.	Name and address of manufacturer/ Applicant	M/s. Hamaz Pharmaceuticals (Pvt.) Ltd. 13 KM, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form + Strength	Telfin Tablet 125mg
	Composition	Each Uncoated Tablet Contains: Terbinafine HCl…125mg
	Diary No. Date of R & I & fee	Dy.No 15719 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Terbinafine 125mg Tablets by M/s Dr. Reddy"s Laboratories, MHRA Approved.
	Me-too status	Logirid Tablet 125mg by M/s Lowitt Pharmaceutical, Reg No.80846
	GMP status	GMP certificate issued to Hamaz pharmaceuticals on dated 25-05-2021 based on inspection conducted on 13-04-2021. Further, firm submitted the panel inspection report conducted for grant of renewal of DML dated 21-02-2022,22-02-2022 and 04-08-2022 concluded with the remarks that the panel is of the opinion to recommend the renewal of M/s. Hamaz Pharmaceuticals Pvt. Ltd., Multan.
	Remarks of the Evaluator	
	Decision: Approved	
976.	Name and address of manufacturer/ Applicant	M/s. Hamaz Pharmaceuticals (Pvt.) Ltd. 13 KM, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form + Strength	Telfin Tablet 250mg
	Composition	Each Uncoated Tablet Contains: Terbinafine HCl…250mg
	Diary No. Date of R & I & fee	Dy.No 15720 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Terbinafine 250mg Tablet Genus Pharmaceuticals Limited, MHRA Approved
	Me-too status	Lamisil Tablet by M/s Sandoz (Reg.no.013209)
	GMP status	GMP certificate issued to Hamaz pharmaceuticals on dated 25-05-2021 based on inspection conducted on 13-04-2021. Further, firm submitted the panel inspection report conducted for grant of renewal of DML dated 21-02-2022,22-02-2022 and 04-08-2022 concluded with the remarks that the panel is of the opinion to recommend the renewal of M/s. Hamaz Pharmaceuticals Pvt. Ltd., Multan.
	Remarks of the Evaluator	
	Decision: Approved	
977.	Name and address of manufacturer/ Applicant	M/s. Hamaz Pharmaceuticals (Pvt.) Ltd. 13 KM, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form + Strength	Climycin Cream 20gm
	Composition	Each Gram Contains: Clindamycin As Phosphate…20mg (2%)
	Diary No. Date of R & I & fee	Dy.No 15708 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Clindanor 2 % Cream M/S Nortech Pharmaceuticals, Industrial Traingle, Kahuta Road, Islamabad 077982
	GMP status	GMP certificate issued to Hamaz pharmaceuticals on dated 25-05-2021 based on inspection conducted on 13-04-2021. Further, firm submitted the panel inspection report conducted for grant of renewal of DML dated 21-02-2022,22-02-2022 and 04-08-2022 concluded with the remarks that the panel is of the opinion to recommend the renewal of M/s. Hamaz Pharmaceuticals Pvt. Ltd., Multan.
	Remarks of the Evaluator	Panel inspection report for renewal of DML recommends section in which Ointment/cream/Gel section (General) included.
	Decision: Approved	
978.	Name and address of manufacturer/ Applicant	M/s. Hamaz Pharmaceuticals (Pvt.) Ltd. 13 KM, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form + Strength	Ulsec Tablet 1gm
	Composition	Each Uncoated Tablet Contains: Sucralfate…1gm
	Diary No. Date of R & I & fee	Dy.No 15716 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Cytoprotective agent
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Antepsin 1g uncoated Tablets by M/s Chugai Pharma UK Limited, MHRA Approved.
	Me-too status	Crusate 1gm tablet of M/s High-Q pharmaceuticals, Karachi. Registration No.100496

	GMP status	GMP certificate issued to Hamaz pharmaceuticals on dated 25-05-2021 based on inspection conducted on 13-04-2021. Further, firm submitted the panel inspection report conducted for grant of renewal of DML dated 21-02-2022,22-02-2022 and 04-08-2022 concluded with the remarks that the panel is of the opinion to recommend the renewal of M/s. Hamaz Pharmaceuticals Pvt. Ltd., Multan.
	Remarks of the Evaluator	
	Decision: Approved	
979.	Name and address of manufacturer/ Applicant	M/s. Hamaz Pharmaceuticals (Pvt.) Ltd. 13 KM, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form + Strength	Climycin B Gel 1% w/w +5% w/w
	Composition	Each Gram Contains: Clindamycin Phosphate…1% 10mg Benzoyl Peroxide…5% 50mg
	Diary No. Date of R & I & fee	Dy.No 15710 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Benclin Gel of M/s Elko Org. (Pvt), Ltd. 061908
	GMP status	GMP certificate issued to Hamaz pharmaceuticals on dated 25-05-2021 based on inspection conducted on 13-04-2021. Further, firm submitted the panel inspection report conducted for grant of renewal of DML dated 21-02-2022,22-02-2022 and 04-08-2022 concluded with the remarks that the panel is of the opinion to recommend the renewal of M/s. Hamaz Pharmaceuticals Pvt. Ltd., Multan.
	Remarks of the Evaluator	Panel inspection report for renewal of DML recommends section in which Ointment/cream/Gel section (General) included.
	Decision: Approved	
980.	Name and address of manufacturer/ Applicant	M/s. Hamaz Pharmaceuticals (Pvt.) Ltd. 13 KM, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form + Strength	Aqva Injection 10ml
	Composition	Each Ampoule Contains: Water For Injection…10ml
	Diary No. Date of R & I & fee	Dy.No 15725 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Solvents and diluting agents, incl. irrigating solutions
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Sterile water for injection (1ml, 2ml, 3.2ml, 5ml and 10ml) ampule Glass class I. MHRA approved
	Me-too status	Water for Injection (sterile) 10ml in ampule. Reg. No. 076972
	GMP status	GMP certificate issued to Hamaz pharmaceuticals on dated 25-05-2021 based on inspection conducted on 13-04-2021. Further, firm submitted the panel inspection report conducted for grant of renewal of DML dated 21-02-2022,22-02-2022

		and 04-08-2022 concluded with the remarks that the panel is of the opinion to recommend the renewal of M/s. Hamaz Pharmaceuticals Pvt. Ltd., Multan.
	Remarks of the Evaluator	Panel inspection report for renewal of DML recommends section in which Liquid Injection (Ampoule & vial) (General & Antibiotic) included.
	Decision: Approved	
981.	Name and address of manufacturer/ Applicant	M/s. Hamaz Pharmaceuticals (Pvt.) Ltd. 13 KM, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form + Strength	Tgesic Tablet 100mg
	Composition	Each Extended Release Tablet Contains: Tramadol Hcl…100mg
	Diary No. Date of R & I & fee	Dy.No 15709 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Analgesics, other opioids
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA RYZOLT™ tablet
	Me-too status	Allay SR Tablet of Tabros Karachi (Reg.no. 074962)
	GMP status	GMP certificate issued to Hamaz pharmaceuticals on dated 25-05-2021 based on inspection conducted on 13-04-2021. Further, firm submitted the panel inspection report conducted for grant of renewal of DML dated 21-02-2022,22-02-2022 and 04-08-2022 concluded with the remarks that the panel is of the opinion to recommend the renewal of M/s. Hamaz Pharmaceuticals Pvt. Ltd., Multan
	Remarks of the Evaluator	Submit of master formulation & manufacturing method of applied formulation in line with reference product which is composed of a dual-matrix delivery system with both immediate-release and extended-release characteristics.
	Decision: Deferred for submission of master formulation & manufacturing method of applied formulation in line with reference product which is composed of a dual-matrix delivery system with both immediate-release and extended-release characteristics.	
982.	Name and address of manufacturer/ Applicant	M/s. Hamaz Pharmaceuticals (Pvt.) Ltd. 13 KM, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form + Strength	Muskel 100mg Tablet
	Composition	Each Tablet Contains: Diclofenac Potassium…100mg
	Diary No. Date of R & I & fee	Dy.No 15722 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Analgesics, other opioids
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Declam Tablet 100mg of M/s. Novamed Pharmaceuticals, Lahore (Reg.no. 064842)
	GMP status	GMP certificate issued to Hamaz pharmaceuticals on dated 25-05-2021 based on inspection conducted on 13-04-2021. Further, firm submitted the panel inspection report conducted for grant of renewal of DML dated 21-02-2022,22-02-2022

		and 04-08-2022 concluded with the remarks that the panel is of the opinion to recommend the renewal of M/s. Hamaz Pharmaceuticals Pvt. Ltd., Multan.
	Remarks of the Evaluator	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
983.	Name and address of manufacturer/ Applicant	M/s. Hamaz Pharmaceuticals (Pvt.) Ltd. 13 KM, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form + Strength	Relentus 2mg Tablet
	Composition	Each Tablet Contains: Tizanidine…2mg
	Diary No. Date of R & I & fee	Dy.No 15712 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Skeletal Muscle relaxant
	Type of Form	Form-5
	Finished product Specification	….
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Tizanidine of MHRA approved
	Me-too status	Tandolax 2mg Tablet M/s High-Q Pharmaceuticals
	GMP status	GMP certificate issued to Hamaz pharmaceuticals on dated 25-05-2021 based on inspection conducted on 13-04-2021
	Remarks of the Evaluator	• Firm did not mention the finished product specification in the submitted dossier. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Tablet Contains: Tizanidine Hcl Eq. to Tizanidine…2mg
	Decision: Approved with USP specification and with the following label claim: **Each Tablet Contains:** **Tizanidine Hcl Eq. to Tizanidine…2mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
984.	Name and address of manufacturer/ Applicant	M/s. Hamaz Pharmaceuticals (Pvt.) Ltd. 13 KM, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form + Strength	Epison 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Eprisone HCl…50mg
	Diary No. Date of R & I & fee	Dy.No 15718 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	
	Type of Form	Form-5
	Finished product Specification	
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	

	Me-too status	
	GMP status	GMP certificate issued to Hamaz pharmaceuticals on dated 25-05-2021 based on inspection conducted on 13-04-2021
	Remarks of the Evaluator	Firm submitted the covering letter and fee challan related to product Epison 50mg Tablet (Eprisone HCL 50mg), while the form 5 and the remaining dossier was containing the information of Ondansetron (as HCL Dihydrate)8mg/4ml Injection.
	Decision: Deferred for the submission of complete dossier on Form-5 related to the product/formulation mentioned on fee challan and covering letter along with full fee of registration.	
985.	Name and address of manufacturer/ Applicant	M/s. Hamaz Pharmaceuticals (Pvt.) Ltd. 13 KM, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form + Strength	Celexi 200mg Tablet
	Composition	Each Tablet Contains: Celecoxib…200mg
	Diary No. Date of R & I & fee	Dy.No 15713 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	
	Type of Form	Form-5
	Finished product Specification	
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	GMP certificate issued to Hamaz pharmaceuticals on dated 25-05-2021 based on inspection conducted on 13-04-2021
	Remarks of the Evaluator	Firm submitted the covering letter and fee challan related to product Celexi 200mg Tablet (Celecoxib), while the form 5 and the remaining dossier was containing the information of Lorcin Injection (Phloroglucinol hydrate 40mg and Trimethylphloroglucinol 0.04mg/4ml). Clarification is required in this regard.
	Decision: Deferred for the submission of complete dossier on Form-5 related to the product/formulation mentioned on fee challan and covering letter along with full fee of registration.	
986.	Name and address of manufacturer/ Applicant	M/s. Hamaz Pharmaceuticals (Pvt.) Ltd. 13 KM, Bosan Road, Lutfabad, Multan
	Brand Name + Dosage Form + Strength	Gastad 150mg Tablet
	Composition	Each Tablet Contains: Ranitidine…150mg
	Diary No. Date of R & I & fee	Dy.No 15711 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	
	Type of Form	Form-5
	Finished product Specification	
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	GMP certificate issued to Hamaz pharmaceuticals on dated 25-05-2021 based on inspection conducted on 13-04-2021

	Remarks of the Evaluator	Firm submitted the covering letter and fee challan related to product Gastad 150mg Tablet (Ranitidine), while the form 5 and the remaining dossier was containing the information of Lorcin Injection (Phloroglucinol hydrate 40mg and Trimethylphloroglucinol 0.04mg/4ml). Clarification is required in this regard.
	Decision: Deferred till the decision by reference regulatory authorities regarding ranitidine containing medicinal products. Further, Registration Board diected to submit the complete dossier of registration on the requisite Form as per the product mentioned on fee challan and covering letter along with submission of full fee of Registration.	
987.	Name and address of manufacturer/ Applicant	M/s. Fassgen Pharmaceuticals Plot No. 67/1-A,Phase-III, Industrial Estate, Hattar
	Brand Name + Dosage Form + Strength	C Ride 1mg Tablet
	Composition	Each Uncoated Tablet Contains: Cinitapride As Hydrogen Tartrate…1mg
	Diary No. Date of R & I & fee	Dy.No 15908 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Pro-kinetic agent
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cidine 1mg tablets (Spain Approved)
	Me-too status	Cinlite 1mg tablet by M/s PharmEvo (Reg no.090995)
	GMP status	
	Remarks of the Evaluator	Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three yars before issuance of registration letter.	
988.	Name and address of manufacturer/ Applicant	M/s. Fassgen Pharmaceuticals Plot No. 67/1-A,Phase-III, Industrial Estate, Hattar
	Brand Name + Dosage Form + Strength	Ecxob Tablet 60mg
	Composition	Each Film Coated Tablet Contains: Etoricoxib…60mg
	Diary No. Date of R & I & fee	Dy.No 15899 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti-inflammatory and anti-rheumatic products, Nonsteroids
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Etoricoxib 60 mg Film-coated Tablets MHRA Approved.
	Me-too status	Arcoxia 60mg Tablets. By M/s Muller & Phipps Pakistan (Private) Limited, Uzma Court, 1st Floor, Main Clifton Road, Karachi." (Reg.no. 047529)
	GMP status	
	Remarks of the Evaluator	• Reference of finished product specification. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with Innovator's Specifications.	

	The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three yars before issuance of registration letter.	
989.	Name and address of manufacturer/ Applicant	M/s. Fassgen Pharmaceuticals Plot No. 67/1-A,Phase-III, Industrial Estate, Hattar
	Brand Name + Dosage Form + Strength	Fexit 80mg Tablet
	Composition	Each Film Coated Tablet Contains: Febuxostat…80mg
	Diary No. Date of R & I & fee	Dy.No 15897 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Preparations inhibiting uric acid production
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ULORIC (febuxostat) tablets, USFDA Approved with box warning.
	Me-too status	Febuxin 80mg Tablet by M/s AGP Pvt. Ltd. Karachi. (Reg.no. 081105)
	GMP status	
	Remarks of the Evaluator	• Reference of finished product specification. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three yars before issuance of registration letter.	
990.	Name and address of manufacturer/ Applicant	M/s. Fassgen Pharmaceuticals Plot No. 67/1-A,Phase-III, Industrial Estate, Hattar
	Brand Name + Dosage Form + Strength	Fexit 40mg Tablet
	Composition	Each Film Coated Tablet Contains: Febuxostat…40mg
	Diary No. Date of R & I & fee	Dy.No 15896 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Preparations inhibiting uric acid production
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ULORIC (febuxostat) tablets, USFDA Approved with box warning.
	Me-too status	Febuxin 40mg Tablet by M/s AGP Pvt. Ltd. Karachi. (Reg.no. 081104)
	GMP status	
	Remarks of the Evaluator	• Reference of finished product specification. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three yars before issuance of registration letter.	
991.	Name and address of manufacturer/ Applicant	M/s. Fassgen Pharmaceuticals Plot No. 67/1-A,Phase-III, Industrial Estate, Hattar

	Brand Name + Dosage Form + Strength	L Mide 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…100mg
	Diary No. Date of R & I & fee	Dy.No 15903 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	VIMPAT® (lacosamide) film coated tablet, for oral use (50mg, 100mg, 150mg, 200mg). USFDA approved
	Me-too status	Lacomide 100mg Tablet film-coated. Reg. No. 083976
	GMP status	
	Remarks of the Evaluator	• Reference of finished product specification. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three yars before issuance of registration letter.	
992.	Name and address of manufacturer/ Applicant	M/s. Fassgen Pharmaceuticals Plot No. 67/1-A,Phase-III, Industrial Estate, Hattar
	Brand Name + Dosage Form + Strength	L Mide 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Lacosamide…50mg
	Diary No. Date of R & I & fee	Dy.No 15902 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	VIMPAT® (lacosamide) film coated tablet, for oral use (50mg, 100mg, 150mg, 200mg). USFDA approved
	Me-too status	Lalap 50mg tablet. Reg. No. 070470
	GMP status	
	Remarks of the Evaluator	• Reference of finished product specification. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three yars before issuance of registration letter.	
993.	Name and address of manufacturer/ Applicant	M/s. Fassgen Pharmaceuticals Plot No. 67/1-A,Phase-III, Industrial Estate, Hattar
	Brand Name + Dosage Form + Strength	Terizel 2.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Letrozole…2.5mg
	Diary No. Date of R & I & fee	Dy.No 15901 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Aromatase Inhibitor

	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Letrozole Tablets 2.5mg of M/s Hakimsons Overseas Trading 072582
	GMP status	
	Remarks of the Evaluator	Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
994.	Name and address of manufacturer/ Applicant	M/s. Fassgen Pharmaceuticals Plot No. 67/1-A,Phase-III, Industrial Estate, Hattar
	Brand Name + Dosage Form + Strength	Lenzo 600mg Tablet
	Composition	Each Film Coated Tablet Contains: Linezolid…600mg
	Diary No. Date of R & I & fee	Dy.No 15907 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti- infective
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Barizold Tablet 600mg Barrett Hodgson Karachi. 076341
	GMP status	
	Remarks of the Evaluator	Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
995.	Name and address of manufacturer/ Applicant	M/s. Fassgen Pharmaceuticals Plot No. 67/1-A,Phase-III, Industrial Estate, Hattar
	Brand Name + Dosage Form + Strength	Maverin 200mg SR Capsule
	Composition	Each Modified Release Capsule Contains Mebeverine HCl As Extended Release Pellets Eq To Mebeverine…200mg
	Diary No. Date of R & I & fee	Dy.No 15911 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Synthetic anticholinergics, esters with tertiary amino group
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status	Berrin 200 mg Capsules of M/s Focus & Rulz Pharmaceuticals, (Reg#066660)
	GMP status	
	Remarks of the Evaluator	• Reference of finished product specification. • Latest GMP inspection report conducted within a period of last three years.

		• Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets).
	Decision: Deferred for submission of following shortcomings: • **Reference of finished product specification.** • **Latest GMP inspection report conducted within a period of last three years.** • **Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets).**	
996.	Name and address of manufacturer/ Applicant	M/s. Fassgen Pharmaceuticals Plot No. 67/1-A,Phase-III, Industrial Estate, Hattar
	Brand Name + Dosage Form + Strength	Acidol 325/37.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Paracetamol…325mg Tramadol As HCl…37.5mg
	Diary No. Date of R & I & fee	Dy.No 15904 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Opioids in combination with non-opioid analgesics. N02AJ13
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Tramacet film coated Manufacturer/sponsor: Janssen Ortho Inc. Health Canada Approved
	Me-too status	Radol-P Tablet 325/37.5 mg M/s Regal Pharmaceuticals, Plot # 2-A, Street # S-5, National industrial zone Rawat. Islamabad (Reg.no.081956)
	GMP status	
	Remarks of the Evaluator	Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
997.	Name and address of manufacturer/ Applicant	M/s. Fassgen Pharmaceuticals Plot No. 67/1-A,Phase-III, Industrial Estate, Hattar
	Brand Name + Dosage Form + Strength	Florgen Tablet 80/80mg
	Composition	Each Sugar Coated Tablet Contains: Hydrated Phloroglucinol…80mg Eq. to Anhydrous Phloroglucinol…62.233mg Trimethyl phloroglucinol…80mg
	Diary No. Date of R & I & fee	Dy.No 15900 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Macrolides
	Type of Form	Form-5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	PHLOROGLUCINOL/TRIMETHYLPHLOROGLUCINOL ACINO 62.233 mg / 80 mg, coated tablet by ACINO France SAS. Approved by ANSM
	Me-too status	Despasm Tablet by Irza Pharmaceuticals. Reg. No. 85210
	GMP status	

	Remarks of the Evaluator	• Reference of finished product specification. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three yars before issuance of registration letter.	
998.	Name and address of manufacturer/ Applicant	M/s. Fassgen Pharmaceuticals Plot No. 67/1-A,Phase-III, Industrial Estate, Hattar
	Brand Name + Dosage Form + Strength	Sitfor 50/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin as Phosphate Monohydrate…50mg Metformin Hcl…1000mg
	Diary No. Date of R & I & fee	Dy.No 15890 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form-5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	JANUMET® (sitagliptin and metformin HCl) tablet, 50/1000mg film-coated. USFDA approved
	Me-too status	Neoglip 50/1000mg Tablets. Reg. No. 53100 (does not depict hydrate form).
	GMP status	
	Remarks of the Evaluator	• Reference of finished product specification. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three yars before issuance of registration letter.	
999.	Name and address of manufacturer/ Applicant	M/s. Fassgen Pharmaceuticals Plot No. 67/1-A,Phase-III, Industrial Estate, Hattar
	Brand Name + Dosage Form + Strength	Sitfor 50/500mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin as Phosphate Monohydrate…50mg Metformin Hcl…500mg
	Diary No. Date of R & I & fee	Dy.No 15890 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form-5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	JANUMET® (sitagliptin and metformin HCl) tablet, 50/500mg film-coated. USFDA approved
	Me-too status	Neoglip 50/500mg Tablets. Reg. No. 053099 (does not depict hydrate form).
	GMP status	
	Remarks of the Evaluator	• Reference of finished product specification. • Latest GMP inspection report conducted within a period of

		last three years.
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three yars before issuance of registration letter.	
1000.	Name and address of manufacturer/ Applicant	M/s. Fassgen Pharmaceuticals Plot No. 67/1-A,Phase-III, Industrial Estate, Hattar
	Brand Name + Dosage Form + Strength	Flucin 6/0.4mg Tablet
	Composition	Each Film Coated Tablet Contains: Solifenacin Succinate…6mg Tamsulosin Hcl…0.4mg
	Diary No. Date of R & I & fee	Dy.No 15914 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antimuscarinic/alpha adrenergic blocker
	Type of Form	Form-5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved.
	Me-too status	Tasolin-S tablet by M/s Getz Pharma, Reg. No. 089374
	GMP status	
	Remarks of the Evaluator	• Stability data required as per directions of 278th meeting of registration Board. • Reference of finished product specification. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Registration Board decided to reject the application since the firm has not submitted stability study data of 3 batches of the drug product before the lapse of deadline decided by DRAP Authority i.e. till 31st December 2022.	
1001.	Name and address of manufacturer/ Applicant	M/s. Fassgen Pharmaceuticals Plot No. 67/1-A,Phase-III, Industrial Estate, Hattar
	Brand Name + Dosage Form + Strength	Mezpin 15mg Tablet
	Composition	Each Film Coated Tablet Contains: Mirtazapine…15mg
	Diary No. Date of R & I & fee	Dy.No 15912 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti-depressant
	Type of Form	Form-5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Mirtazapine 15 mg, 30 mg and 45 mg film-coated tablets - PL 28444/0097-9 MHRA Approved.
	Me-too status	Tazemir 15mg Tablet Reg. No. 058172 M/s Lisko Pakistan Karachi.
	GMP status	
	Remarks of the Evaluator	• Reference of finished product specification. • Latest GMP inspection report conducted within a period of last three years.

	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three yars before issuance of registration letter.	
1002.	Name and address of manufacturer/ Applicant	M/s. Fassgen Pharmaceuticals Plot No. 67/1-A,Phase-III, Industrial Estate, Hattar
	Brand Name + Dosage Form + Strength	Mezpin 30mg Tablet
	Composition	Each Film Coated Tablet Contains: Mirtazapine…30mg
	Diary No. Date of R & I & fee	Dy.No 15913 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti-depressant
	Type of Form	Form-5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Mirtazapine 15 mg, 30 mg and 45 mg film-coated tablets - PL 28444/0097-9 MHRA Approved.
	Me-too status	Tazemir 30mg Tablet Reg. No. 058173 M/s Lisko Pakistan Karachi.
	GMP status	
	Remarks of the Evaluator	• Reference of finished product specification. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with USP specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three yars before issuance of registration letter.	
1003.	Name and address of manufacturer/ Applicant	M/s. Fassgen Pharmaceuticals Plot No. 67/1-A,Phase-III, Industrial Estate, Hattar
	Brand Name + Dosage Form + Strength	Flucin 0.5/10mg Tablet
	Composition	Each Film Coated Tablet Contains: Flupentixol As Dihydrochloride…0.5mg Melitracen As Hcl…10mg
	Diary No. Date of R & I & fee	Dy.No 15915 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti-depressant
	Type of Form	Form-5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Deanxit tablet by M/s. Lundbeck Pakistan (Reg.no. 018966)
	GMP status	
	Remarks of the Evaluator	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Reference of finished product specification. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for evidence of approval of applied formulation in reference	

	regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
1004.	Name and address of manufacturer/ Applicant	M/s. Fassgen Pharmaceuticals Plot No. 67/1-A,Phase-III, Industrial Estate, Hattar
	Brand Name + Dosage Form + Strength	Masoride 0.4/0.5mg Capsule
	Composition	Each Capsule Contains Tamsulosin Hcl…0.4mg Dutasteride…0.5mg
	Diary No. Date of R & I & fee	Dy.No 15905 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Drugs Used in Benign Prostatic Hyperplasia
	Type of Form	Form-5
	Finished product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Combodart 0.5 mg / 0.4 mg hard capsules of M/s GSK, (approved by MHRA of UK)
	Me-too status	DUODART of M/s GSK, Karachi (Reg.no. 069515)
	GMP status	
	Remarks of the Evaluator	The product approved in reference country contains Tamsulosin HCl SR pellets and Soft gel capsule of Dutasteride filled in hard gelatin capsule shell. Provide the following information regarding manufacturing of the product. 1. Provide source of Tamsulosin Pellets, GMP certificate of pellet manufacturer, Certificate of analysis, stability study data of 3 batches according to the climatic conditions of zone IV-A and in case of imported pellets submit differential fee as well. 2. Provide source of Dutasteride soft gel capsule. In case of In-house manufacturing of Dutasteride soft gel capsule, provide approval of relevant section/manufacturing facility that is soft gel capsule. Section. In case of imported dutasteride soft gel capsule provide the following along with the submission of differential fee; ➢ GMP certificate of manufacturer of Dutasteride soft gel capsule. ➢ Certificate of analysis. ➢ Attested copy of valid Drug Sale License. ➢ Attested copy of Valid Sole agency agreement /Authority letter ➢ Original Embassy attested COPP ➢ Original Embassy attested GMP certificate of manufacturer ➢ Accelerated stability study data & Long term Stability studies according to Zone IV-A 3. Complete method of manufacturing of tamsulosin and dutasteride soft gel capsule into final dosage form.

		4. Manufacturing facility and equipment for manufacturing. 5. Evidence of capsule in capsule filling machine. 6. Reference of finished product specification. 7. Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for submission of following shortcomings: • **Provide source of Tamsulosin Pellets, GMP certificate of pellet manufacturer, Certificate of analysis, stability study data of 3 batches according to the climatic conditions of zone IV-A and in case of imported pellets submit differential fee as well.** • **Provide source of Dutasteride soft gel capsule. In case of In-house manufacturing of Dutasteride soft gel capsule, provide approval of relevant section/manufacturing facility that is soft gel capsule. Section. In case of imported dutasteride soft gel capsule provide the following along with the submission of differential fee;** ➢ **GMP certificate of manufacturer of Dutasteride soft gel capsule.** ➢ **Certificate of analysis.** ➢ **Attested copy of valid Drug Sale License.** ➢ **Attested copy of Valid Sole agency agreement /Authority letter** ➢ **Original Legalized COPP** ➢ **Original Legalized GMP certificate of manufacturer** ➢ **Accelerated stability study data & Long term Stability studies according to Zone IV-A** • **Complete method of manufacturing of tamsulosin and dutasteride soft gel capsule into final dosage form.** • **Manufacturing facility and equipment for manufacturing.** • **Evidence of capsule in capsule filling machine.** • **Reference of finished product specification.** • **Latest GMP inspection report conducted within a period of last three years.**	
1005.	Name and address of manufacturer/ Applicant	M/s. Fassgen Pharmaceuticals Plot No. 67/1-A,Phase-III, Industrial Estate, Hattar
	Brand Name + Dosage Form + Strength	Terfin 250mg Tablet
	Composition	Each Uncoated Tablet Contains: Terbinafine HCl…250mg
	Diary No. Date of R & I & fee	Dy.No 15910 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Terbinafine 250mg Tablet Genus Pharmaceuticals Limited, MHRA Approved
	Me-too status	Lamisil Tablet by M/s Novartis Pharma, Karachi (Reg.no. 013209)
	GMP status	
	Remarks of the Evaluator	• Latest GMP inspection report conducted within a period of last three years.

	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
1006.	Name and address of manufacturer/ Applicant	M/s. Fassgen Pharmaceuticals Plot No. 67/1-A,Phase-III, Industrial Estate, Hattar
	Brand Name + Dosage Form + Strength	Thiside 4mg Capsule
	Composition	Each Capsule Contains: Thiocolchicoside…4mg
	Diary No. Date of R & I & fee	Dy.No 15898 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MYOPLEGE 4 mg hard capsule of M/s Genevrier SA Laboratories approved by ANSM of France
	Me-too status	Muscodid 4mg Capsule M/s Regal Pharmaceuticals, Rawat (Reg #081968)
	GMP status	
	Remarks of the Evaluator	• Reference of finished product specification. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within last three years before issuance of registration letter.	
1007.	Name and address of manufacturer/ Applicant	M/s. Fassgen Pharmaceuticals Plot No. 67/1-A,Phase-III, Industrial Estate, Hattar
	Brand Name + Dosage Form + Strength	Vilfor 50/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin …50mg Metformin Hcl…1000mg
	Diary No. Date of R & I & fee	Dy.No 15894 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti- diabetic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved as film- coated
	Me-too status	Vildabar PLUS Tablet Barrett Hodgson Karachi. Reg.no.085998
	GMP status	
	Remarks of the Evaluator	• Clarification is required either the applied formulation is the combination of sitagliptin phosphate/Metformin HCl or Vildagliptin/Metformin HCl, since you have mentioned both on Form-5. • Reference of finished product specification. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for the submission of complete dossier on Form-5 in accordance with the product/formulation mentioned on fee challan and covering letter along with full fee of registration.	

1008.	Name and address of manufacturer/ Applicant	M/s. Fassgen Pharmaceuticals Plot No. 67/1-A,Phase-III, Industrial Estate, Hattar
	Brand Name + Dosage Form + Strength	Vilfor 50/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin …50mg Metformin Hcl…850mg
	Diary No. Date of R & I & fee	Dy.No 15893 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti- diabetic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved as film- coated
	Me-too status	Vildabar PLUS Tablet Barrett Hodgson Karachi. Reg.no.085997
	GMP status	
	Remarks of the Evaluator	• Clarification is required either the applied formulation is the combination of sitagliptin phosphate/Metformin HCl or Vildagliptin/Metformin HCl, since you have mentioned both on Form-5. • Reference of finished product specification. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for the submission of complete dossier on Form-5 in accordance with the product/formulation mentioned on fee challan and covering letter along with full fee of registration.	
1009.	Name and address of manufacturer/ Applicant	M/s. Fassgen Pharmaceuticals Plot No. 67/1-A,Phase-III, Industrial Estate, Hattar
	Brand Name + Dosage Form + Strength	Lexocam 8mg Tablet
	Composition	Each Film Coated Tablet Contains: Lornoxicam…8mg
	Diary No. Date of R & I & fee	Dy.No 15895 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti- inflammatory and Anti- rheumatic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo 8 mg Film tabletten by M/s Takeda Pharma AG,(Swiss Medic Approved)
	Me-too status	Lornox 8mg tablet of M/s Ray Pharma (Reg. # 061083)
	GMP status	
	Remarks of the Evaluator	• Reference of finished product specification. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with Innovator's specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021 along with latest GMP inspection report conducted within last three yars before issuance of registration letter.	

1010.	Name and address of manufacturer/ Applicant	M/s.Baxter Pharmaceuticals.A-1/A, Scheme No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Baxnovate N Cream 0.1%/0.5%
	Composition	Each Gram Contains: Betamethasone Valerate…0.1% Neomycin Sulphate…0.5%
	Diary No. Date of R & I & fee	Dy.No 14671 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Corticosteroids, potent, combinations with antibiotics
	Type of Form	Form 5
	Finished product Specification	Firm has claimed in house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Betnovate N cream by GSK
	GMP status	
	Remarks of the Evaluator	• Reference of finished product specifications. • Latest GMP inspection report conducted within a period of last three years. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of required manufacturing facility / section approval letter from Licensing Division.
	Decision: Registration Board decided to defer the application till decision of CLB regarding renewal of DML of M/s Baxter Pharmaceuticals A-1/A, Scheem No.33, Phase-1, S.I.T.E,Super Highway, Karachi.	
1011.	Name and address of manufacturer/ Applicant	M/s.Baxter Pharmaceuticals.A-1/A, Scheme No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Cloplet Tablet 75mg
	Composition	Each Tablet Contains: Clopidogrel…75mg
	Diary No. Date of R & I & fee	Dy.No 14672 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antiplatelet/Anticoagulant
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	PLAVIX of USFDA Approved
	Me-too status	Ducati Tablet of M/s NOA Hemis Pharmaceuticals, (Reg.no.058685)
	GMP status	
	Remarks of the Evaluator	• Reference of finished product specifications. • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the innovator's product as under along with submission of full fee of registration: Each Film Coated Tablet Contains: Clopidogrel As Bisulphate…75mg
	Decision: Registration Board decided to defer the application till decision of CLB regarding renewal of DML of M/s Baxter Pharmaceuticals A-1/A, Scheem No.33, Phase-1, S.I.T.E,Super Highway, Karachi.	

1012.	Name and address of manufacturer/ Applicant	M/s.Baxter Pharmaceuticals.A-1/A, Scheme No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Cloplet plus Tablet 75/75mg
	Composition	Each Tablet Contains: Clopidogrel…75mg Aspirin…75mg
	Diary No. Date of R & I & fee	Dy.No 14673 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antithrombotic Agents
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	DuoCover EMA Approved
	Me-too status	075978 CoPlavix Tablets 75/75mg by M/s Sanofi Karachi.
	GMP status	
	Remarks of the Evaluator	• Reference of finished product specifications. • Latest GMP inspection report conducted within a period of last three years. Internationally it is available as bilayer tablet. Whereas, firm has applied for monolayer tablet and combination contains clopidogrel instead of clopidogrel bisulphate. Revision of formulation with submission of requisite fee. Evaluation: EMA Approved Duo Cover is presented as film-coated tablets containing two active substances. Tablets are bilayer clopidogrel and acetylsalicylic acid (ASA). Pharmaceutical Development The objective of the formulation development was to obtain fixed-dose combination tablets, which would be equivalent to therapy consisting of Iscover 75 mg tablets combined with commercially available acetylsalicylic acid tablets. The product has been developed as film-coated bilayer tablets containing two active substances. The aim of a preliminary development was to define the technology to be used for manufacturing tablets containing two active substances. Film-coated tablets were finally selected. The 75 mg clopidogrel granulate corresponds to the already marketed Iscover 75 mg core formula and is granulated according to the existing processing for this product. No modifications have been introduced to the formula, batch size and granulation process of the clopidogrel granulation. Further formulation development was performed on the blend containing acetylsalicylic acid. Various grades of acetylsalicylic acid granulated with maize starch with varying particle size distribution were mixed with additional excipients in order to achieve a homogenized blend. The weight of the acetylsalicylic acid blend varies proportionally in order to achieve the various strengths of the combination. The acetylsalicylic acid granulation blend was optimised for consistent release of acetylsalicylic acid and to produce granulation with good flow and compressibility properties.

	Decision: Registration Board decided to defer the application till decision of CLB regarding renewal of DML of M/s Baxter Pharmaceuticals A-1/A, Scheem No.33, Phase-1, S.I.T.E,Super Highway, Karachi.	
1013.	Name and address of manufacturer/ Applicant	M/s.Baxter Pharmaceuticals.A-1/A, Scheme No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Sposma 40mg Tablet
	Composition	Each Tablet Contains: Drotaverine…40mg
	Diary No. Date of R & I & fee	Dy.No 14674 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Drugs for functional GIT disorders
	Type of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in three EMA states as un-coated tablets in Hungary, Romania & Solvakia
	Me-too status	Paspa Tablets of M/s Pliva Pharma 026881
	GMP status	
	Remarks of the Evaluator	• Reference of finished product specifications. • Latest GMP inspection report conducted within a period of last three years. • Revise your label claim as per the innovator's product as under along with submission of full fee of registration: Each Tablet Contains: Drotaverine HCL…40mg
	Decision: Registration Board decided to defer the application till decision of CLB regarding renewal of DML of M/s Baxter Pharmaceuticals A-1/A, Scheem No.33, Phase-1, S.I.T.E,Super Highway, Karachi.	
1014.	Name and address of manufacturer/ Applicant	M/s.Baxter Pharmaceuticals.A-1/A, Scheme No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Gabin Tablet 100mg
	Composition	Each Tablet Contains: Gabapentin…100mg
	Diary No. Date of R & I & fee	Dy.No 14684 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Gablax 100mg Tablet of M/s. Shrooq Pharmaceuticals(Reg.no 042840).
	GMP status	
	Remarks of the Evaluator	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Registration Board decided to defer the application till decision of CLB regarding renewal of DML of M/s Baxter Pharmaceuticals A-1/A, Scheem No.33, Phase-1, S.I.T.E,Super Highway, Karachi.	

1015.	Name and address of manufacturer/ Applicant	M/s.Baxter Pharmaceuticals.A-1/A, Scheme No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Gabin Tablet 300mg
	Composition	Each Tablet Contains: Gabapentin…300mg
	Diary No. Date of R & I & fee	Dy.No 14685 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved (Gralise FILM COATED Tablet 300mg)
	Me-too status	Gatin 300mg Tablet of M/s Shawan Pharmaceuticals, Rawalpindi (Reg. no. 080826)
	GMP status	
	Remarks of the Evaluator	Revise your label claim as per the innovator's product as under along with submission of fee of pre-registration variation: Each Film coated Tablet Contains: Gabapentin…300mg • Latest GMP inspection report conducted within a period of last three years.
	Decision: Registration Board decided to defer the application till decision of CLB regarding renewal of DML of M/s Baxter Pharmaceuticals A-1/A, Scheem No.33, Phase-1, S.I.T.E,Super Highway, Karachi.	
1016.	Name and address of manufacturer/ Applicant	M/s.Baxter Pharmaceuticals.A-1/A, Scheme No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Canarl Tablet 16mg
	Composition	Each Tablet Contains: Candesartan Cilexetil…16mg
	Diary No. Date of R & I & fee	Dy.No 14815 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Angiotensin II Receptor Antagonist
	Type of Form	Form 5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ATACAND® (candesartan cilexetil) 16 mg non-film-coated tablets, for oral use. US-FDA approved
	Me-too status	Cansart Tablets by CCL Pharma. Reg. No. 33953
	GMP status	
	Remarks of the Evaluator	Latest GMP inspection report conducted within a period of last three years.
	Decision: Registration Board decided to defer the application till decision of CLB regarding renewal of DML of M/s Baxter Pharmaceuticals A-1/A, Scheem No.33, Phase-1, S.I.T.E,Super Highway, Karachi.	
1017.	Name and address of manufacturer/ Applicant	M/s.Baxter Pharmaceuticals.A-1/A, Scheme No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Canarl Tablet 8mg
	Composition	Each Tablet Contains: Candesartan Cilexetil…8mg
	Diary No. Date of R & I & fee	Dy.No 14814 dated 07-03-2019 Rs.20,000/- dated 06-03-2019

	Pharmacological Group	Angiotensin II Receptor Antagonist
	Type of Form	Form 5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ATACAND® (candesartan cilexetil) 8 mg non-film-coated tablets, for oral use by ANI Pharms Inc. US-FDA approved
	Me-too status	Cansart 8mg Tablets by CCL Pharma. Reg. No. 82665
	GMP status	
	Remarks of the Evaluator	Latest GMP inspection report conducted within a period of last three years.
	Decision: Registration Board decided to defer the application till decision of CLB regarding renewal of DML of M/s Baxter Pharmaceuticals A-1/A, Scheem No.33, Phase-1, S.I.T.E,Super Highway, Karachi.	
1018.	Name and address of manufacturer/ Applicant	M/s.Baxter Pharmaceuticals.A-1/A, Scheme No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Telis 20mg Tablet
	Composition	Each Tablet Contains: Telmisartan…20mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 14822 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Angiotensin receptor blocker
	Type of Form	Form 5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Micardis of (USFDA Approved)
	Me-too status	Misar 20mg Tab by Highnoon Laboratories (Reg #065686)
	GMP status	
	Remarks of the Evaluator	Latest GMP inspection report conducted within a period of last three years.
	Decision: Registration Board decided to defer the application till decision of CLB regarding renewal of DML of M/s Baxter Pharmaceuticals A-1/A, Scheem No.33, Phase-1, S.I.T.E,Super Highway, Karachi.	
1019.	Name and address of manufacturer/ Applicant	M/s.Baxter Pharmaceuticals.A-1/A, Scheme No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Telis 40mg Tablet
	Composition	Each Tablet Contains: Telmisartan…40mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 14823 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Angiotensin receptor blocker
	Type of Form	Form 5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Micardis of (USFDA Approved)
	Me-too status	Misar 40mg Tab by Highnoon Laboratories Reg# (065687)
	GMP status	
	Remarks of the Evaluator	Latest GMP inspection report conducted within a period of last three years.
	Decision: Registration Board decided to defer the application till decision of CLB regarding renewal of DML of M/s Baxter Pharmaceuticals A-1/A, Scheem No.33, Phase-1, S.I.T.E,Super Highway, Karachi.	

1020.	Name and address of manufacturer/ Applicant	M/s.Baxter Pharmaceuticals.A-1/A, Scheme No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Telis 80mg Tablet
	Composition	Each Tablet Contains: Telmisartan…80mg
	Diary No. Date of R & I & fee	Form-5 Dy.No 14824 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Angiotensin receptor blocker
	Type of Form	Form 5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Micardis of (USFDA Approved)
	Me-too status	Misar 80mg Tab by Highnoon Laboratories Reg # (065689)
	GMP status	
	Remarks of the Evaluator	Latest GMP inspection report conducted within a period of last three years.
	Decision: Registration Board decided to defer the application till decision of CLB regarding renewal of DML of M/s Baxter Pharmaceuticals A-1/A, Scheem No.33, Phase-1, S.I.T.E,Super Highway, Karachi.	
1021.	Name and address of manufacturer/ Applicant	M/s.Baxter Pharmaceuticals.A-1/A, Scheme No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Valart H Tablet 80/12.5mg
	Composition	Each Tablet Contains: Valsartan…80mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R & I & fee	Dy.No 14816 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Angiotensin II Receptor Antagonist and diuretic
	Type of Form	Form 5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Co-Diovan® 80/12.5 mg film-coated tablets. (MHRA Approved)
	Me-too status	Co-Diovan Tablets by Novartis (027359)
	GMP status	
	Remarks of the Evaluator	• Firm applied for simple plain tablet as per the submitted label claim while the reference product is film coated, submit the correct formulation in line with innovator product along with requisite fee. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Registration Board decided to defer the application till decision of CLB regarding renewal of DML of M/s Baxter Pharmaceuticals A-1/A, Scheem No.33, Phase-1, S.I.T.E,Super Highway, Karachi.	
1022.	Name and address of manufacturer/ Applicant	M/s.Baxter Pharmaceuticals.A-1/A, Scheme No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Valart H Tablet 160/12.5mg
	Composition	Each Tablet Contains: Valsartan…160mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R & I & fee	Dy.No 14817 dated 07-03-2019 Rs.20,000/- dated 06-03-2019

	Pharmacological Group	Angiotensin II Receptor Antagonist and diuretic
	Type of Form	Form 5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Co-Diovan 160/12.5 mg film-coated tablets MHRA Approved.
	Me-too status	Cova-H 160mg/12.5mg Tablet by M/s Getz Pharma (Reg#83311)
	GMP status	
	Remarks of the Evaluator	• Firm applied for simple plain tablet as per the submitted label claim while the reference product is film coated, submit the correct formulation in line with innovator product along with requisite fee. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Registration Board decided to defer the application till decision of CLB regarding renewal of DML of M/s Baxter Pharmaceuticals A-1/A, Scheem No.33, Phase-1, S.I.T.E,Super Highway, Karachi.	
1023.	Name and address of manufacturer/ Applicant	M/s.Baxter Pharmaceuticals.A-1/A, Scheme No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Valart H Tablet 160/25mg
	Composition	Each Tablet Contains: Valsartan…160mg Hydrochlorothiazide…25mg
	Diary No. Date of R & I & fee	Dy.No 14818 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Angiotensin II Receptor Antagonist and diuretic
	Type of Form	Form 5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Co-Diovan 160/25 mg film-coated tablets MHRA Approved.
	Me-too status	Cova-H 160mg/25mg Tablet by M/s Getz Pharma (Reg#83312)
	GMP status	
	Remarks of the Evaluator	• Firm applied for simple plain tablet as per the submitted label claim while the reference product is film coated, submit the correct formulation in line with innovator product along with requisite fee. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Registration Board decided to defer the application till decision of CLB regarding renewal of DML of M/s Baxter Pharmaceuticals A-1/A, Scheem No.33, Phase-1, S.I.T.E,Super Highway, Karachi.	
1024.	**Deleted due to duplication at Sr. no. 1023**	
1025.	Name and address of manufacturer/ Applicant	M/s.Baxter Pharmaceuticals.A-1/A, Scheme No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Baxadol Tablet 37.5/325mg
	Composition	Each Tablet Contains: Tramadol…37.5mg Paracetamol…325mg
	Diary No. Date of R & I & fee	Dy.No 14660 dated 07-03-2019 Rs.20,000/- dated 06-03-

		2019
	Pharmacological Group	Antipyretic/Analgesic
	Type of Form	Form 5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ultraset film coated tablet by M/s Janssen Pharms, USFDA Approved
	Me-too status	Tramal Plus tablet by M/s Searle Company Ltd, Reg No.77129
	GMP status	
	Remarks of the Evaluator	• Firm applied for simple plain tablet as per the submitted label claim while the reference product is film coated, submit the correct formulation in line with innovator product along with requisite fee. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Registration Board decided to defer the application till decision of CLB regarding renewal of DML of M/s Baxter Pharmaceuticals A-1/A, Scheem No.33, Phase-1, S.I.T.E,Super Highway, Karachi.	
1026.	Name and address of manufacturer/ Applicant	M/s.Baxter Pharmaceuticals.A-1/A, Scheme No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Pitast 2mg Tablet
	Composition	Each Tablet Contains: Pitavastatin…2mg
	Diary No. Date of R & I & fee	Dy.No 14661 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	HMG Co-A reductase inhibitor
	Type of Form	Form 5
	Finished product Specification	……..
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Livalo of USFDA approved
	Me-too status	Pitalip 2mg Tablet by Hilton Karachi (Reg. no. 070756)
	GMP status	
	Remarks of the Evaluator	• Firm applied for simple pitavastatin while the innovator formulation is calcium salt of pitavasatatin. So, firm shall apply for correct formulation in line with reference product and accordingly correct the label claim i.e. as under along with full registration fee. Each Film Coated Tablet Contains: Pitavastatin Calcium eq. to Pitavastatin…2mg • Latest GMP inspection report conducted within a period of last three years. • Firm did not mention the specification of finished product in the submitted dossier.
	Decision: Registration Board decided to defer the application till decision of CLB regarding renewal of DML of M/s Baxter Pharmaceuticals A-1/A, Scheem No.33, Phase-1, S.I.T.E,Super Highway, Karachi.	
1027.	Name and address of manufacturer/ Applicant	M/s.Baxter Pharmaceuticals.A-1/A, Scheme No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Ronin 150mg Tablet
	Composition	Each Tablet Contains:

		Ranitidine …150mg
	Diary No. Date of R & I & fee	Dy.No 14682 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anti- allergic
	Type of Form	Form 5
	Finished product Specification	
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved as film- coated
	Me-too status	Ranitidine 150mg tablet of M/s. Ferozsons Laboratories Reg.no.010115
	GMP status	
	Remarks of the Evaluator	• Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Ranitidine Hydrochloride eq. to 150mg of Ranitidine • Latest GMP inspection report conducted within a period of last three years. • Firm did not mentioned the specification of finished product in the submitted dossier.
	Decision: Registration Board decided to defer the application till decision of CLB regarding renewal of DML of M/s Baxter Pharmaceuticals A-1/A, Scheem No.33, Phase-1, S.I.T.E,Super Highway, Karachi.	
1028.	Name and address of manufacturer/ Applicant	M/s.Baxter Pharmaceuticals.A-1/A, Scheme No.33,Phase-1,S.I.T.E,Super Highway, Karachi
	Brand Name + Dosage Form + Strength	Ronin 300mg Tablet
	Composition	Each Tablet Contains: Ranitidine …300mg
	Diary No. Date of R & I & fee	Dy.No 14683 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Anti- allergic
	Type of Form	Form 5
	Finished product Specification	
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved as film- coated
	Me-too status	Ranitidine 300mg tablet of M/s. Ferozsons Laboratories Reg.no.010114
	GMP status	
	Remarks of the Evaluator	• Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Film Coated Tablet Contains: Ranitidine Hydrochloride eq. to 300mg of Ranitidine • Latest GMP inspection report conducted within a period of last three years. • Firm did not mentioned the specification of finished product in the submitted dossier.
	Decision: Registration Board decided to defer the application till decision of CLB regarding renewal of DML of M/s Baxter Pharmaceuticals A-1/A, Scheem No.33, Phase-1, S.I.T.E,Super Highway, Karachi.	
1029.	Name and address of manufacturer/ Applicant	M/s Neutro pharma (Pvt) Ltd., 9.5Km, Sheikhupura Road, Lahore

	Brand Name + Dosage Form + Strength	Baclin Tablet 10mg
	Composition	Each Tablet Contains: Baclofen…10mg
	Diary No. Date of R & I & fee	Dy.No 13977 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Muscle Relaxant and antispastic
	Type of Form	Form 5
	Finished product Specification	….
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Baclofen of (MHRA approved)
	Me-too status	Aerofin 10mg Tablet of M/s. Noa Hemis Pharmaceuticals Reg.no. 085646
	GMP status	**Firm submitted the GMP certificate dated 30-06-2022 based on evaluation conducted on 14-04-2022 and valid for three years from the date of inspection.**
	Remarks of the Evaluator	• Firm did not mention the specification of finished product in the submitted dossier. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with USP specification. **Firm shall submit 7,500/- fee for pre-registration variation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1030.	Name and address of manufacturer/ Applicant	M/s Neutro pharma (Pvt) Ltd., 9.5Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Ciprine 30mg Capsule
	Composition	Each Capsule Contains: Cyclobenzaprine Hcl…30mg
	Diary No. Date of R & I & fee	Dy.No 13983 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Skeletal Muscle relaxant
	Type of Form	Form 5
	Finished product Specification	….
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	AMRIX 30mg extended release capsule of USFDA approved
	Me-too status	Cyclorest ER 30mg capsules of M/s Martin Dow (Reg. 080638)
	GMP status	**Firm submitted the GMP certificate dated 30-06-2022 based on evaluation conducted on 14-04-2022 and valid for three years from the date of inspection.**
	Remarks of the Evaluator	• Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets). • **Firm informed that the source of pellet is vision Pharmaceuticals (Pvt.) Ltd.) and submitted the COA along stability data of three batches of cyclobenzaprine HCl SR 22% pellets.** • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each Capsule contains: Cyclobenzaprine HCl (extended release pellets

		22%)……30mg • Firm did not mention the specification of finished product in the submitted dossier. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with USP specification and with the following label claim: **Each Capsule contains:** **Cyclobenzaprine HCl (extended release pellets 22%)……30mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
1031. U S P	Name and address of manufacturer/ Applicant	M/s Neutro pharma (Pvt) Ltd., 9.5Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Ciprine 150mg Capsule
	Composition	Each Capsule Contains: Cyclobenzaprine Hcl as extended release pellets…150mg
	Diary No. Date of R & I & fee	Dy.No 13984 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Skeletal Muscle relaxant
	Type of Form	Form 5
	Finished product Specification	….
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	**AMRIX 15mg extended release capsule of USFDA approved**
	Me-too status	**Ezibenz SR 15mg capsules of M/s Global Pharma (Reg. 079433)**
	GMP status	**Firm submitted the GMP certificate dated 30-06-2022 based on evaluation conducted on 14-04-2022 and valid for three years from the date of inspection.**
	Remarks of the Evaluator	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • **Firm informed that mistakenly it was written as 150mg while the applied formulation is Cyclobenzaprine Hcl as extended release pellets…15mg** • **Firm informed that the source of pellet is vision Pharmaceuticals (Pvt.) Ltd.) and submitted the COA along stability data of three batches of cyclobenzaprine HCl SR 22% pellets.** • Firm did not mention the specification of finished product in the submitted dossier. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with USP specification and with the following label claim: **Each Capsule contains:** **Cyclobenzaprine HCl (extended release pellets 22%)……15mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
1032.	Name and address of manufacturer/ Applicant	M/s Neutro pharma (Pvt) Ltd., 9.5Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Ciprine 5mg Tablet

	Composition	Each Film coated Contains: Cyclobenzaprine as Hcl …5mg
	Diary No. Date of R & I & fee	Dy.No 13976 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Skeletal Muscle relaxant
	Type of Form	Form 5
	Finished product Specification	….
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	FLEXERIL 5mg film coated tablets USFDA Approved Discontinued **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**
	Me-too status	Eumytic 5mg Tablet by M/s Atco Labarotories (Reg#67273)
	GMP status	**Firm submitted the GMP certificate dated 30-06-2022 based on evaluation conducted on 14-04-2022 and valid for three years from the date of inspection.**
	Remarks of the Evaluator	• Firm did not mention the specification of finished product in the submitted dossier. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with USP specification and with the following label claim: **Each Capsule contains:** **Cyclobenzaprine HCl (extended release pellets 22%)……5mg** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
1033.	Name and address of manufacturer/ Applicant	M/s Neutro pharma (Pvt) Ltd., 9.5Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Dulxin Capsule 30mg
	Composition	Each Capsule Contains: Duloxetine As Hcl Enteric Coated Pellets 17% w/w…30mg
	Diary No. Date of R & I & fee	Dy.No 13982 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Other antidepressants
	Type of Form	Form 5
	Finished product Specification	….
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Dutor 30 mg gastro-resistant capsules, hard. MHRA approved
	Me-too status	Oxcym DR 30 mg Capsule. Reg. No. 53101 of M/s. Atco Laboratories Limited, Karachi
	GMP status	**Firm submitted the GMP certificate dated 30-06-2022 based on evaluation conducted on 14-04-2022 and valid for three years from the date of inspection.**
	Remarks of the Evaluator	• Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets). • **Firm informed that the source of pellet is vision Pharmaceuticals (Pvt.) Ltd.) and submitted the COA along stability data of three batches Duloxetine as Hcl Enteric Coated Pellets 17% pellets.** • Firm did not mention the specification of finished product in the submitted dossier.

		• Latest GMP inspection report conducted within a period of last three years.
	Decision: Aprroved with USP specifications: **Firm shall submit 7,500/- fee for pre-registration variation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1034.	Name and address of manufacturer/ Applicant	M/s Neutro pharma (Pvt) Ltd., 9.5Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Dulxin Capsule 30mg
	Composition	Each Capsule Contains: Duloxetine as HCl Enteric Coated Pellets 17% w/w…60mg
	Diary No. Date of R & I & fee	Dy.No 13981 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Other antidepressants
	Type of Form	Form 5
	Finished product Specification	….
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Dutor 60 mg gastro-resistant capsules, hard. MHRA approved
	Me-too status	Duloxa 60mg Capsule. Reg. No. 082093
	GMP status	**Firm submitted the GMP certificate dated 30-06-2022 based on evaluation conducted on 14-04-2022 and valid for three years from the date of inspection.**
	Remarks of the Evaluator	• Provide source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets). • **Firm informed that the source of pellet is vision Pharmaceuticals (Pvt.) Ltd.) and submitted the COA along stability data of three batches Duloxetine as Hcl Enteric Coated Pellets 17% pellets.** • Firm did not mention the specification of finished product in the submitted dossier. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Aprroved with USP specifications: **Firm shall submit 7,500/- fee for pre-registration variation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1035.	Name and address of manufacturer/ Applicant	M/s Neutro pharma (Pvt) Ltd., 9.5Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	FC-Zole Infusion 200mg/100ml
	Composition	Each ml Contains: Fluconazole…2mg
	Diary No. Date of R & I & fee	Dy.No 13987 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Anti-Fungal
	Type of Form	Form 5
	Finished product Specification	….
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Diflucan 2 mg/ml (200mg/100ml vial) solution for infusion by M/s Pfizer Limited (MHRA Approved)
	Me-too status	CANDISEPT 200mg/100ml Infusion of M/s. Bristol Mayer Biotech,Lahore Reg. no. 105608.

	GMP status	**Firm submitted the GMP certificate dated 30-06-2022 based on evaluation conducted on 14-04-2022 and valid for three years from the date of inspection.** Firm has both Small volume Parenteral and Large Volume parenteral section as per the submitted GMP certificate.
	Remarks of the Evaluator	• Evidence of applied formulation/drug already approved with the filled volume of 100ml by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Firm provide the evidence of me-too approved by DRAP and details are given in the above relevant column. • Section approval letter of liquid Injectable/Infusion section by CLB. • Firm did not mention the specification of finished product in the submitted dossier. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Aprroved with USP specifications: **Firm shall submit 7,500/- fee for pre-registration variation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1036.	Name and address of manufacturer/ Applicant	M/s Neutro pharma (Pvt) Ltd., 9.5Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Onderon 4mg Tablet
	Composition	Each Film Coated Oral Tablet Contains: Ondansetron (As Hydrochloride Dehydrate)…4mg
	Diary No. Date of R & I & fee	Dy.No 13980 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antiemetics and Antinauseants A04AA01 Serotonin (5HT3) antagonists
	Type of Form	Form 5
	Finished product Specification	….
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ZOFRAN® (ondansetron hydrochloride) tablets USFDA Approved.
	Me-too status	081545 Ondonix 4mg Tablet By M/s Genix Pharma Karachi.
	GMP status	**Firm submitted the GMP certificate dated 30-06-2022 based on evaluation conducted on 14-04-2022 and valid for three years from the date of inspection.**
	Remarks of the Evaluator	• Firm did not mention the specification of finished product in the submitted dossier. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Aprroved with USP specifications: **Firm shall submit 7,500/- fee for pre-registration variation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1037.	Name and address of manufacturer/ Applicant	M/s Neutro pharma (Pvt) Ltd., 9.5Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Phlnol Tablet 80/80mg
	Composition	Each Film Coated Tablet Contains: Phloroglucinol Hydrated Corresponding to 62.233mg Anhydrous Phloroglucinol…80mg

		Trimethylhloroglucinol…80mg
	Diary No. Date of R & I & fee	Dy.No 13995 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Macrolides
	Type of Form	Form-5
	Finished product Specification	
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	PHLOROGLUCINOL/TRIMETHYLPHLOROGLUCINOL ACINO 62.233 mg / 80 mg, coated tablet by ACINO France SAS. Approved by ANSM
	Me-too status	Despasm Tablet by Irza Pharmaceuticals. Reg. No. 085210
	GMP status	**Firm submitted the GMP certificate dated 30-06-2022 based on evaluation conducted on 14-04-2022 and valid for three years from the date of inspection.**
	Remarks of the Evaluator	• Firm did not mention the specification of finished product in the submitted dossier. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Aprroved with Innovator's specifications: **Firm shall submit 7,500/- fee for pre-registration variation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1038.	Name and address of manufacturer/ Applicant	M/s Neutro pharma (Pvt) Ltd., 9.5Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Neuprazol 10mg Capsule
	Composition	Each Capsule Contains: Rabeprazole …10mg
	Diary No. Date of R & I & fee	Dy.No 13988 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form-5
	Finished product Specification	
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	**Firm submitted the GMP certificate dated 30-06-2022 based on evaluation conducted on 14-04-2022 and valid for three years from the date of inspection.**
	Remarks of the Evaluator	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Firm did not mention the specification of finished product in the submitted dossier. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. **Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.**	

1039.	Name and address of manufacturer/ Applicant	M/s Neutro pharma (Pvt) Ltd., 9.5Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Neudin 50mg Injection
	Composition	Each 2ml Ampoule Contains: Ranitidine Hcl…50mg
	Diary No. Date of R & I & fee	Dy.No 13990 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	H2 receptor antagonist
	Type of Form	Form-5
	Finished product Specification	
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ranitidine 50mg/2ml Solution (ampoule) for Injection and Infusion (MHRA Approved)
	Me-too status	Ranigen 50mg/2ml Injection by Genix Pharma (Reg# 083773)
	GMP status	**Firm submitted the GMP certificate dated 30-06-2022 based on evaluation conducted on 14-04-2022 and valid for three years from the date of inspection.**
	Remarks of the Evaluator	• Section approval letter of liquid ampoule/vial section issued by CLB is required. • Firm did not mention the specification of finished product in the submitted dossier. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred till the decision by reference regulatory authorities regarding ranitidine containing medicinal products.	
1040.	Name and address of manufacturer/ Applicant	M/s Neutro pharma (Pvt) Ltd., 9.5Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Varox 2.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…2.5mg
	Diary No. Date of R & I & fee	Dy.No 13993 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	anticoagulant
	Type of Form	Form-5
	Finished product Specification	
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Xarelto of M/s Bayer healthcare approved by EMA
	Me-too status	Xarelto 2.5mg Tablet by M/s. Bayer Pakistan (Reg no.074794)
	GMP status	**Firm submitted the GMP certificate dated 30-06-2022 based on evaluation conducted on 14-04-2022 and valid for three years from the date of inspection.**
	Remarks of the Evaluator	• Firm did not mention the specification of finished product in the submitted dossier. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Aprroved with USP specifications: **Firm shall submit 7,500/- fee for pre-registration variation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	

1041.	Name and address of manufacturer/ Applicant	M/s Neutro pharma (Pvt) Ltd., 9.5Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Salzone 125mcg/25mcg Rotacaps
	Composition	Each Rotacap Contains: Fluticasone Propionate…125 mcg Salmeterol Xinafoate…25 mcg
	Diary No. Date of R & I & fee	Dy.No 13996 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Adrenergic in combination with corticosteroids or other drugs, excl. anticholinergics
	Type of Form	Form-5
	Finished product Specification	
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	ADVAIR DISKUS (100/50mcg, 250/50mcg, 500/50mcg) inhalation powder USFDA approved
	Me-too status	Salmicort DPI Capsule 500mcg/50mcg by M/s Macter International (Reg#095139)
	GMP status	**Firm submitted the GMP certificate dated 30-06-2022 based on evaluation conducted on 14-04-2022 and valid for three years from the date of inspection.**
	Remarks of the Evaluator	• Firm shall submit section approval letter of capsule (steroidal DPI) section issued by CLB. • As per 290th decision of Registration board, provide evidence of separate manufacturing facility/section for manufacturing of DPIs including specialized mixing facility to ensure the required particle size of the formulation blend. • As per 290th decision of Registration board, provide evidence of equipment for performing the test of "Uniformity of Delivered Dose" and "Aerodynamic Particle Size Distribution" as per Pharmacopoeia. • Submit the detailed information regarding accompanied dose delivery device. • Firm did not mention the specification of finished product in the submitted dossier. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Registration Board decided to reject the application since the firm has not submitted stability study data of 3 batches of the drug product before the lapse of deadline decided by DRAP Authority i.e. till 31st December 2022.	
1042.	Name and address of manufacturer/ Applicant	M/s Neutro pharma (Pvt) Ltd., 9.5Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Metoca 10mg Injection IM/IV
	Composition	Each 2ml Ampoule Contains: Metoclopramide…10mg
	Diary No. Date of R & I & fee	Dy.No 13991 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antiemetic/ Dopamine D2 Receptor Antagonists
	Type of Form	Form-5
	Finished product Specification	
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	METOCLOPRAMIDE 10mg/2ml Solution for Injection by M/s Advanz Pharma, MHRA Approved.
	Me-too status	Metanil Injection 10mg/2ml by M/s Dosaco Laboratories, Reg. No. 25510
	GMP status	**Firm submitted the GMP certificate dated 30-06-2022 based on evaluation conducted on 14-04-2022 and valid for three years from the date of inspection.**
	Remarks of the Evaluator	• Firm shall submit section approval letter of Liquid injectable section issued by CLB. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each ml contains: Metoclopramide Hydrochloride monohydrate equivalent to 5mg of anhydrous metoclopramide hydrochloride. • Firm did not mention the specification of finished product in the submitted dossier. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Approved with USP specification and with the following label claim: **Each ml contains:** **Metoclopramide Hydrochloride monohydrate equivalent to 5mg of anhydrous metoclopramide hydrochloride.** **The firm shall submit fee of Rs. 30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
1043.	Name and address of manufacturer/ Applicant	M/s Neutro pharma (Pvt) Ltd., 9.5Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Bisonid F 200mcg/6mcg Rotacaps
	Composition	Each Rotacap Contains: Budesonide…200mcg Formoterol Fumarate…6mcg
	Diary No. Date of R & I & fee	Dy.No 13994 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Glucocorticosteroid/Selective β2 adrenoceptor agonist
	Type of Form	Form-5
	Finished product Specification	
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Symbicort 200/6 Turbohaler, Inhalation Powder by M/s AstraZeneca (MHRA Approved)
	Me-too status	Combivair 200mcg + 6mcg capsule of M/s Highnoon
	GMP status	**Firm submitted the GMP certificate dated 30-06-2022 based on evaluation conducted on 14-04-2022 and valid for three years from the date of inspection.**
	Remarks of the Evaluator	1. As per 290th decision of Registration board, provide evidence of separate manufacturing facility/section for manufacturing of DPIs including specialized mixing facility to ensure the required particle size of the formulation blend. 2. As per 290th decision of Registration board, provide evidence of equipment for performing the test of "Uniformity of Delivered Dose" and "Aerodynamic Particle Size Distribution" as per Pharmacopoeia.

		3. The reference formulation has mentioned the hydrated form (dihydrate) of Formoterol fumarate in the label claim while you have not mentioned the hydrated form. Revise the label claim as per reference formulation mentioning the hydrated form along with submission of applicable fee. 4. Submission of stability studies data of three batches as per Requirements of Registration Board decision of 293rd meeting. 5. Submit the detailed information regarding accompanied dose delivery device. 6. Firm shall submit section approval letter of steroidal DPI capsule section issued by CLB. 7. Latest GMP inspection report conducted within a period of last three years.
	Decision: Registration Board decided to reject the application since the firm has not submitted stability study data of 3 batches of the drug product before the lapse of agreed deadline decided by DRAP Authority i.e. till 31st December 2022.	
1044.	Name and address of manufacturer/ Applicant	M/s Neutro pharma (Pvt) Ltd., 9.5Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Fibride Injection 12.5mg/50ml
	Composition	Each ml Contains: Tirofiban As HCl Monohydrate…0.25mg
	Diary No. Date of R & I & fee	Dy.No 13989 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	Antithrombotic agents
	Type of Form	Form-5
	Finished product Specification	
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	AGGRASTAT (250 micrograms/ml) concentrate for solution for infusion 50ml vial by M/s Correvio (UK) Ltd (MHRA Approved)
	Me-too status	Aggrastat Injection 0.25mg/ml 50ml vial by M/s Atco Labs (Reg#025299)
	GMP status	**Firm submitted the GMP certificate dated 30-06-2022 based on evaluation conducted on 14-04-2022 and valid for three years from the date of inspection.**
	Remarks of the Evaluator	• Same formulation with the same filled volume has been approved in the name of M/s. Neutro Pharma (Pvt.) Ltd. in 295th meeting of Registration Board. **(Registered with the brand name neutirof injection and Reg.no. 109753)** • Firm did not mention the specification of finished product in the submitted dossier. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Registration Board was apprised that the applicant already hold registration of the above mentioned finished products. The Board discussed that the new applied products contain same formulation as that of already registered products thus the Board decided to reject the applications for Tirofiban as HCl 0.25mg Injection.	
1045.	Name and address of manufacturer/ Applicant	M/s Neutro pharma (Pvt) Ltd., 9.5Km, Sheikhupura Road, Lahore

	Brand Name + Dosage Form + Strength	Tenox 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Tenoxicam…20mg
	Diary No. Date of R & I & fee	Dy.No 13979 dated 07-03-2019 Rs.20,000/- dated 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Mobiflex Tablets 20mg. approved by MHRA
	Me-too status	Tex-20 Tablet of M/s. Glitz Pharma (Reg.no.038575)
	GMP status	**Firm submitted the GMP certificate dated 30-06-2022 based on evaluation conducted on 14-04-2022 and valid for three years from the date of inspection.**
	Remarks of the Evaluator	• Firm did not mention the specification of finished product in the submitted dossier. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Aprroved with BP specifications: **Firm shall submit 7,500/- fee for pre-registration variation as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1046.	Name and address of manufacturer/ Applicant	M/s Neutro pharma (Pvt) Ltd., 9.5Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Bacrid Injection 200mg/100ml
	Composition	Each 100ml Contains: Ofloxacin (As HCl)…200mg
	Diary No. Date of R & I & fee	Dy.No 13986 dated 07-03-2019 Rs.20,000/- dated 06-03-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Tarivid IV Infusion Solution 2mg/ml (50ml, 100ml, 200ml) by M/s Aventis Pharma Limited, MHRA Approved.
	Me-too status	Lawrflox Inj. 200mg/100ml by M/s Lawrence Pharma R.No.71166
	GMP status	**Firm submitted the GMP certificate dated 30-06-2022 based on evaluation conducted on 14-04-2022 and valid for three years from the date of inspection.**
	Remarks of the Evaluator	• Same formulation with the same filled volume has been approved in the name of M/s. Neutro Pharma (Pvt.) Ltd. in 295th meeting of Registration Board. Registered with the brand name of Bacrid Injection and Reg.no. 105632. • Firm did not mention the specification of finished product in the submitted dossier. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Registration Board was apprised that the applicant already hold registration of the above mentioned finished products. The Board discussed that the new applied products contain same formulation as that of already registered products thus the Board decided to reject the applications for Ofloxacin as HCl 200mg/100ml Injection.	

1047.	Name and address of manufacturer/ Applicant	M/s Neutro pharma (Pvt) Ltd., 9.5Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Rasti Sachet
	Composition	
	Diary No. Date of R & I & fee	Dy.No 13965 dated 07-03-2019 Rs.50,000/- dated 06-03-2019
	Pharmacological Group	
	Type of Form	Form-5D (just mentioned form name without the form content and requisite documents)
	Finished product Specification	
	Pack size & Demanded Price	
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	**Firm submitted the GMP certificate dated 30-06-2022 based on evaluation conducted on 14-04-2022 and valid for three years from the date of inspection.**
	Remarks of the Evaluator	• Firm has not submitted the requisite Form nor the requisite documents as per the requirement. • Latest GMP inspection report conducted within a period of last three years.
	Decision: Deferred for submission of complete dossier on the requisite Form as per the formulation mentioned on the covering letter and fee challan along with full fee of registration.	
1048.	Name and address of manufacturer/ Applicant	M/s Neutro pharma (Pvt) Ltd., 9.5Km, Sheikhupura Road, Lahore
	Brand Name + Dosage Form + Strength	Rasti Sachet
	Composition	
	Diary No. Date of R & I & fee	Dy.No 13965 dated 07-03-2019 Rs.50,000/- dated 06-03-2019
	Pharmacological Group	
	Type of Form	Form-5D (just mentioned the form name without the form content)
	Finished product Specification	
	Pack size & Demanded Price	
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	
	GMP status	**Firm submitted the GMP certificate dated 30-06-2022 based on evaluation conducted on 14-04-2022 and valid for three years from the date of inspection.**
	Remarks of the Evaluator	• Firm has not submitted the requisite Form nor the requisite documents as per the requirement, only the specification and analytical procedure details revealed that label claim of applied formulation is Each film coated tablet contains: Linagliptin …2.5mg Metformin HCl…500mg. • Latest GMP inspection report conducted within a period of last three years. • Submit of stability study data for applied formulation as per guidelines approved in 293rd meeting of Registration Board is required, as the applied formulation is

		subsequent drug generic version.
	Decision: Deferred for submission of complete dossier on the requisite Form as per the formulation mentioned on the covering letter and fee challan along with full fee of registration.	

Previously Deferred Cases of Form-5:

1049.	Name and address of manufacturer / Applicant	Bryon Pharmaceuticals (Pvt.) Ltd. 48-Hayatabad Industrial Estate, Peshawar
	Brand Name +Dosage Form + Strength	Paroxil-CR Tablets
	Diary No. Date of R& I & fee	(Duplicate Dossier) Dy. No. dated 04/04/2012 of Rs. 8,000/- (Photocopy) Differential fee (photocopy) of Rs. 12,000/- submitted on 09/10/2015 (Receipt of application was verified by R&I)
	Composition	Each CR tablet contains: Paroxetine HCl eq. to Paroxetine…12.5mg
	Pharmacological Group	Selective Serotonin Reuptake Inhibitors (SSRIs)
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	As per S.R. O
	Approval Status of Product in Reference Regulatory Authorities	USFDA Approved (PAXIL® CR™ (paroxetine hydrochloride) Controlled-Release Tablets)
	Me-too Status	Paroxiwel 20 mg Tablets of M/s Welwrd Pharmaceuticals
	GMP Status	GMP Inspection conducted on 17/10/2019 and concluded with the following remarks "The firm may be considered operating in satisfactory level of cGMP compliance".
	Remarks of the Evaluator.	• Firm applied for registration of drug on Form 5-B instead of Form-5, firm inform that it is a typographical error instead of "Form-5" word "Form 5-B" was printed and request to replace the incorrect form with the rectified copy. Correct copy has been submitted by the firm. • According to the reference/innovator product it is an enteric, film-coated, bilayer, controlled-release tablet, while the manufacturing method/master formulation submitted by the firm did not clarify that which polymer has been for enteric coating.
	Decision of 308th meeting of Registration Board:	*Deferred for submission of manufacturing outline as per reference formulation which is enteric, film-coated, bilayer, controlled-release tablet contains paroxetine hydrochloride equivalent to paroxetine 12.5mg. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.*
	Response of the Firm	Firm submitted the manufacturing outline in line with innovator formulation but the label claim is not in accordance with innovator product. Further, firm submit the fee of Rs 30,000/- in the head of correction of composition (pre-registration variation) vide slip no. 16600215752 dated 08-22-2022. • Revise your label claim along with submission of full fee as per the innovator's product as per following: Each enteric, film coated, controlled release tablet contains: Paroxetine (as HCl)…12.5mg
	Decision: Approved	

Registration applications of locally manufactured (Human) drugs on Form 5F.

1050.	Name, address of Applicant / Marketing Authorization Holder	M/s Horizon Healthcare (Formerly M/s Wellness Pharmaceutical Pvt. Ltd. Pvt. Ltd.) Plot No.33, Sundar Industrial Estate, Lahore. (DML No.000782)
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Formerly M/s Wellness Pharmaceutical Pvt. Ltd. Pvt. Ltd.) Plot No.33, Sundar Industrial Estate, Lahore. (DML No.000782)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F, Dy. No. 2810 dated 28-01-2022
	Details of fee submitted	PKR: 75,000/- vide online deposit slip No.286415270 dated 13-01-2022.
	The proposed proprietary name / brand name	PRINONE Tablets 267mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film-Coated Tablet Contains: Pirfenidone……267 mg
	Pharmaceutical form of applied drug	Film-coated red color, oval tablet in alu-alu blister with leaflet pack in unit carton.
	Pharmacotherapeutic Group of (API)	Immuno-suppressants, other immune-suppressants, WHO ATC Code: L04AX05
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ESBRIET® (Pirfenidone) 267mg film-coated tablets (USFDA approved)
	For generic drugs (me-too status)	Pirfedow 267mg tablet of M/s Martin Dow Limited. Registration No. 107754
	GMP status of the Finished product manufacturer	GMP certificate issued on 06-07-2020, based on evaluation conducted on 18-06-2020. Tablet Section (General) mentioned GMP certificate.
	Name and address of API manufacturer.	M/s Optimus Drugs Pvt. Ltd. Sy.No. 239 & 240, Dothigudem Village, Pochampally Mandal, Yadadri – Bhuvanagiri District – 508 284, Telangana, India.
	Module-II (Quality	Firm has submitted QOS as per WHO QOS-PD template. Summarized

	Overall Summary)	information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data on CTD format related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications and analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Pirfenidone: Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months at 0, 3rd, 6th, 9th, 12th months. Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months at 0, 1st, 2nd, 3rd & 6th months. Batches: (OP-PIF-A1-001/20, OP-PIF-A1-002/20, OP-PIF-A1-003/20)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacturing process and process control, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence established against innovators product Esbriet 267mg film-coated tablet (Batch No. M100221, Mfg. Date: 03-2021). Summarized test report/results submitted. Comparative dissolution was performed against the same product (Esbriet 267mg film-coated tablet, Batch No. M100221, Mfg. Date: 03-2021) in HCl buffer (pH 1.2), Acetate buffer (pH 4.5), Phosphate buffer (pH 6.8) and water as dissolution time with sampling time points as 05, 10, 15, 20, 30 & 45 minutes. The dissolution profile similarity factor f2 calculated as 92 (acidic buffer pH 1.2), 97 (Acetate buffer pH 4.5), 94 (Phosphate buffer pH 6.8) and 89 (water as dissolution medium).
	Analytical method validation/verification of product	Method validation studies have submitted including introduction, verification of assay method, Specificity, linearity, range, accuracy, precision Repeatability, Intermediate precision, Robustness, System Suitability.

STABILITY STUDY DATA	
Manufacturer of API	M/s Optimus Drugs Pvt. Ltd. Sy.No. 239 & 240, Dothigudem Village, Pochampally Mandal, Yadadri – Bhuvanagiri District – 508 284, Telangana, India.
API Lot No.	OP-PIF-A1-002/20
Description of Pack (Container closure system)	A Film coated yellow color, oval tablet in Alu-Alu blister pack in unit carton occupied 21′s tablets.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PFL-001	PFL-002	PFL-003
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	10.2021	10.2021	10.2021
Date of Initiation	08.10.2021	09.10.2021	09.10.2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product: EMPAZON 10mg Tablets, EMPAZON 25mg Tablets (Empagliflozin), Dayzol 30mg Capsules, Dayzol 60mg Capsules (Dexlansoprazole), which was conducted on 1st June, 2021 and was presented in 307th meeting of Registration Board held on 08-10th June, 2021. Following observations were reported: i. The HPLC software is 21 CFR compliant. ii. Audit trail on the testing reports of EMPAZON 10mg and 25mg Tablets, Dayzol 30mg and 60mg Capsules is available. iii. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	G.M.P Certificate dated 22-05-2020, issued by Drug Control Administration, Government of Telangana. Valid for one year from the date of issuance. Firm has also submitted DML copy of API manufacturer which is valid till 09- 09- 2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. 2122OD029/EXP dated 29-04-2021 from Optimus Drug Pvt. Ltd. Sy.No. 239 & 240, Dothigudem Village, Pochampally Mandal, Yadadri – Bhuvanagiri District – 508 284, Telangana, India for import of Pirfenidone (Batch No. OP-PIF-A1-002/20, Mfg. Date: 01-07-2020), quantity 08kgs. However, the invoice has not been attested by the concerned AD (I & E). Working standard Batch No. 21 WS0161 (Mfg.Date 26-06-2021), Mfg. date 28-06-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted

6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator: (PEC-XVII)

Sr. No.	Observation	Reply by the firm
1.	Provide valid GMP certificate of API manufacturer as the submitted GMP certificate validity is for one year from the date of issuance that is 22-05-2020.	Firm submitted the GMP certificate of API manufacturer M/s. Optimus Drugs Pvt. Ltd. which is valid up till 09-09-2023.
3.	The batch number of Pirfenidone 267mg mentioned in pharmaceutical equivalence studies and that mentioned for comparative dissolution studies and of trial batches manufactured are different.	Firm replied that the batch of perfenidone tablets used for pharmaceutical equivalence was proposed trial batches while the batches of pirfenidone tablets used for CDP study are those batches of pirfenidone batches which are manufactured for the evaluation of stability studies.
4.	Chromatographic conditions given by API manufacturer has a C8 column, while that mentioned by the Drug product manufacturer as C18 column. Moreover, the run time as recommended by the BP monograph is 4 times that of Pirfenidone, while the run time employed in analysis is about 20 minutes.	Firm replied that the C18 column and run time in analytical method verification report of drug manufacturer was typographical mistake. The actual column was used C8 and run time was 48 minutes, so they submitted the amended analytical procedure and analytical method verification report. Moreover, the chromatograms have been attached as evidence.
5.	Provide AD (I & E) attested invoice copy for import of Pirfenidone.	Firm submitted the ADC attested invoice for import of Pirfenidone dated 31-08-2021 Dy.no. 13061/2021-DRAP.
6.	Provide Evidence for import of innovators products (Esbriet 267mg, 534mg & 801mg) for pharmaceutical equivalence and comparative dissolution studies.	Not provided.
7.	Provide details of available minimum handling capacity for trial batches manufacturing.	Firm provide the details of machines used for manufacturing of trial batches.
8.	Potency as per CoA of drug product manufacturer is 100.33% (on dried basis), while that given in stability studies calculation/analysis as 99.2.	Firm clarify that 99.2 was the potency of working standard while 100.33%(on dried basis) is the potency of drug product.
9.	API real time stability data submitted for 12 months	Firm submitted the stability of drug substance of 36 months, details of the batches is as under:
10.	Only 03 months stability studies data (both accelerated & real time) have been provided	Updated stability data till 6 month has submitted by the Firm

Decision: Deferred for submission of image/picture/snapshot of innovator pack i.e. (Esbriet 267mg, 534mg & 801mg) against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed.		
1051.	Name, address of Applicant / Marketing Authorization Holder	M/s Horizon Healthcare (Formerly M/s Wellness Pharmaceutical Pvt. Ltd. Pvt. Ltd.) Plot No.33, Sundar Industrial Estate, Lahore. (DML No.000782)
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Formerly M/s Wellness Pharmaceutical Pvt. Ltd. Pvt. Ltd.) Plot No.33, Sundar Industrial Estate, Lahore. (DML No.000782)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F, Dy. No. 2369 dated 25-01-2022
	Details of fee submitted	PKR: 75,000/- vide online deposit slip No.89888688266 dated 13-01-2022.
	The proposed proprietary name / brand name	PRINONE Tablets 534mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film-Coated Tablet Contains: Pirfenidone……534 mg
	Pharmaceutical form of applied drug	Film-coated red color, oval tablet in alu-alu blister with leaflet pack in unit carton.
	Pharmacotherapeutic Group of (API)	Immuno-suppressants, other immune-suppressants, WHO ATC Code: L04AX05
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ESBRIET® (Pirfenidone) 534mg film-coated tablets (USFDA approved) **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	For generic drugs (me-too status)	Not available
	GMP status of the Finished product manufacturer	GMP certificate issued on 06-07-2020, based on evaluation conducted on 18-06-2020. Tablet Section (General) mentioned GMP certificate.
	Name and address of API manufacturer.	M/s Optimus Drugs Pvt. Ltd. Sy.No. 239 & 240, Dothigudem Village, Pochampally Mandal, Yadadri – Bhuvanagiri District – 508 284, Telangana, India.

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data on CTD format related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications and analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Pirfenidone: Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months at 0, 3rd, 6th, 9th, 12th months. Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months at 0, 1st, 2nd, 3rd & 6th months. Batches: (OP-PIF-A1-001/20, OP-PIF-A1-002/20, OP-PIF-A1-003/20)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacturing process and process control, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence established against innovators product Esbriet 534mg film-coated tablet (Batch No. M1010321, Mfg. Date: 03-2021). Summarized test report/results submitted. Comparative dissolution was performed against the same product (Esbriet 534mg film-coated tablet, Batch No. M1010321, Mfg. Date: 03-2021) in HCl buffer (pH 1.2), Acetate buffer (pH 4.5), Phosphate buffer (pH 6.8) and water as dissolution medium with sampling time points as 05, 10, 15, 20, 30 & 45 minutes. The dissolution profile similarity factor f2 calculated as 96 (acidic buffer pH 1.2), 95 (Acetate buffer pH 4.5), 92 (Phosphate buffer pH 6.8) and 96 (water as dissolution medium).
	Analytical method validation/verification of product	Method validation studies have submitted including, Specificity, linearity, range, accuracy, precision Repeatability, Intermediate precision, Robustness, System Suitability.

STABILITY STUDY DATA	
Manufacturer of API	M/s Optimus Drugs Pvt. Ltd. Sy.No. 239 & 240, Dothigudem Village, Pochampally Mandal, Yadadri – Bhuvanagiri District – 508 284, Telangana, India.
API Lot No.	OP-PIF-A1-002/20
Description of Pack (Container closure system)	A Film coated red color, oval tablet in Alu-Alu blister pack in unit carton occupied 21′s tablets.
Stability Storage	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH

Condition			
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PFM-001	PFM-002	PFM-003
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	10.2021	10.2021	10.2021
Date of Initiation	11.10.2021	12.10.2021	13.10.2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product: EMPAZON 10mg Tablets, EMPAZON 25mg Tablets (Empagliflozin), Dayzol 30mg Capsules, Dayzol 60mg Capsules (Dexlansoprazole), which was conducted on 1st June, 2021 and was presented in 307th meeting of Registration Board held on 08-10th June, 2021. Following observations were reported: iv. The HPLC software is 21 CFR compliant. v. Audit trail on the testing reports of EMPAZON 10mg and 25mg Tablets, Dayzol 30mg and 60mg Capsules is available. vi. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	G.M.P Certificate dated 22-05-2020, issued by Drug Control Administration, Government of Telangana. Valid for one year from the date of issuance. Firm has also submitted DML copy of API manufacturer which is valid till 09- 09- 2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. 2122OD029/EXP dated 29-04-2021 from Optimus Drug Pvt. Ltd. Sy.No. 239 & 240, Dothigudem Village, Pochampally Mandal, Yadadri – Bhuvanagiri District – 508 284, Telangana, India for import of Pirfenidone (Batch No. OP-PIF-A1-002/20, Mfg. Date: 01-07-2020), quantity 08kgs. However, the invoice has not been attested by the concerned AD (I & E). Working standard Batch No. 21 WS0161 (Mfg.Date 26-06-2021), Mfg. date 28-06-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail	Submitted

	reports on product testing	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator: (PEC-XVII)

Sr. No.	Observation	Reply by the firm
1.	Provide valid GMP certificate of API manufacturer as the submitted GMP certificate validity is for one year from the date of issuance that is 22-05-2020.	Firm submitted the GMP certificate of API manufacturer M/s. Optimus Drugs Pvt. Ltd. which is valid up till 09-09-2023.
3.	The batch number of Pirfenidone 267mg mentioned in pharmaceutical equivalence studies and that mentioned for comparative dissolution studies and of trial batches manufactured are different.	Firm replied that the batch of perfenidone tablets used for pharmaceutical equivalence was proposed trial batches while the batches of pirfenidone tablets used for CDP study are those batches of pirfenidone batches which are manufactured for the evaluation of stability studies.
4.	Chromatographic conditions given by API manufacturer has a C8 column, while that mentioned by the Drug product manufacturer as C18 column. Moreover, the run time as recommended by the BP monograph is 4 times that of Pirfenidone, while the run time employed in analysis is about 20 minutes.	Firm replied that the C18 column and run time in analytical method verification report of drug manufacturer was typographical mistake. The actual column was used C8 and run time was 48 minutes, so they submitted the amended analytical procedure and analytical method verification report. Moreover, the chromatograms have been attached as evidence.
5.	Provide AD (I & E) attested invoice copy for import of Pirfenidone.	Firm submitted the ADC attested invoice for import of Pirfenidone dated 31-08-2021 Dy.no. 13061/2021-DRAP.
6.	Provide Evidence for import of innovators products (Esbriet 267mg, 534mg & 801mg) for pharmaceutical equivalence and comparative dissolution studies.	Not provided.
7.	Provide details of available minimum handling capacity for trial batches manufacturing.	Firm provide the details of machines used for manufacturing of trial batches.
8.	Potency as per CoA of drug product manufacturer is 100.33% (on dried basis), while that given in stability studies calculation/analysis as 99.2.	Firm clarify that 99.2 was the potency of working standard while 100.33%(on dried basis) is the potency of drug product.
9.	API real time stability data submitted for 12 months	Firm submitted the stability of drug substance of 36 months, details of the batches is as under:

10.	Only 03 months stability studies data (both accelerated & real time) have been provided	Updated stability data till 6 month has submitted by the Firm
Decision: Deferred for submission of image/picture/snapshot of innovator pack i.e. (Esbriet 267mg, 534mg & 801mg) against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed.		
1052.	Name, address of Applicant / Marketing Authorization Holder	M/s Horizon Healthcare (Formerly M/s Wellness Pharmaceutical Pvt. Ltd. Pvt. Ltd.) Plot No.33, Sundar Industrial Estate, Lahore. (DML No.000782)
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Formerly M/s Wellness Pharmaceutical Pvt. Ltd. Pvt. Ltd.) Plot No.33, Sundar Industrial Estate, Lahore. (DML No.000782)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F, Dy. No. 2370 dated 25-01-2022
	Details of fee submitted	PKR: 75,000/- vide online deposit slip No.35641913 dated 13-01-2022.
	The proposed proprietary name / brand name	PRINONE Tablets 801mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film-Coated Tablet Contains: Pirfenidone……801 mg
	Pharmaceutical form of applied drug	Film-coated green color, oval tablet in alu-alu blister with leaflet pack in unit carton.
	Pharmacotherapeutic Group of (API)	Immuno-suppressants, other immune-suppressants, WHO ATC Code: L04AX05
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ESBRIET® (Pirfenidone) 801mg film-coated tablets (USFDA approved)
	For generic drugs (me-too status)	Mac-Fenid 801mg tablet of M/s Macter International Limited. Registration No. 105300
	GMP status of the Finished product manufacturer	GMP certificate issued on 06-07-2020, based on evaluation conducted on 18-06-2020. Tablet Section (General) mentioned GMP certificate.

	Name and address of API manufacturer.	M/s Optimus Drugs Pvt. Ltd. Sy.No. 239 & 240, Dothigudem Village, Pochampally Mandal, Yadadri – Bhuvanagiri District – 508 284, Telangana, India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data on CTD format related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications and analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Pirfenidone: Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months at 0, 3rd, 6th, 9th, 12th months. Accelerated: 40°C ± 2°C / 75% ± 5%RH for 06 months at 0, 1st, 2nd, 3rd & 6th months. Batches: (OP-PIF-A1-001/20, OP-PIF-A1-002/20, OP-PIF-A1-003/20)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacturing process and process control, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence established against innovators product Esbriet 801mg film-coated tablet (Batch No. M1020321, Mfg. Date: 03-2021). Summarized test report/results submitted. Comparative dissolution was performed against the same product (Esbriet 801mg film-coated tablet, Batch No. M1020321, Mfg. Date: 03-2021) in HCl buffer (pH 1.2), Acetate buffer (pH 4.5), Phosphate buffer (pH 6.8) and water as dissolution medium with sampling time points as 05, 10, 15, 20, 30 & 45 minutes. The dissolution profile similarity factor f2 calculated as 95 (acidic buffer pH 1.2), 99 (Acetate buffer pH 4.5), 96 (Phosphate buffer pH 6.8) and 91 (water as dissolution medium).
	Analytical method validation/verification of product	Method validation studies have submitted including, Specificity, linearity, range, accuracy, precision Repeatability, Intermediate precision, Robustness, System Suitability.

STABILITY STUDY DATA	
Manufacturer of API	M/s Optimus Drugs Pvt. Ltd. Sy.No. 239 & 240, Dothigudem Village, Pochampally Mandal, Yadadri – Bhuvanagiri District – 508 284, Telangana, India.
API Lot No.	OP-PIF-A1-002/20
Description of	A Film coated green color, oval tablet in alu alu blister pack in unit carton

Pack (Container closure system)			
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	PFH-001	PFH-002	PFH-003
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	10.2021	10.2021	10.2021
Date of Initiation	15.10.2021	16.10.2021	17.10.2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product: EMPAZON 10mg Tablets, EMPAZON 25mg Tablets (Empagliflozin), Dayzol 30mg Capsules, Dayzol 60mg Capsules (Dexlansoprazole), which was conducted on 1st June, 2021 and was presented in 307th meeting of Registration Board held on 08-10th June, 2021. Following observations were reported: vii. The HPLC software is 21 CFR compliant. viii. Audit trail on the testing reports of EMPAZON 10mg and 25mg Tablets, Dayzol 30mg and 60mg Capsules is available. ix. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	G.M.P Certificate dated 22-05-2020, issued by Drug Control Administration, Government of Telangana. Valid for one year from the date of issuance. Firm has also submitted DML copy of API manufacturer which is valid till 09- 09- 2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice No. 2122OD029/EXP dated 29-04-2021 from Optimus Drug Pvt. Ltd. Sy.No. 239 & 240, Dothigudem Village, Pochampally Mandal, Yadadri – Bhuvanagiri District – 508 284, Telangana, India for import of Pirfenidone (Batch No. OP-PIF-A1-002/20, Mfg. Date: 01-07-2020), quantity 08kgs. However, the invoice has not been attested by the concerned AD (I & E). Working standard Batch No. 21 WS0161 (Mfg.Date 26-06-2021), Mfg. date 28-06-2021.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets,	Submitted

	COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator: (PEC-XVII)

Sr. No.	Observation	Reply by the firm
1.	Provide valid GMP certificate of API manufacturer as the submitted GMP certificate validity is for one year from the date of issuance that is 22-05-2020.	Firm submitted the GMP certificate of API manufacturer M/s. Optimus Drugs Pvt. Ltd. which is valid up till 09-09-2023.
3.	The batch number of Pirfenidone 267mg mentioned in pharmaceutical equivalence studies and that mentioned for comparative dissolution studies and of trial batches manufactured are different.	Firm replied that the batch of perfenidone tablets used for pharmaceutical equivalence was proposed trial batches while the batches of pirfenidone tablets used for CDP study are those batches of pirfenidone batches which are manufactured for the evaluation of stability studies.
4.	Chromatographic conditions given by API manufacturer has a C8 column, while that mentioned by the Drug product manufacturer as C18 column. Moreover, the run time as recommended by the BP monograph is 4 times that of Pirfenidone, while the run time employed in analysis is about 20 minutes.	Firm replied that the C18 column and run time in analytical method verification report of drug manufacturer was typographical mistake. The actual column was used C8 and run time was 48 minutes, so they submitted the amended analytical procedure and analytical method verification report. Moreover, the chromatograms have been attached as evidence.
5.	Provide AD (I & E) attested invoice copy for import of Pirfenidone.	Firm submitted the ADC attested invoice for import of Pirfenidone dated 31-08-2021 Dy.no. 13061/2021-DRAP.
6.	Provide Evidence for import of innovators products (Esbriet 267mg, 534mg & 801mg) for pharmaceutical equivalence and comparative dissolution studies.	Not provided.
7.	Provide details of available minimum handling capacity for trial batches manufacturing.	Firm provide the details of machines used for manufacturing of trial batches.
8.	Potency as per CoA of drug product manufacturer is 100.33% (on dried basis),	Firm clarify that 99.2 was the potency of working standard while 100.33%(on dried basis) is the potency of drug product.

	while that given in stability studies calculation/analysis as 99.2.	
9.	API real time stability data submitted for 12 months	Firm submitted the stability of drug substance of 36 months, details of the batches is as under:
10.	Only 03 months stability studies data (both accelerated & real time) have been provided	Updated stability data till 6 month has submitted by the Firm

Decision: Deferred for submission of image/picture/snapshot of innovator pack i.e. (Esbriet 267mg, 534mg & 801mg) against which Pharmaceutical equivalence/Comparative dissolution profile studies have been performed.

1053.	Name, address of Applicant / Marketing Authorization Holder	M/s Horizon Healthcare (Formerly M/s Wellness Pharmaceutical Pvt. Ltd.) Plot No.33, Sundar Industrial Estate, Lahore. (DML No.000782)
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Formerly M/s Wellness Pharmaceutical Pvt.Ltd.) Plot No.33, Sundar Industrial Estate, Lahore. (DML No.000782)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F, Dy. No. 404 dated 05-01-2022
	Details of fee submitted	PKR: 75,000/- vide online deposit slip No.998823005 dated 24-11-2021.
	The proposed proprietary name / brand name	OBETIZON 5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Obeticholic acid ……5mg
	Pharmaceutical form of applied drug	Oral
	Pharmacotherapeutic Group of (API)	Bile and liver therapy, Bile acid preparations.
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory	OCALIVA® Tablet by Intercept Pharmaceuticals, Inc. New York, NY 10001 (US FDA approved with boxed warning as: HEPATIC

	authorities	DECOMPENSATION AND FAILURE IN PRIMARY BILIARY CHOLANGITIS PATIENTS WITH CIRRHOSIS)
	For generic drugs (me-too status)	Ocafib 5mg film-coated tablet of M/s Sami pharmaceuticals, Karachi. Registration No. 112710
	GMP status of the Finished product manufacturer	GMP certificate issued on 28-03-2022, based on evaluation conducted on 14-10-2021.Tablet Section (General) mentioned in Licensing Division letter for renewal of Drug Manufacturing License.
	Name and address of API manufacturer.	M/s KIMIA BIOSCIENCES LIMITED (Formerly Laurel Organics Ltd.),Village: Bhondsi, Tehsil: Sohna, Distt: Gurugram (Haryana).
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data on CTD format related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications and analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Obeticholic acid: (Storage conditions 2 -8 ^{o}C) Stability study conditions: Real time: 5°C ± 3°C for 18 months at 0, 3rd, 6th, 9th, 12^{th,} 18th months. Accelerated: 25°C ± 2°C / 60% ± 5%RH for 06 months at 0, 1st, 3rd & 6th months. Batches:(KB/OBT/SPP/19/001,KB/OBT/SPP/19/002,KB/OBT/SPP/20/001)
	Module-III(Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacturing process and process control, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence established against innovators product Ocaliva 5mg film-coated tablet (Batch No. A452035, Mfg. Date: 08-2020). Summarized test report/results submitted. Comparative dissolution was performed against the same product Ocaliva 5mg film-coated tablet (Batch No. A452035, Mfg. Date: 08-2020) in HCl buffer (pH 1.2), Acetate buffer (pH 4.5), Phosphate buffer (pH 6.8) and Sod. Phosphate dibasic + Tween 80 (dissolution medium) with sampling time points as 10, 15, 20, 30, 45 & 60 minutes. The dissolution profile similarity factor f2 calculated as 70 (acidic buffer pH 1.2), 77 (Acetate buffer pH 4.5), 75 (Phosphate buffer pH 6.8) and 74 (Sodium Phosphate dibasic + Tween 80, pH 6.8).
	Analytical method validation/verification of product	Method validation studies have submitted including, Specificity, linearity, range, accuracy, precision Repeatability, Intermediate precision, Robustness, System Suitability.
STABILITY STUDY DATA		
Manufacturer of API	M/s KIMIA BIOSCIENCES LIMITED (Formerly Laurel Organics Ltd.),Village: Bhondsi, Tehsil: Sohna, Distt: Gurugram (Haryana).	

API Lot No.	KB/OBI/SPP/21/004		
Description of Pack (Container closure system)	A Film coated Light Yellow Colored, round shape, biconvex tablet Which is Plain at both sides.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	OBL-001	OBL-002	
Batch Size	5000Tab	5000Tab	
Manufacturing Date	08-2021	08-2021	
Date of Initiation	25-08-2021	26-08-2021	
No. of Batches	02		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product: EMPAZON 10mg Tablets, EMPAZON 25mg Tablets (Empagliflozin), Dayzol 30mg Capsules, Dayzol 60mg Capsules (Dexlansoprazole), which was conducted on 1st June, 2021 and was presented in 307th meeting of Registration Board held on 08-10th June, 2021. Following observations were reported: x. The HPLC software is 21 CFR compliant. xi. Audit trail on the testing reports of EMPAZON 10mg and 25mg Tablets, Dayzol 30mg and 60mg Capsules is available. xii. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	G.M.P Certificate dated 18-11-2019, issued by the State Drugs Controller, Haryana (Food & Drug Administration, Haryana, Panchkula). The certificate is valid till 17-11-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice attested on 01-07-2021 by AD I&E DRAP, Lahore, has been submitted

Batch No.	Invoice No & Date	Quantity Imported	Exporter
KB/OBI/SPP/21/004	KBLEXP/21-22/048 dated 28-05-2021.	200 GM (1 Box)	M/s KIMIA BIOSCIENCES LIMITED

Working standard Batch No. WS-OBI004/21, quantity 2gm.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator: (PEC-XVII)

Sr. No.	Observation	Reply by the firm
1.	Mobile phase ratio at 3.2.P.5.2 (Drug Product analytical procedure) for assay determination given as Acetonitrile and 0.02% of Formic acid (65:35) and flow rate of 1.3ml/minute while in the "analytical method validation summary report for Obeticholic acid" at 3.2.P.5.3 (Validation of analytical procedure), the Mobile phase mentioned as Acetonitrile: Buffer Solution (35:65), with flow rate as 01 ml/minute. Moreover, the standard solution preparation (0.5mg/ml), quantity of Obeticholic acid WS given as 50mg in 50ml diluent.	Firm replied that the mobile phase ratio, flow rate and standard dilution preparation written in the analytical method validation summary had a typographical error. We have replaced the summary report, which is concordant with our standard analytical procedure and detailed method validation report. Changed summary report is attached.
	The firm has submitted two different finished analysis report titled as "Finished analysis report" and "Finished Product Certificate of analysis" for trial batch No. OBH-002 with different assay and dissolution results as 100.73%, 94.15% & 100.93%, 95.08% respectively. Same variation observed in the trial batch No.OBH-001 also. Moreover, chromatograms for sample 1 & sample 2 for assay determination of finished product also not provided.	The finished product certificate of analysis in the batch analysis sheet contains the results based on observations. The finished analysis report was a typographical error. We have changed it as per the certificate of analysis in the batch analysis sheet. The changed finished analysis reports are attached.
2.	Chromatograms for the analytical method validation of raw material not provided by the drug product manufacturer. The title given as analytical method verification report of Obeticholic acid with specificity and accuracy studies.	Firm replied that API analytical method verification was performed for specificity, repeatability and accuracy. Detailed report is attached with the chromatograms.

3.	The stability studies data of both trial batches has been submitted in disorder fashion making it difficult to evaluate and understand. It is therefore advised to submit the requisite data in properly arranged form for both trial batches.	Firm replied that the properly arranged data has submitted.
4.	API stability studies data submitted for 18 months.	Firm submitted the API stability data of 24months and the period of study mentioned on stability data sheets is 60months.

Decision: Deferred for submission of Module 3 of Form 5-F compiled in accordance with CTD guidance document along with full fee of registration.

1054.	Name, address of Applicant / Marketing Authorization Holder	M/s Horizon Healthcare (Formerly M/s Wellness Pharmaceutical Pvt. Ltd. Pvt. Ltd.) Plot No.33, Sundar Industrial Estate, Lahore. (DML No.000782)
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Formerly M/s Wellness Pharmaceutical Pvt. Ltd. Pvt. Ltd.) Plot No.33, Sundar Industrial Estate, Lahore. (DML No.000782)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Form-5F, Dy. No. 405 dated 05-01-2022
	Details of fee submitted	PKR: 75,000/- vide online deposit slip No.31455909705 dated 24-11-2021.
	The proposed proprietary name / brand name	OBETIZON 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Obeticholic acid ……10mg
	Pharmaceutical form of applied drug	Oral
	Pharmacotherapeutic Group of (API)	Bile and liver therapy, Bile acid preparations.
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	OCALIVA® 5mg, 10mg Tablet by Intercept Pharmaceuticals, Inc. New York, NY 10001 (US FDA approved with boxed warning as:

		HEPATIC DECOMPENSATION AND FAILURE IN PRIMARY BILIARY CHOLANGITIS PATIENTS WITH CIRRHOSIS)
	For generic drugs (me-too status)	Ocafib 10mg film-coated tablet of M/s Sami pharmaceuticals, Karachi. Registration No. 112711
	GMP status of the Finished product manufacturer	GMP certificate issued on 28-03-2022, based on evaluation conducted on 14-10-2021. Tablet Section (General) mentioned in Licensing Division letter for renewal of Drug Manufacturing License.
	Name and address of API manufacturer.	M/s KIMIA BIOSCIENCES LIMITED (Formerly Laurel Organics Ltd.),Village: Bhondsi, Tehsil: Sohna, Distt: Gurugram (Haryana).
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Firm has submitted detailed drug substance data on CTD format related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications and analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Obeticholic acid: (Storage conditions 2 -8 ^{o}C. Stability study conditions: Real time: 5°C ± 3°C for 18 months at 0, 3rd, 6th, 9th, 12^{th,} 18th months. Accelerated: 25°C ± 2°C / 60% ± 5%RH for 06 months at 0, 1st, 3rd & 6th months. Batches: (KB/OBT/SPP/19/001, KB/OBT/SPP/19/002, KB/OBT/SPP/20/001)
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacturing process and process control, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical equivalence established against innovators product Ocaliva 10mg film-coated tablet (Batch No. B482037, Mfg. Date: 09-2020). Summarized test report/results submitted. Comparative dissolution was performed against the same product Ocaliva 10mg film-coated tablet (Batch No. B482037, Mfg. Date: 09-2020) in HCl buffer (pH 1.2), Acetate buffer (pH 4.5), Phosphate buffer (pH 6.8) and Sod. Phosphate dibasic + Tween 80 (dissolution medium) with sampling time points as 10, 15, 20, 30, 45 & 60 minutes. The dissolution profile similarity factor f2 calculated as 80 (acidic buffer pH 1.2), 72 (Acetate buffer pH 4.5), 86 (Phosphate buffer pH 6.8) and 87 (Sodium Phosphate dibasic + Tween 80, pH 6.8).
	Analytical method validation/verification of product	Method validation studies have submitted including, Specificity, linearity, range, accuracy, precision Repeatability, Intermediate precision, Robustness, System Suitability.

<table>
<tr><td colspan="5">STABILITY STUDY DATA</td></tr>
<tr><td colspan="2">Manufacturer of API</td><td colspan="3">M/s KIMIA BIOSCIENCES LIMITED (Formerly Laurel Organics Ltd.),Village: Bhondsi, Tehsil: Sohna, Distt: Gurugram (Haryana).</td></tr>
<tr><td colspan="2">API Lot No.</td><td colspan="3">KB/OBI/SPP/21/004</td></tr>
<tr><td colspan="2">Description of Pack (Container closure system)</td><td colspan="3">A Film coated Light Blue Colored, round shape, biconvex tablet Which is Plain at both sides.</td></tr>
<tr><td colspan="2">Stability Storage Condition</td><td colspan="3">Real time: 30˚C ± 2˚C / 65% ± 5%RH
Accelerated: 40˚C ± 2˚C / 75% ± 5%RH</td></tr>
<tr><td colspan="2">Time Period</td><td colspan="3">Real time: 3 months
Accelerated: 3 months</td></tr>
<tr><td colspan="2">Frequency</td><td colspan="3">Accelerated: 0, 3, 6 (Months)
Real Time: 0, 3, 6 (Months)</td></tr>
<tr><td colspan="2">Batch No.</td><td>OBH-001</td><td>OBH-002</td><td></td></tr>
<tr><td colspan="2">Batch Size</td><td>5000Tab</td><td>5000Tab</td><td></td></tr>
<tr><td colspan="2">Manufacturing Date</td><td>08-2021</td><td>08-2021</td><td></td></tr>
<tr><td colspan="2">Date of Initiation</td><td>30-08-2021</td><td>31-08-2021</td><td></td></tr>
<tr><td colspan="2">No. of Batches</td><td colspan="3">02</td></tr>
<tr><td colspan="5">Administrative Portion</td></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm (if any)</td><td colspan="3">Firm has referred to onsite inspection report of their product:
EMPAZON 10mg Tablets, EMPAZON 25mg Tablets (Empagliflozin), Dayzol 30mg Capsules, Dayzol 60mg Capsules (Dexlansoprazole), which was conducted on 1st June, 2021 and was presented in 307th meeting of Registration Board held on 08-10th June, 2021.
Following observations were reported:
xiii. The HPLC software is 21 CFR compliant.
xiv. Audit trail on the testing reports of EMPAZON 10mg and 25mg Tablets, Dayzol 30mg and 60mg Capsules is available.
xv. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td colspan="3">G.M.P Certificate dated 18-11-2019, issued by the State Drugs Controller, Haryana (Food & Drug Administration, Haryana, Panchkula). The certificate is valid till 17-11-2022.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="3">Copy of commercial invoice attested on 01-07-2021 by AD I&E DRAP, Lahore, has been submitted
<table>
<tr><td>Batch No.</td><td>Invoice No & Date</td><td>Quantity Imported</td><td>Exporter</td></tr>
<tr><td>KB/OBI/SPP/21/004</td><td>KBLEXP/21-22/048 dated 28-05-2021.</td><td>200 GM (1 Box)</td><td>M/s KIMIA BIOSCIENCES LIMITED</td></tr>
</table></td></tr>
</table>

		Working standard Batch No. WS-OBI004/21, quantity 2gm.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator: (PEC-XVII)

Sr. No.	Observation	Reply by the firm
1.	Mobile phase ratio at 3.2.P.5.2 (Drug Product analytical procedure) for assay determination given as Acetonitrile and 0.02% of Formic acid (65:35) and flow rate of 1.3ml/minute while in the "analytical method validation summary report for Obeticholic acid" at 3.2.P.5.3 (Validation of analytical procedure), the Mobile phase mentioned as Acetonitrile: Buffer Solution (35:65), with flow rate as 01 ml/minute. Moreover, the standard solution preparation (0.5mg/ml), quantity of Obeticholic acid WS given as 50mg in 50ml diluent.	Firm replied that the mobile phase ratio, flow rate and standard dilution preparation written in the analytical method validation summary had a typographical error. We have replaced the summary report, which is concordant with our standard analytical procedure and detailed method validation report. Changed summary report is attached.
2.	Chromatograms for the analytical method validation of raw material not provided by the drug product manufacturer. The title given as analytical method verification report of Obeticholic acid with specificity and accuracy studies. Whether validation or verification studies required??	Firm replied that API analytical method verification was performed for specificity, repeatability and accuracy. Detailed report is attached with the chromatograms.
3.	The firm has submitted two different finished analysis report titled as "Finished analysis report" and "Finished Product Certificate of analysis" for trial batch No. OBH-002 with different assay and dissolution results as 100.73%, 94.15% & 100.93%, 95.08% respectively. Same variation observed in the trial batch No.OBH-001 also. Moreover, chromatograms for sample 1 & sample 2 for assay determination of finished product also not provided.	The finished product certificate of analysis in the batch analysis sheet contains the results based on observations. The finished analysis report was a typographical error. We have changed it as per the certificate of analysis in the batch analysis sheet. The changed finished analysis reports are attached.

4.	Chromatograms for standard runs not provided for trial batch OBH # 001 for accelerated stability data at 3rd month time point.	The chromatograms for standard run of OBH-001 3rd month accelerated study has attached.
5.	Starting dates for stability studies given as 30th & 31st August 2021, while the 3rd month & 6th month stability studies conducted on 21st, 22nd November 2021 & 20th February 2022 that is few days earlier than the scheduled dates.	Firm replied that "The ending date of stability was 28 February,2022, which was written as 31-02-2022, which does not exist. Therefore, our stability study schedule dates are within ± 7 days of the stability ending date. We have corrected the stability ending date on the certificates of analysis of stability studies".
6.	Submit audit trial reports for the 6th month time stability studies data	The audit trail reports stability data is submitted.
7.	Submit digital data logger record from 14th November onward till 6th month time point for stability chambers (both accelerated & real time).	The audit trail reports of 6th month stability data is submitted by the firm.
8.	API stability studies data submitted for 18 months.	Firm submitted the API stability data of 24months and the period of study mentioned on stability data sheets is 60months.
Decision: Deferred for submission of Module 3 of Form 5-F compiled in accordance with CTD guidance document along with full fee of registration.		

Agenda of Evaluator PEC-XX

A) Priority consideration on account of Export Facilitation:

In pursuance of decision of 133rd meeting of the Authority held on 13th April 2022, wherein it was decided that for each 100,000 USD worth of export of medicine during a fiscal year, one molecule will be considered on priority subject to fulfilment of all prescribed requirements

Following registration application of firms may be considered on priority in light of Export Facilitation Policy as communicated vide letter No.F.1-6/2019-PR-I (EFD) dated 11.04.2023:

1055.	Name, address of Applicant / Marketing Authorization Holder	The Searle Company Limited F-319, S.I.T.E., Karachi, Pakistan.
	Name, address of Manufacturing site.	The Searle Company Limited F-319, S.I.T.E., Karachi, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale

		☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 7089 dated 10/03/2023
	Details of fee submitted	PKR 30,000/-: dated 17/02/2023
	The proposed proprietary name / brand name	ACTINIB 5mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	ACTINIB 5mg Tablets Each Film coated tablet contains: Tofacitinib (as Citrate) ……5mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Immunosuppressant
	Reference to Finished product specifications	As per Innovator's Specifications
	Proposed Pack size	As per DPC
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Approved by EMA with the name of XELIJANZ 5mg Tablet https://www.medicines.org.uk/emc/product/2500/smpc#gref
	For generic drugs (me-too status)	TOFAJAK 5mg Tablets by Hiranis Pharmaceuticals (Pvt.) Limited Reg No 110057
	GMP status of the Finished product manufacturer	GMP inspection report dated 07.07.2022 wherein firm was considered to be operating at GOOD level of GMP compliance. Tablet (General) section approved dated 29.10.2020.
	Name and address of API manufacturer.	TOFACITINB CITRATE: Manufacturer: Nantong Chanyoo Pharmatech Co., Ltd Address: No.2 Tonghai Road, Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, 226407 P.R. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Tofacitinib is not present in any pharmacopeia. The firm has submitted details of nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, structure elucidation, tests for impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	TOFACITINIB CITRATE Stability study conditions: Long term: 30°C ± 2°C / 75% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months

		Batches: [TFBB-707-210101, TFBB-707-210102, TFBB-707-210103]
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the brand leader that is TOFAJAK 5mg Tablet by Hiranis Pharmaceuticals (Pvt.) Limited Batch No 014 by performing quality tests (Physical Appearance, Assay, Disintegration, Dissolution, Content uniformity and test for related substance) against Test Product Batch No 082D04 CDP has been performed against the same the brand leader that is TOFAJAK 5mg Tablet by Hiranis Pharmaceuticals (Pvt.) Limited Batch No 014 in Hydrochloric Acid Solution (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8) against Test Product Batch No 082D06 The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity, robustness, and system suitability

STABILITY STUDY DATA			
Manufacturer of API	TOFACITINB CITRATE: Manufacturer: Nantong Chanyoo Pharmatech Co., Ltd Address: No.2 Tonghai Road, Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, 226407 P.R. China		
API Lot No.	TOFACITINB CITRATE: RD-TFBB-202109181		
Description of Pack (Container closure system)	ALU-ALU Blister in Unit Carton (1 x 10's)		
Stability Storage Condition	Real time: 30±2ºC, 75±5%RH Accelerated: 40±2ºC, 75±5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0,3, 6, 9, 12, 18 & 24 (Months)		
Batch No.	082D03	082D04	082D05
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	Apr-2022	Apr-2022	Apr-2022
Date of Initiation	May-2022	May-2022	May-2022
No. of Batches	03		
Administrative Portion			
Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted documents for Reference of Previous Approval Tapendol tablet approved in 289th meeting of RB		

	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	TOFACITINB CITRATE: GMP Certificate of Manufacturer: Nantong Chanyoo Pharmatech Co., Ltd Valid Till: 21-Feb-2026
	Documents for the procurement of API with approval from DRAP (in case of import).	TOFACITINB CITRATE: Invoice Invoice Number: CY121448 dated 02-Mar-2022 Quantity: 0.36 kg Batch: RD-TFBB-202109181 Mfg Date: Sep-18-2021 Retest Date: Sep-18-2023 Approval from DRAP is not provided.
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted all documents related to stability data i.e Chromatograms, Raw data sheets, COA, summary data sheets
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Assessor (DD PEC-XX):

Sr.#	Observation	Reply	Remarks
1.	The active substance specification includes tests for description, identification (IR, Chiral LC), particle size, assay (LC), counterion of citric acid (LC), impurities (LC), residue on ignition (USP), heavy metals (USP), residual solvents (GC), water content, palladium (ICP-OES). https://www.ema.europa.eu/en/documents/assessment-report/xeljanz-epar-public-assessment-report_en.pdf Tests such as Heavy metals, particle size and water content have not been mentioned in CoA of Drug Substance.	Particle size distribution was not performed at that time due to unavailability of equipment. Now we have procured the equipment and have performed the test, results have been incorporated in CoA accordingly. Heavy metals test evaluation in Drug Substance because USP eliminated the Heavy metal test chapter in their official monograph after	Tofacitinib is not found in USP or any other monograph hence specifications/tests of Drug Substance to be adopted as per innovator, justification for not performing heavy metal tests in drug substance (either by DS

		January 2018 that's why not mentioned on drug substance CoA. Water content test has been incorporated in CoA	manufacturer or product manufacturer) is not acceptable. ***Later on firm has provided CoA from DS Manufacturer wherein specification of heavy metal testing was mentioned.***
2.	Results of specificity parameter along with HPLC chromatograms (sample, standard, blank) has not been provided under Analytical method verification study	Provided	Complied
3.	Documents for the procurement of API with approval from DRAP to be provided.	License to import drug 0.36Kg dated 24.03.2022 issued by DRAP, Karachi is submitted.	Clearance certificate from DRAP yet to be submitted ***Later on firm has provided approval from DRAP (I&E Karachi)***

Remarks: ***Reply submitted against above mentioned shortcomings found satisfactory.***

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1056	Name, address of Applicant / Marketing Authorization Holder	The Searle Company Limited F-319, S.I.T.E., Karachi, Pakistan.
	Name, address of Manufacturing site.	The Searle Company Limited F-319, S.I.T.E., Karachi, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 7986 dated 10/03/2023
	Details of fee submitted	PKR 30,000/-: dated 17/02/2023
	The proposed proprietary name / brand name	ACTINIB 10mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	ACTINIB 10mg Tablets Each Film coated tablet contains: Tofacitinib (as Citrate) ……10mg
	Pharmaceutical form of applied drug	Film coated tablet

	Pharmacotherapeutic Group of (API)	Immunosuppressant
	Reference to Finished product specifications	As per Innovator's Specifications
	Proposed Pack size	As per DPC
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	Approved by EMA with the name of XELIJANZ 10mg Tablet
	For generic drugs (me-too status)	Not available
	GMP status of the Finished product manufacturer	GMP inspection report dated 07.07.2022 wherein firm was considered to be operating at GOOD level of GMP compliance. Tablet (General) section approved dated 29.10.2020.
	Name and address of API manufacturer.	TOFACITINB CITRATE: Manufacturer: Nantong Chanyoo Pharmatech Co., Ltd Address: No.2 Tonghai Road, Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, 226407 P.R. China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Tofacitinib is not present in any pharmacopeia. The firm has submitted details of nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, structure elucidation, tests for impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Long term: 30°C ± 2°C / 75% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: [TFBB-707-210101, TFBB-707-210102, TFBB-707-210103]
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence has been established against the innovator that is XELIJANZ 10mg Tablet by Pfizer Inc., Ireland Batch No GG3975by performing quality tests

		(Physical Appearance, Assay, Disintegration, Dissolution, Content uniformity and test for related substance) against Test product Batch No 077D10 CDP has been performed against the same the brand leader that is XELIJANZ 10mg Tablet by Pfizer Inc., Ireland in Hydrochloric Acid Solution (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). T he values for f1 and f2 are in the acceptable range.		
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity, robustness, and system suitability		
STABILITY STUDY DATA				
Manufacturer of API		TOFACITINB CITRATE: Manufacturer: Nantong Chanyoo Pharmatech Co., Ltd Address: No.2 Tonghai Road, Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province, 226407 P.R. China		
API Lot No.		TOFACITINB CITRATE: RD-TFBB-202109181		
Description of Pack (Container closure system)		ALU-ALU Blister in Unit Carton		
Stability Storage Condition		Real time: 30±2ºC, 75±5%RH Accelerated: 40±2ºC, 75±5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0,3, 6, 9, 12, 18 & 24 (Months)		
Batch No.		077D09	077D10	077D11
Batch Size		2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date		Apr-2022	Apr-2022	Apr-2022
Date of Initiation		May-2022	May-2022	May-2022
No. of Batches		03		
Administrative Portion				
	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted documents for Reference of Previous Approval Tapendol tablet approved in 289th meeting of RB.		
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	TOFACITINB CITRATE: GMP Certificate of Manufacturer: Nantong Chanyoo Pharmatech Co., Ltd Valid Till: 21-Feb-2026		

	Documents for the procurement of API with approval from DRAP (in case of import).	TOFACITINB CITRATE: Invoice Invoice Number: CY121448 dated 02-Mar-2022 Quantity: 0.36 kg Batch: RD-TFBB-202109181 Mfg Date: Sep-18-2021 Retest Date: Sep-18-2023 Approval from DRAP is not provided.
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted all documents related to stability data i.e Chromatograms, Raw data sheets, COA, summary data sheets
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Assessor (DD PEC-XX):

Sr.#	Observation	Reply	Remarks
1.	The generic version of "Tofacitinb (as citrate) 10mg tablet" has not been registered hence differential fee of 45000/- to be submitted.	Differential fee of Rs 45000/- has been submitted dated 25/05/2023 Challan No 049230710910	Complied
2.	The active substance specification includes tests for description, identification (IR, Chiral LC), particle size, assay (LC), counterion of citric acid (LC), impurities (LC), residue on ignition (USP), heavy metals (USP), residual solvents (GC), water content, palladium (ICP-OES). https://www.ema.europa.eu/en/documents/assessment-report/xeljanz-epar-public-assessment-report_en.pdf Tests such as Heavy metals, particle size and water content have not been mentioned in CoA of Drug Substance.	Particle size distribution was not performed at that time due to unavailability of equipment. Now we have procured the equipment and have performed the test, results have been incorporated in CoA accordingly. Heavy metals test evaluation in Drug Substance because USP eliminated the Heavy metal test chapter in their official monograph after January 2018 that's why not	Tofacitinib is not found in USP or any other monograph hence specifications/tests of Drug Substance to be adopted as per

		mentioned on drug substance CoA. Water content test has been incorporated in CoA	innovator . justification for not performing heavy metal tests in drug substance (either by DS manufacturer or product manufacturer) is not acceptable. ***Later on firm has provided CoA from DS Manufacturer wherein specification of heavy metal testing was mentioned.***
3.	Results of specificity parameter along with HPLC chromatograms (sample, standard, blank) has not been provided under Analytical method verification study	Provided	Complied
4.	Documents for the procurement of API with approval from DRAP to be provided.	License to import drug 0.36Kg dated 24.03.2022 issued by DRAP, Karachi is submitted.	Clearance certificate from DRAP yet to be submitted ***Later on firm has provided approval from DRAP (I&E Karachi)***

Remarks: ***Reply submitted against above mentioned shortcomings found satisfactory.***

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

In pursuance of decision of 133rd meeting of the Authority held on 13th April 2022, wherein it was decided that for each 100,000 USD worth of export of medicine during a fiscal year, one molecule will be considered on priority subject to fulfilment of all prescribed requirements

Following registration application of firms may be considered on priority in light of Export Facilitation Policy as communicated vide letter No.F.1-6/2019-PR-I (EFD) dated 28.02.2023:

1057	Name, address of Applicant / Marketing Authorization Holder	M/s Ferozsons Laboratories Limited, PO Ferozsons, Nowshera - Pakistan.
	Name, address of Manufacturing site.	M/s Ferozsons Laboratories Limited, PO Ferozsons, Nowshera - Pakistan.
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24363 dated 29/08/2022
	Details of fee submitted	PKR 75,000/-: dated 23/08/2022
	The proposed proprietary name / brand name	PRUDAC TABLET 1mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Prucalopride succinate eq. to Prucalopride ….1mg
	Pharmaceutical form of applied drug	film coated tablet
	Pharmacotherapeutic Group of (API)	Serotonin receptor agonists
	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	10's, 14's, 20's, 28's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MOTEGRITY TABLET USFDA approved
	For generic drugs (me-too status)	NA
	GMP status of the Finished product manufacturer	GMP certificate No. F. 11-6/2021-DRAP-65 dated 25/08/2021 Valid up to 10-08-2023. Tablet (General) section approved vide letter No. F.3-14/2004-Lic, dated: 08-04-2015 is submitted.
	Name and address of API manufacturer.	M/s Kimia Biosciences Limited, Address: Village Bhondsi Tehsil-Sohna District-Gurugram Harryana, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Prucalopride succinate is non pharmacopoeial substance, the firm submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, tests for single/total impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months

		Batches: (LA/PPD/SF/18/001, LA/PPD/SF/18/002, LA/PPD/SF/18/003)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Reference Brand that is Resolor 1mg Tablets (Batch No KLL1Q02) by Janssen-Cilag S.p.A. via C. Janssen, 04100 Borgo S. Michele, Latina, Italy, by performing quality tests (Description, Assay, Dissolution, Disintegration time and impurities) against Test product PCTab-001 CDP has been performed against the same brand that is Resolor 1mg Tablets (Batch No KLL1Q02) by Janssen-Cilag S.p.A. via C. Janssen, 04100 Borgo S. Michele, Latina, Italy against Test product PCTab-001 Dissolution profile of Prucalopride 1mg tablets and Resolor 1mg tablets has shown Similarity factor f2 is more than 50 in all three media, Buffer pH 1.2, Phosphate Buffer pH 6.8 and Acetate Buffer pH 4.5. Hence dissolution profile of both Prucalopride 2mg tablets and Resolor 2mg tablets is similar.
	Analytical method validation/verification of product	Method verification studies have submitted including specificity, linearity, range, accuracy, precision.

STABILITY STUDY DATA	
Manufacturer of API	M/s Kimia Biosciences Limited Address: Village Bhondsi Tehsil-Sohna District-Gurugram Harryana, India
API Lot No.	KB/PPD/SPP/21/001
Description of Pack (Container closure system)	Alu-Alu blisters of 10's
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)
Batch No.	PCTab-001, PCTab-002, PCTab-003.
Batch Size	1350 film-coated tablets
Manufacturing Date	12-2021
Date of Initiation	27-12-2021
No. of Batches	03

Administrative Portion		
	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted the document.
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 4/138-1 Drug 1-2019/8359 issued by State-Drugs-Controller-Cum-Controlling & Licensing Authority. Food and Drugs administration Haryana, Sco No 94, Sector-5, Panchkula valid till 17/11/2022.
	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of, Commercial invoice No KBLEXP/21-22/032 dated 28.06.2021 wherein Prucalopride succinate (0.025Kg) was purchased (Batch No KB/PPD/SPP/21/001). Acknowledgment from DRAP Peshawar dated 03.08.2021
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Assessor (DD PEC-XX):
Firm has taken the dissolution specification from FDA assessment report of innovator "Motegrity tablet" NDA 210166 which specify following dissolution parameters:

Apparatus	USP Apparatus 2 (Paddle)
Speed	50 rpm
Dissolution media	0.1 N Hydrochloric Acid
Volume	900 mL
Time	10, 20, 30, and 45 min
Temperature	37 ± 0.5 °C
Specifications	NL (b) (4)% (Q) in 20 minutes

S. No	Observations	Reply	Remarks
1.	Valid Approval of API/ DML/GMP certificate of API issued by concerned regulatory authority of country of origin to be provided.	Firm has provided updated GMP certificate No 4/138-1Drugs-1-2022/6790 dated 07.09.2022 valid till two years issued by Food and Drug Administration, Haryana	Complied
2.	Same Batch No of reference product was mentioned in CDP report i.e KLL1Q02 both for Resolor 1mg tablet and Resolor 2mg tablet. Clarify it	There was a typographic mistake. The actual batch No of Resolor 2mg tablet was mentioned on chromatogram and CDP protocol i.e KJL3200	Complied

3.	Under specificity parameter of Analytical Method Verification studies of Drug Product, results of sample and its HPLC Chromatogram has not been included	Results of specificity parameter and HPLC chromatogram is provided	Complied

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter will be issued upon submission of Rs. 7,500/- fee for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.**

1058.	Name, address of Applicant / Marketing Authorization Holder	M/s Ferozsons Laboratories Limited, PO Ferozsons, Nowshera - Pakistan.
	Name, address of Manufacturing site.	M/s Ferozsons Laboratories Limited, PO Ferozsons, Nowshera - Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 24364 dated 29/08/2022
	Details of fee submitted	PKR 75,000/-: dated 23/08/2022
	The proposed proprietary name / brand name	PRUDAC TABLET 2mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Prucalopride succinate eq. to Prucalopride ….2mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Serotonin receptor agonists

	Reference to Finished product specifications	Innovator's specifications
	Proposed Pack size	10's, 14's, 20's, 28's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MOTEGRITY TABLET USFDA approved
	For generic drugs (me-too status)	NA
	GMP status of the Finished product manufacturer	GMP certificate No. F. 11-6/2021-DRAP-65 dated 25/08/2021 Valid up to 10-08-2023. Tablet (General) section approved vide letter No. F.3-14/2004-Lic, dated: 08-04-2015 is submitted.
	Name and address of API manufacturer.	M/s Kimia Biosciences Limited, Address: Village Bhondsi Tehsil-Sohna District-Gurugram Harryana, India
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Prucalopride succinate is non pharmacopoeial substance , the firm submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, tests for single/total impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (LA/PPD/SF/18/001, LA/PPD/SF/18/002, LA/PPD/SF/18/003)

	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Reference Brand that is Resolor 2mg Tablets (Batch No KJL3200) by Janssen-Cilag S.p.A. via C. Janssen, 04100 Borgo S. Michele, Latina, Italy, by performing quality tests (Description, Assay, Dissolution, Disintegration time and impurities) against Test product PCTab-004 CDP has been performed against the same brand that is Resolor 2mg Tablets (Batch No KLL1Q02) by Janssen-Cilag S.p.A. via C. Janssen, 04100 Borgo S. Michele, Latina, Italy against Test product PCTab-001 Dissolution profile of Prucalopride 2mg tablets and Resolor 2mg tablets has shown Similarity factor f2 is more than 50 in all three media, Buffer pH 1.2, Phosphate Buffer pH 6.8 and Acetate Buffer pH 4.5. Hence dissolution profile of both Prucalopride 2mg tablets and Resolor 2mg tablets is similar.
	Analytical method validation/verification of product	Method verification studies have submitted including specificity, linearity, range, accuracy, precision.

STABILITY STUDY DATA	
Manufacturer of API	M/s Kimia Biosciences Limited Address: Village Bhondsi Tehsil-Sohna District-Gurugram Harryana, India
API Lot No.	KB/PPD/SPP/21/001
Description of Pack (Container closure system)	Alu-Alu blister of 10’s
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3, 6 (Months)

	Real Time: 0, 3, 6 (Months)	
Batch No.	PCTab-004, PCTab-005, PCTab-006.	
Batch Size	1250 film-coated tablets	
Manufacturing Date	12-2021	
Date of Initiation	27-12-2021	
No. of Batches	03	
Administrative Portion		
	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has submitted the document.
	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 4/138-1 Drug 1-2019/8359 issued by State-Drugs-Controller-Cum-Controlling & Licensing Authority. Food and Drugs administration Haryana, Sco No 94, Sector-5, Panchkula valid till 17/11/2022.
	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of, Commercial invoice No KBLEXP/21-22/032 dated 28.06.2021 wherein Prucalopride succinate (0.025Kg) was purchased (Batch No KB/PPD/SPP/21/001). Acknowledgment from DRAP Peshawar dated 03.08.2021
	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Assessor (DD PEC-XX): Firm has taken the dissolution specification from FDA assessment report of innovator “Motegrity tablet” NDA 210166 which specify following dissolution parameters:		

Apparatus	USP Apparatus 2 (Paddle)
Speed	50 rpm
Dissolution media	0.1 N Hydrochloric Acid
Volume	900 mL
Time	10, 20, 30, and 45 min
Temperature	37 ± 0.5 °C
Specifications	NL (%) (Q) in 20 minutes

S. No	Observations	Reply	Remarks
1.	Valid Approval of API/ DML/GMP certificate of API issued by concerned regulatory authority of country of origin to be provided.	Firm has provided updated GMP certificate No 4/138-1Drugs-1-2022/6790 dated 07.09.2022 valid till two years issued by Food and Drug Administration, Haryana	Complied
2.	Same Batch No of reference product was mentioned in CDP report i.e KLL1Q02 both for Resolor 1mg tablet and Resolor 2mg tablet. Clarify it	There was a typographic mistake. The actual batch No of Resolor 2mg tablet was mentioned on chromatogram and CDP protocol i.e KJL3200	Complied
3.	Under specificity parameter of Analytical Method Verification studies of Drug Product, results of sample and its HPLC Chromatogram has not been included	Results of specificity parameter and HPLC chromatogram is provided	Complied

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter will be issued upon submission of Rs. 7,500/- fee for revision of specifications as per notification No.F.7-11/2021-B&A/DRAP dated 07-05-2021.**

In pursuance of decision of 133rd meeting of the Authority held on 13th April 2022, wherein it was decided that for each 100,000 USD worth of export of medicine during a fiscal year, one molecule will be considered on priority subject to fulfilment of all prescribed requirements

Following registration application of firms may be considered on priority in light of Export Facilitation Policy as communicated vide letter No.F.1-6/2019-PR-I (EFD) dated 29.12.2022:

Deferred case of 263rd meeting

1059.	Name and address of manufacturer / Applicant	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
	Brand Name +Dosage Form + Strength	Napra MR Tablet 375/ 20mg
	Composition	Napra MR 375/20mg Tablet Each Delayed Release tablet contains: Naproxen…….375 mg Esomeprazole……..20 mg
	Diary No. Date of R& I & fee	Form-5D dated 06-08-2011 Dy.No.75 Rs.8000/- & Rs.42,000/- 27-6-2014
	Pharmacological Group	Anti-Arthritis
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	Rs.2500/-10's Rs.5000/-20's Rs.7500/-30's
	Approval status of product in Reference Regulator Authorities	VIMOVO delayed release Tablet 375mg/ 20mg by UCB Inc. USFDA Approved
	Me-too status	Not Available
	GMP status	Inspection report dated 04-04-2016 stated GMP compliance as Acceptable.
	Decision 263rd meeting of RB: Deferred for submission of stability studies as per 251st RB meeting guidelines	

Now the firm has submitted stability data vide Dy. No. 34277 dated 28.11.2022 as follows:

STABILITY STUDY DATA

Manufacturer of API	Metrochem API Private Limited (Esomeprazole) DIVI's Laboratories Limited (Naproxen)		
API Lot No.	ESM/2104199 (Esomeprazole) 2-M-C-4311120 (Naproxen)		
Description of Pack (Container closure system)	Alu/Alu blister		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,3, 6 (Months) Real Time: 0,3, 6 (Months)		
Batch No.	22SB(B)-354-01	22SB(B)-355-02	22SB(B)-356-03
Batch Size	650 Tablets	650 Tablets	650 Tablets
Manufacturing Date	01-2022	01-2022	01-2022
Date of Initiation	01-02-2022	01-02-2022	01-02-2022
No. of Batches	03		

<table>
<tr><td colspan="3">DOCUMENTS / DATA PROVIDED BY THE APPLICANT</td></tr>
<tr><td>Sr. No.</td><td>Documents to Be Provided</td><td>Status</td></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm</td><td>Provided

Wymly Tablet 25mg, considered in 281st meeting of RB.</td></tr>
<tr><td>2.</td><td>Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Certificate of Analysis of API from finished product manufacturer has not been provided</td></tr>
<tr><td>3.</td><td>Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer</td><td>Not provided</td></tr>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>Not provided</td></tr>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Naproxen:
Copy of license retention certificate No 1537/AP/DCA/2017 dated 02.02.2018 valid till 17-01-2023

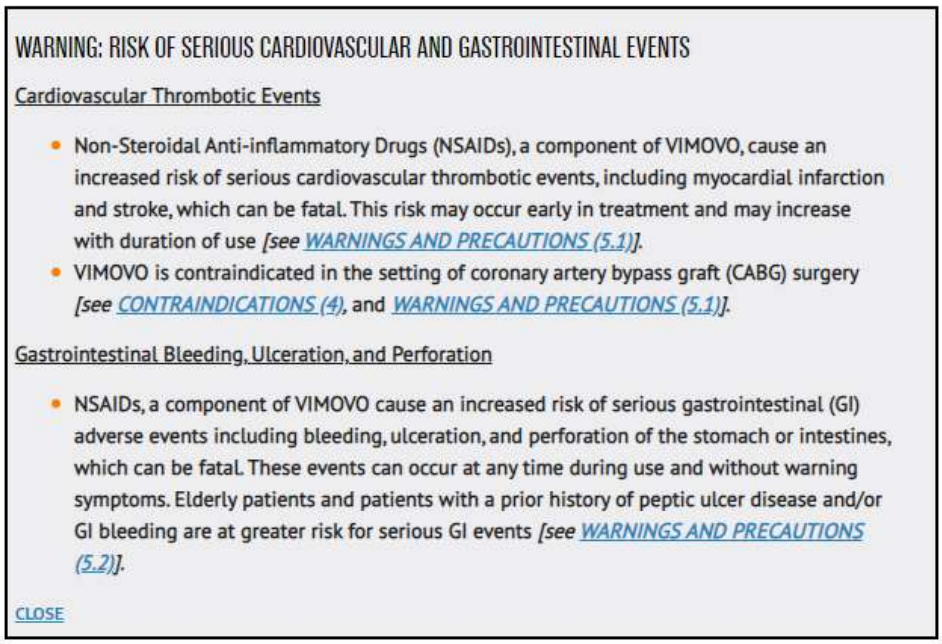
Esomeprazole:
GMP certificate L. Dis No 4084/A3/2019 dated 20-05-2020. Valid for three years.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of Purchase Invoice No. AE/21-22/0082 (Esomeprazole magnesium, batch No ESM/2104199, 01 Kg) dated 27-05-2021. Approved from DRAP Karachi dated 23.06.2021

Copy of Purchase invoice No ZHI-CI/5446/0621 (Naproxen, Batch No 2-M-C-4311120, 2Kg) dated 16-06-2021. Approved from DRAP Karachi dated 29.06.2021</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Drug excipients compatibility study not provided.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><td>Batch No.</td><td>Batch Size</td><td>Mfg. Date</td></tr>
<tr><td>22SB(B)-354-01</td><td>650 Tablets</td><td>02-2022</td></tr>
<tr><td>22SB(B)-355-02</td><td>650 Tablets</td><td>02-2022</td></tr>
<tr><td>22SB(B)-356-03</td><td>650 Tablets</td><td>02-2022</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>CDP has been performed against the brand that is VIMOVO Tablet 375mg/ 20mg (B#FL0015) by Horizon Pharma, USA, in Acid media (0.1N HCl), acetate buffer 4.5 & Phosphate Buffer pH (6.8) against Test product i.e NAPRA MR tablet Batch No 22SB(B)-354-01.</td></tr>
</table>

		The f1 and f2 value was in acceptable range.
12.	Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
13.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted
14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Assessor (DD-PEC XX):

Formulation is approved in USFDA with Box warning:



WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS

Cardiovascular Thrombotic Events

- Non-Steroidal Anti-inflammatory Drugs (NSAIDs), a component of VIMOVO, cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use *[see WARNINGS AND PRECAUTIONS (5.1)]*.
- VIMOVO is contraindicated in the setting of coronary artery bypass graft (CABG) surgery *[see CONTRAINDICATIONS (4)*, and *WARNINGS AND PRECAUTIONS (5.1)]*.

Gastrointestinal Bleeding, Ulceration, and Perforation

- NSAIDs, a component of VIMOVO cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events *[see WARNINGS AND PRECAUTIONS (5.2)]*.

CLOSE

S.No	Observations	Reply	Remarks
1.	Formulation/label claim to be standardized in line with RRA, as follows: Napra MR 375/20mg Tablet Each modified release tablet contains: Naproxen …….. 375mg (enteric coated core) Esomeprazole (as Magnesium trihydrate) …… 20mg (immediate release outer coating)	Firm has submitted fee of Rs 30,000/- for correction of label claim in line with RRA as: Napra MR 375/20mg Tablet Each modified release tablet contains: Naproxen …….. 375mg (enteric coated core) Esomeprazole (as Magnesium trihydrate) …… 20mg (immediate release outer coating)	Complied

2.	Provide updated GMP status of finished product manufacturer along with relevant section approval letter.	Firm has submitted updated GMP status of finished product manufacturer dated 15.06.2021valid till two years	Complied
3.	Enteric coating solution, seal coating solution, Esomeprazole magnesium coating solution and film coating solution was prepared 30% in excess to compensate loss during coating (as provided in stability BMR) Justify it.	*To obtain optimum results Enteric coating solution, seal coating solution, Esomeprazole magnesium coating solution and film coating solution was prepared 30% in excess* *(required dissolution, complete covering, desired assay and uniform appearance)*	
4.	Esomeprazole degrades rapidly in acidic solutions; more than 80% of esomeprazole drug substance is degraded within 10 minutes. Therefore, it is not relevant to quantitatively determine the amount and rate of esomeprazole dissolution under acidic conditions as per PAR of the Medicines Evaluation Board in the Netherlands https://db.cbg-meb.nl/pars/h106235.pdf However, CDP report submitted by firm revealed that Esomeprazole Drug substance did not release (found undetected) in acid medium (0.1N HCl) and acetate buffer medium (pH 6.8). Justify it.	*Esomeprazole is acid liable in nature so, it will rapidly degrade in acidic mediums (0.1N HCl & Acetate buffer pH 4.5) within 10 minutes. Hence, because of the complete degradation of esomeprazole it does not quantified in the sample while analyzing on chromatographic system so we describe the absence of esomeprazole peak as a term not detected i.e. ND*	Justified
5.	Provide Drug excipients compatibility study report for Microcrystalline cellulose and Magnesium Carbonate, being qualitatively different from innovator product.	*Microcrystalline Cellulose (Avicel PH 101) is used as a diluent. Magnesium carbonate is incorporated into the coating solution as opacifier that improve product appearance and protect the Esomeprazole from light. Both excipients contribute in product processing performance and finished product quality attributes. Thus, the development of an optimized formulation/process*	Firm has to perform Drug excipients compatibility study or provide relevant literature reference wherein aforementioned excipients found compatible with Drug substance.

		requires the addition of Microcrystalline Cellulose (Avicel PH 101) and Magnesium carbonate in order to obtain product with satisfactory physical and chemical parameters. *The product kept on stability and no changes observed in physical and chemical parameters throughout the shelf life.* *Stability studies demonstrated the compatibility of the formulation excipients with the drug substance.* *Because stability studies are one of the techniques for Drug-Excipients compatibility studies.*	
6.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer to be provided	Provided	complied
7.	Certificate of Analysis of API from finished product manufacturer has not been provided	Provided	complied

8.	Stability study data of API from API manufacturer to be provided.	Stability data of both API is submitted as follows: **Naproxen** Batch No M5M042 M5M043 M5M042 Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months **Esomeprazole** Batch No ESM-M/089 ESM-SPC/100 ESM-SPC/001 Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months	complied

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter will be issued after performance of Drug excipient compatibility study or relevant literature reference to be provided wherein aforementioned excipients found compatible with Drug substance**.

a) Registration applications of drugs for which stability study data is submitted for exemption from onsite verification of stability data

Deferred case of 268th meeting :

1060	Name and address of manufacturer / Applicant	M/s Genix Pharma Private Limited 44-45B Korangi creek road Karachi
	Brand Name +Dosage Form + Strength	Napra MR Tablet 500mg/ 20mg
	Composition	Each tablet contains: Naproxen 500mg

		Esomeprazole as magnesium trihydrate …….20 mg
	Diary No. Date of R& I & fee	Form-5D Duplicate dated 06-08-2011 Dy.No.73 Rs.8000/- (Copy), Rs.42,000/- dated 27-6-2014
	Pharmacological Group	Anti-Arthritis
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10's, 20's,30's Rs.3000/-, Rs.6000/- Rs.9000/-
	Approval status of product in Reference Regulator Authorities	VIMOVO delayed release Tablet 500mg/ 20mg by UCB Inc. USFDA Approved
	Me-too status	Not Available
	GMP status	Last inspection report 26-01-2017 Acceptable level of GMP compliance.
	Decision of 268th meeting of RB: Deferred for evaluation of dossier as per Innovator's product and submission of stability data as per guidelines of 251st Registration board meeting along with verification of fee challan of Rs. 8000/-	
	Now the firm has submitted stability data vide Dy. No. 34275 dated 28.11.2022 as follows:	

STABILITY STUDY DATA			
Manufacturer of API	Metrochem API Private Limited (Esomeprazole) DIVI's Laboratories Limited (Naproxen)		
API Lot No.	ESM/2104199 (Esomeprazole) 2-M-C-4311120 (Naproxen)		
Description of Pack (Container closure system)	Alu/Alu blister		
Stability Storage Condition	Real time: 30°C ± 2° C / 65% ± 5% RH Accelerated: 40 °C ± 2 °C / 75% ± 5%		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,3, 6 (Months) Real Time: 0,3, 6 (Months)		
Batch No.	21SB(B)-332-01	21SB(B)-333-02	21SB(B)-334-03
Batch Size	650 Tablets	650 Tablets	650 Tablets
Manufacturing Date	12-2021	12-2021	12-2021
Date of Initiation	12-01-2022	12-01-2022	12-01-2022
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	Documents to Be Provided	Status
1.	Reference of previous approval of applications with stability study data of the firm	Provided Wymly Tablet 25mg, considered in 281st meeting of RB.

<table>
<tr><td>2.</td><td>Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer.</td><td>Certificate of Analysis of API from finished product manufacturer has not been provided</td></tr>
<tr><td>3.</td><td>Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer</td><td>Not provided</td></tr>
<tr><td>4.</td><td>Stability study data of API from API manufacturer</td><td>Not provided</td></tr>
<tr><td>5.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Naproxen:
Copy of license retention certificate No 1537/AP/DCA/2017 dated 02.02.2018 valid till 17-01-2023

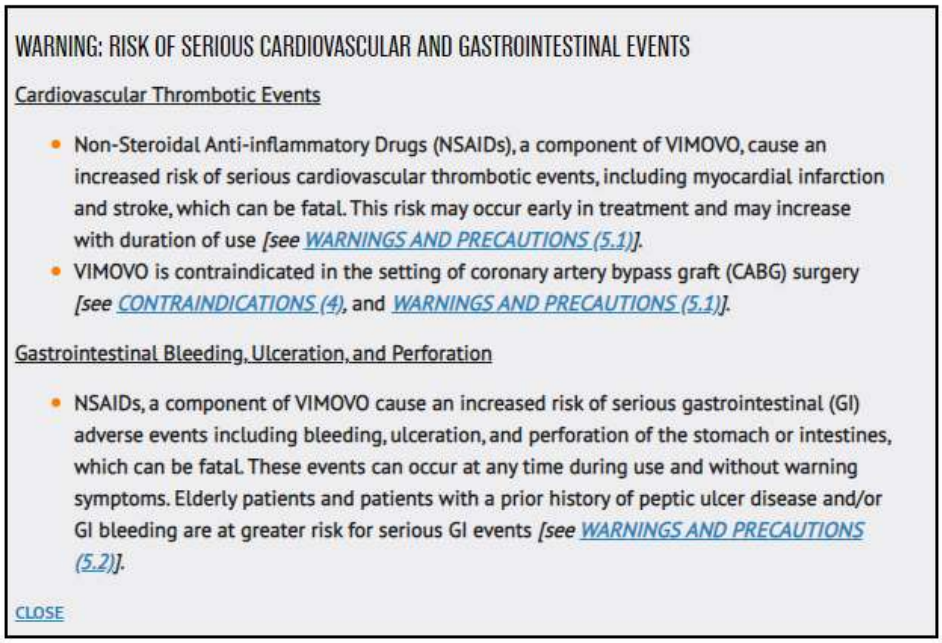
Esomeprazole:
GMP certificate L. Dis No 4084/A3/2019 dated 20-05-2020. Valid for three years.</td></tr>
<tr><td>6.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of Purchase Invoice No. AE/21-22/0082 (Esomeprazole magnesium, batch No ESM/2104199, 01 Kg) dated 27-05-2021. Approved from DRAP Karachi dated 23.06.2021

Copy of Purchase invoice No ZHI-CI/5446/0621 (Naproxen, Batch No 2-M-C-4311120, 2Kg) dated 16-06-2021. Approved from DRAP Karachi dated 29.06.2021</td></tr>
<tr><td>7.</td><td>Protocols followed for conduction of stability study</td><td>Submitted</td></tr>
<tr><td>8.</td><td>Method used for analysis of FPP</td><td>Submitted</td></tr>
<tr><td>9.</td><td>Drug-excipients compatibility studies (where applicable)</td><td>Drug excipients compatibility study report not provided.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted Batch Manufacturing record of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>21SB(B)-332-01</td><td>650 Tablets</td><td>12-2021</td></tr>
<tr><td>21SB(B)-333-02</td><td>650 Tablets</td><td>12-2021</td></tr>
<tr><td>21SB(B)-334-03</td><td>650 Tablets</td><td>12-2021</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of comparative dissolution data (where applicable)</td><td>CDP has been performed against the brand that is VIMOVO Tablet 500mg/ 20mg (B#ACAU) by Horizon Pharma, USA, in Acid media (0.1N HCl), acetate buffer 4.5 & Phosphate Buffer pH (6.8) against Test product i.e NAPRA MR tablet Batch No 21SB(B)-332-01.
The f1 and f2 value was in acceptable range.</td></tr>
<tr><td>12.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>13.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Submitted</td></tr>
</table>

14.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Assessor (DD-PEC XX):

Formulation is approved in USFDA with Box warning:



WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS

Cardiovascular Thrombotic Events

- Non-Steroidal Anti-inflammatory Drugs (NSAIDs), a component of VIMOVO, cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use *[see WARNINGS AND PRECAUTIONS (5.1)]*.
- VIMOVO is contraindicated in the setting of coronary artery bypass graft (CABG) surgery *[see CONTRAINDICATIONS (4)*, and *WARNINGS AND PRECAUTIONS (5.1)]*.

Gastrointestinal Bleeding, Ulceration, and Perforation

- NSAIDs, a component of VIMOVO cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events *[see WARNINGS AND PRECAUTIONS (5.2)]*.

CLOSE

S.No	Observations	Reply	Remarks
1.	Formulation/label claim to be standardized in line with RRA, as follows: Napra MR 375/20mg Tablet Each modified release tablet contains: Naproxen ……... 375mg (enteric coated core) Esomeprazole (as Magnesium trihydrate) …… 20mg (immediate release outer coating)	Firm has submitted fee of Rs 30,000/- for correction of label claim in line with RRA as: Napra MR 375/20mg Tablet Each modified release tablet contains: Naproxen ……... 375mg (enteric coated core) Esomeprazole (as Magnesium trihydrate) …… 20mg (immediate release outer coating)	Complied
2.	Provide updated GMP status of finished product manufacturer along with relevant section approval letter.	Firm has submitted updated GMP status of finished product manufacturer dated 15.06.2021valid till two years	Complied
3.	Enteric coating solution, seal coating solution, Esomeprazole magnesium coating solution and film coating solution was prepared 30% in excess	*To obtain optimum results Enteric coating solution, seal coating solution, Esomeprazole magnesium*	

	to compensate loss during coating (as provided in stability BMR) Justify it.	*coating solution and film coating solution was prepared 30% in excess* *(required dissolution, complete covering, desired assay and uniform appearance)*	
4.	Esomeprazole degrades rapidly in acidic solutions; more than 80% of esomeprazole drug substance is degraded within 10 minutes. Therefore, it is not relevant to quantitatively determine the amount and rate of esomeprazole dissolution under acidic conditions as per PAR of the Medicines Evaluation Board in the Netherlands https://db.cbg-meb.nl/pars/h106235.pdf However, CDP report submitted by firm revealed that Esomeprazole Drug substance did not release (found undetected) in acid medium (0.1N HCl) and acetate buffer medium (pH 6.8). Justify it.	*Esomeprazole is acid liable in nature so, it will rapidly degrade in acidic mediums (0.1N HCl & Acetate buffer pH 4.5) within 10 minutes. Hence, because of the complete degradation of esomeprazole it does not quantified in the sample while analyzing on chromatographic system so we describe the absence of esomeprazole peak as a term not detected i.e. ND*	Justified
5.	Provide Drug excipients compatibility study report for Microcrystalline cellulose and Magnesium Carbonate, being qualitatively different from innovator product.	*Microcrystalline Cellulose (Avicel PH 101) is used as a diluent. Magnesium carbonate is incorporated into the coating solution as opacifier that improve product appearance and protect the Esomeprazole from light. Both excipients contribute in product processing performance and finished product quality attributes. Thus, the development of an optimized formulation/process requires the addition of Microcrystalline Cellulose (Avicel PH 101) and Magnesium carbonate in order to obtain product with satisfactory physical and chemical parameters.* *The product kept on stability and no changes*	Firm has to either perform Drug excipients compatibility study or provide relevant literature reference wherein aforementioned excipients found compatible with Drug substance.

		observed in physical and chemical parameters throughout the shelf life. Stability studies demonstrated the compatibility of the formulation excipients with the drug substance. Because stability studies are one of the techniques for Drug-Excipients compatibility studies.	
6.	Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer to be provided	Provided	complied
7.	Certificate of Analysis of API from finished product manufacturer has not been provided	Provided	complied
8.	Stability study data of API from API manufacturer to be provided.	Stability data of both API is submitted as follows: **Naproxen** Batch No M5M042 M5M043 M5M042 Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months **Esomeprazole** Batch No ESM-M/089 ESM-SPC/100 ESM-SPC/001 Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months	complied

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter will be issued after performance of Drug excipient compatibility study or relevant literature reference to be provided wherein aforementioned excipients found compatible with Drug substance**.

Routine applications.

1061	Name, address of Applicant / Marketing Authorization Holder	M/s Global Pharmaceuticals (Pvt) Ltd, Industrial Triangle, Kahuta Road, Islamabad.
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt) Ltd, Industrial Triangle, Kahuta Road, Islamabad.
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3415 dated 04/02/2022
	Details of fee submitted	PKR 30,000/-: dated 05/1/2022
	The proposed proprietary name / brand name	Nimoconil Tablet 500mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: - Azithromycin Dihydrate eq to Azithromycin…….....500mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use, Macrolides (J01FA10)
	Reference to Finished product specifications	USP
	Proposed Pack size	6’s
	Proposed unit price	As per policy
	The status in reference regulatory authorities	USFDA approved
	For generic drugs (me-too status)	Azitma 500mg tablet M/s Sami Pharmaceuticals (Pvt) Lyd Reg No 074900
	GMP status of the Finished product manufacturer	GMP certificate based on inspection dated 24.10.2018, valid for three years. Tablet General section has been approved vide letter dated 13.06.2017.

	Name and address of API manufacturer.	M/s Zhejiang Guobang Pharmaceutical Co Ltd No. 6 Wei Wu Road, HangZhou Gulf Shang Yu,Industrial zone, Zhejiang, P.R China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: B# 129-120715-11, B#129-120716-11, B# 129-120717-11
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the comparator product that is Azitma Tablet Batch No 0015 by Sami Pharmaceutical (Pvt) Ltd, by performing quality tests (Appearance, Assay, Dissolution etc) against Test product Nimocnil Tablet 500mg. Batch No ST20E018 CDP has been performed against the same brand that is Azitma Tablet Batch No 0015 in Acid media (pH 1.0-1.2), Acetate Buffer (pH 4.5) and Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API (pellets)	M/s Zhejang Guobang Pharmaceuticals Co Ltd China
API Lot No.	129-180206-1
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton 6's
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3,6,9,12,18 (Months)		
Batch No.	ST20E018	ST20E019	ST20E020
Batch Size	5000 tablets	5000 tablets	5000 tablets
Manufacturing Date	05-2020	05-2020	05-2020
Date of Initiation	11-05-2020	11-05-2020	11-05-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Provided
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No ZJ20190170 dated 11.30.2019 valid till 11.29.2024 issued by National Medical Products Administration.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted documents for import of 175Kg of azithromycin compacted (Batch No 129-180206-1) and Azithromycin micronized 50Kg (Batch No 129-180415-1). Attested by DRAP (I&E, Islamabad) dated 07.05.2018
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Provided
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor (DD PEC XX):

Sr.#	Observation	Reply	Remarks
1.	Analytical Method Verification studies performed by the Drug Product manufacturer not included specificity parameter and its HPLC Chromatograms	Under Analytical Method Verification studies chromatograms of Blank, Sample and Standard have been provided	Complied
2.	Justify selection of comparator product i.e Azitma Tablet by Sami Pharmaceutical (Pvt) Ltd for conducting pharmaceutical equivalence study/CDP instead of innovator brand.	Innovator pack was not available at the time of study that's why we performed CDP and Pharmaceutical equivalence study against locally available brand (Azitma Tablet by Sami	Justified

		Pharmaceutical (Pvt) Ltd) approved by DRAP	
3.	Analytical Method Verification studies of Drug Product, not included specificity parameter and its HPLC Chromatograms	Under Analytical Method Verification studies chromatograms of Blank, placebo, Sample and Standard have been provided	Complied

Remarks: Reply submitted against above mentioned shortcoming found satisfactory.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter will be issued after performance of pharmaceutical equivalence study/CDP against innovator brand i.e Azomax tablet**

1062.	Name, address of Applicant / Marketing Authorization Holder	M/s Next Pharmaceutical Products (Pvt.) Ltd., Plot # 44 A & B Sundar Industrial Estate, Lahore, Pakistan.
	Name, address of Manufacturing site.	M/s Next Pharmaceutical Products (Pvt.) Ltd., Plot # 44 A & B Sundar Industrial Estate, Lahore, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3889 dated 10.02.2022
	Details of fee submitted	Deposit slip No. 551560363986 PKR 30,000/-: dated 17/01/2022
	The proposed proprietary name / brand name	Dapa-M 5mg/850mg film coated tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dapagliflozin Propanediol monohydrate 6.5mg eq to Dapagliflozin…….5mg

		Metformin HCl…….850mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Dapagliflozin: Selective sodium –glucose cotransporter subtype 2 inhibitor with antihyperglycemic activity Metformin HCl: Biguanide class of antidiabetic.
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	10's, 14's, 20's, 28's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Xigduo film-coated tablets, Bristol-Myers Squibb/AstraZeneca EMA approved
	For generic drugs (me-too status)	Dapa-Met 5mg/850mg by M/s Hilton pharma Reg No 093071
	GMP status of the Finished product manufacturer	GMP certificate granted on 02/06/2022 Tablet (General), Capsule (General), Oral liquid (General), Cream and Ointment (General) & General Antibiotic) sections are approved.
	Name and address of API manufacturer.	Dapagliflozin: Jiangsu Yongan Pharmaceutical Co Ltd 18 Provincial Highway 237, Huaian Economic Development zone, Jiangsu. Metformin HCl: Aarti Drugs Ltd (Unit II) Plot No 211 & 213 Road 2 G.I.D.C At & Post Sarigam
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, physical form, manufacturers,

		description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: (Dapagliflozin propanediol monohydrate) Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (130401, 130402, 130501) Stability study conditions: (Metformin HCl) Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Batch No MEF/1410027, MEF/1410028, MEF/1410029 Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batch No : MET/17010010, MET/17010011, MET/17010012.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator that is Xigduo film-coated tablets, by Bristol-Myers Squibb/AstraZeneca (Batch No Z156A) by performing quality tests including Description, Average weight, Assay, Disintegration etc against Test product Dapa-Met 5/850mg Batch No T-0002TAN CDP has been performed against the same brand that is Xigduo film-coated tablets (Batch No Z156A) by Bristol-Myers Squibb/AstraZeneca in 0.1N HCl (QC medium), Acid media (0.1N HCl), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8 against Test product Dapa-Met 5/850mg Batch No T-0004TAN.

		The % drug release at 15 min was greater than 85% of both Test product and reference product hence f2 value was not calculated.
	Analytical method validation/verification of product	Firm has submitted report of validation studies of Drug Product.

STABILITY STUDY DATA			
Manufacturer of API	Dapagliflozin: Jiangsu Yongan Pharmaceutical Co Ltd 18 Provincial Highway 237, Huaian Economic Development zone, Jiangsu. Metformin HCl: Aarti Drugs Ltd (Unit II) Plot No 211 & 213 Road 2 G.I.D.C At & Post Sarigam		
API Lot No.	Metformin HCl MEF/10082862	Dapagliflozin Propanediol Monohydrate 7100-201910001	
Description of Pack (Container closure system)	Alu—Alu Blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-0002TAN	T-0003TAN	T-0004TAN
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	13-10-2020	13-10-2020	13-10-2020
Date of Initiation	08-01-2021	08-01-2021	08-01-2021
No. of Batches	03		
Administrative Portion			
Reference of previous approval of applications with stability study data of the firm (if any)	Not provided		

Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Dapagliflozin: Firm has submitted GMP certificate No JS2020921 in the name of Jiangsu Yongan Pharmaceutical Co Ltd 18 Provincial Highway 237, Huaian Economic Development zone, Jiangsu valid till 20.09.2025 Metformin HCl: Firm has submitted GMP certificate No. 20031933 in the name of M/s Aarti Drugs Ltd (Unit II) Plot No 211 & 213 Road 2 G.I.D.C At & Post Sarigam, valid till 19.03.2023
Documents for the procurement of API with approval from DRAP (in case of import).	Not provided
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability data in the form of COA summary data sheets and chromatograms. Raw data sheet and BMR of stability batches is not provided.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Assessor DD PECXX:

Firm has submitted reply as follows:

Sr.#	Observation	Reply	Remarks
1.	Valid Approval of API/ DML/GMP certificate of API i.e Metformin HCl manufacturer issued by concerned regulatory authority of country of origin	Firm has provided Retention of License No G/25/2038 dated 21.03.2014 valid from 21.03.2019 to 20.03.2024 issued by Food and Drug Control Administration Gujrat state. Product permission to manufacture Metformin HCl valid from 21.03.2019 to 20.03.2024 issued by Food and Drug Control Administration Gujrat state.	Complied

2.	Results of specificity parameter along with HPLC chromatograms (sample, standard and blank) of Metformin HCl has not been provided under Analytical method verification study of Drug Substance.	Provided	Complied
3.	As per public assessment report of innovator product Dissolution to be analyzed by HPLC method while applicant mentioned dissolution of Metformin HCl by UV-Vis spectroscopic method. Justify it	We have developed the Empagliflozin, Metformin and Dapagliflozin, Metformin combinations. We followed the same dissolution procedure for metformin HCl for both products. The reference of which is provided by FDA for Metformin HCl in Empagliflozin, Metformin Tablets, CENTER FOR DRUG EVALUATION AND RESEARCH, APPLICATION NUMBER:206111Orig1s000, which describes on Page 4, the Dissolution of Metformin HCl on HPLC/UV or UV spectrophotometry. We did validation by UV-VIS spectrophotometer and used for Metformin HCL dissolution in both products.	Verified UV spectrophotometry was mentioned to interchangeably use to determine Metformin HCl in dissolution method.
4.	The finished product specification and stability testing includes quality parameter of microbiological testing as per public assessment report of innovator product while same has not been performed by the applicant. https://www.ema.europa.eu/en/documents/assessment-report/xigduo-epar-public-assessment-report_en.pdf)	Microbiological testing reports of stability batches are provided	Complied
5.	Stability data including Raw data sheet and BMR of stability batches is not provided.	Provided	Complied
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has provided copy of commercial invoice No ZY19101701G/W dated Oct 17,2019 wherein	Complied

		Dapagliflozin propanediol monohydrate 500g was purchased Batch No 7100-201910001. Approved by DRAP dated 24.10.2019 Copy of commercial invoice No EXP/1456/20-21 dated 19/08/2020 wherein Metformin HCl 1000Kg was purchased Batch No MEF/10082862. Approved by DRAP dated 21.09.2020.	
Remarks: The reply submitted against above mentioned shortcomings found satisfactory.			

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1063	Name, address of Applicant / Marketing Authorization Holder	M/s Next Pharmaceutical Products (Pvt.) Ltd., Plot # 44 A & B Sundar Industrial Estate, Lahore, Pakistan.
	Name, address of Manufacturing site.	M/s Next Pharmaceutical Products (Pvt.) Ltd., Plot # 44 A & B Sundar Industrial Estate, Lahore, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3890 dated 10.02.2022
	Details of fee submitted	Deposit slip No. 59303532 PKR 30,000/-: dated 17/01/2022
	The proposed proprietary name / brand name	Dapa-M 5mg/1000mg film coated tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dapagliflozin Propanediol monohydrate 6.15mg eq to Dapagliflozin…….5mg

		Metformin HCl…….1000mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Dapagliflozin: Selective sodium –glucose cotransporter subtype 2 inhibitor with antihyperglycemic activity Metformin HCl: Biguanide class of antidiabetic.
	Reference to Finished product specifications	Innovator Specification
	Proposed Pack size	10's, 14's, 20's, 28's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Xigduo film-coated tablets, Bristol-Myers Squibb/AstraZeneca EMA approved
	For generic drugs (me-too status)	Dapa-Met 5mg/1000mg by M/s Hilton pharma Reg No 093072
	GMP status of the Finished product manufacturer	GMP certificate granted on 02/06/2022 Tablet (General), Capsule (General), Oral liquid (General), Cream and Ointment (General) & General Antibiotic) sections are approved.
	Name and address of API manufacturer.	Dapagliflozin: Jiangsu Yongan Pharmaceutical Co Ltd 18 Provincial Highway 237, Huaian Economic Development zone, Jiangsu. Metformin HCl: Aarti Drugs Ltd (Unit II) Plot No 211 & 213 Road 2 G.I.D.C At & Post Sarigam
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module III (Drug Substance)	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: (Dapagliflozin propanediol monohydrate) Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (130401, 130402, 130501) Stability study conditions: (Metformin HCl) Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Batch No MEF/1410027, MEF/1410028, MEF/1410029 Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months

		Batch No: MET/17010010, MET/17010011, MET/17010012.
	Module-III (Drug Product):	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator that is Xigduo film-coated tablets, by Bristol-Myers Squibb/AstraZeneca (Batch No Z454A) by performing quality tests including Description, Average weight, Assay, Disintegration etc against Test product Dapa-Met 5/1000mg Batch No T-0001TAO CDP has been performed against the same brand that is Xigduo film-coated tablets (Batch No Z454A) by Bristol-Myers Squibb/AstraZeneca in 0.1N HCl (QC medium), Acid media (0.1N HCl), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8 against Test product Dapa-Met 5/1000mg Batch No T-0001TAO. The % drug release at 15 min was greater than 85% of both Test product and reference product hence f2 value was not calculated.
	Analytical method validation/verification of product	Firm has submitted report of validation studies of Drug Product.

STABILITY STUDY DATA			
Manufacturer of API	Dapagliflozin: Jiangsu Yongan Pharmaceutical Co Ltd 18 Provincial Highway 237, Huaian Economic Development zone, Jiangsu. Metformin HCl: Aarti Drugs Ltd (Unit II) Plot No 211 & 213 Road 2 G.I.D.C At & Post Sarigam		
API Lot No.	Metformin HCl Monohydrate MEF/10082862	Dapagliflozin Propanediol 7100-201910001	
Description of Pack (Container closure system)	Alu—Alu Blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-0001TAO	T-0002TAO	T-0003TAO
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	09-11-2020	09-11-2020	03-12-2020
Date of Initiation	08-01-2021	08-01-2021	08-01-2021
No. of Batches	03		
Administrative Portion			
Reference of previous approval of applications with stability study data of the firm (if any)	Not provided		

Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Dapagliflozin: Firm has submitted GMP certificate No JS2020921 in the name of Jiangsu Yongan Pharmaceutical Co Ltd 18 Provincial Highway 237, Huaian Economic Development zone, Jiangsu valid till 20.09.2025 Metformin HCl: Firm has submitted GMP certificate No. 20031933 in the name of M/s Aarti Drugs Ltd (Unit II) Plot No 211 & 213 Road 2 G.I.D.C At & Post Sarigam, valid till 19.03.2023
Documents for the procurement of API with approval from DRAP (in case of import).	Not provided
Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted stability data in the form of COA summary data sheets and chromatograms. Raw data sheet and BMR of stability batches is not provided.
Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.
Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr.#	Observation	Reply	Remarks
1.	Valid Approval of API/ DML/GMP certificate of API i.e Metformin HCl manufacturer issued by concerned regulatory authority of country of origin	Firm has provided Retention of License No G/25/2038 dated 21.03.2014 valid from 21.03.2019 to 20.03.2024 issued by Food and Drug Control Administration Gujrat state. Product permission to manufacture Metformin HCl valid from 21.03.2019 to 20.03.2024 issued by Food and Drug Control Administration Gujrat state.	Complied
2.	Results of specificity parameter along with HPLC chromatograms (sample, standard and blank) of Metformin HCl has not been provided under Analytical method verification study of Drug Substance.	Provided	Complied
3.	As per public assessment report of innovator product Dissolution to be analyzed by HPLC method while applicant mentioned dissolution of Metformin HCl by UV-Vis spectroscopic method. Justify it	We have developed the Empagliflozin, Metformin and Dapagliflozin, Metformin combinations. We followed the same dissolution procedure for metformin HCl for both products.	Verified UV spectrophotometry was mentioned to interchangeably use to determine Metformin HCl in

		The reference of which is provided by FDA for Metformin HCl in Empagliflozin, Metformin Tablets, CENTER FOR DRUG EVALUATION AND RESEARCH, APPLICATION NUMBER:206111Orig1s000, which describes on Page 4, the Dissolution of Metformin HCl on HPLC/UV or UV spectrophotometry. We did validation by UV-VIS spectrophotometer and used for Metformin HCL dissolution in both products.	dissolution method.
4.	The finished product specification and stability testing includes quality parameter of microbiological testing as per public assessment report of innovator product while same has not been performed by the applicant. https://www.ema.europa.eu/en/documents/assessment-report/xigduo-epar-public-assessment-report_en.pdf)	Microbiological testing reports of stability batches are provided	Complied
5.	Stability data including Raw data sheet and BMR of stability batches is not provided.	Provided	Complied
6.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has provided copy of commercial invoice No ZY19101701G/W dated Oct 17,2019 wherein Dapagliflozin propanediol monohydrate 500g was purchased Batch No 7100-201910001. Approved by DRAP dated 24.10.2019 Copy of commercial invoice No EXP/1456/20-21 dated 19/08/2020 wherein Metformin HCl 1000Kg was purchased Batch No MEF/10082862. Approved by DRAP dated 21.09.2020.	Complied
Remarks: The reply submitted against above mentioned shortcomings found satisfactory.			

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1064	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma (Pvt) Ltd, Plot No 44-45B, Korangi Creek Road, Karachi
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt) Ltd, Plot No 44-45B, Korangi Creek Road, Karachi
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4786 dated 21/02/2022
	Details of fee submitted	PKR 30,000/-: dated 07/2/2022
	The proposed proprietary name / brand name	Lura Tablet 80mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: - Lurasidone HCl……....80mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	To treat Schizophrenia and Bipolar disorder
	Reference to Finished product specifications	Innovator specification
	Proposed Pack size	10’s, 30’s
	Proposed unit price	As per PRC
	The status in reference regulatory authorities	USFDA approved Latuda tablet
	For generic drugs (me-too status)	Lurisa 80mg tablet M/s Helix Pharma Reg No 089359

	GMP status of the Finished product manufacturer	GMP certificate dated 07.10.2021 based on inspection dated 15.06.2021 valid for two years. Tablet General section has been approved by CLB in 282nd meeting and letter issued dated 30.09.2021.
	Name and address of API manufacturer.	Jiangsu Yongan Pharmaceutical Co Ltd 18 Provincial Highway 237, Huaian Economic Development zone, Jiangsu.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 12months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: B# 101101, B#101201, B# 101202
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

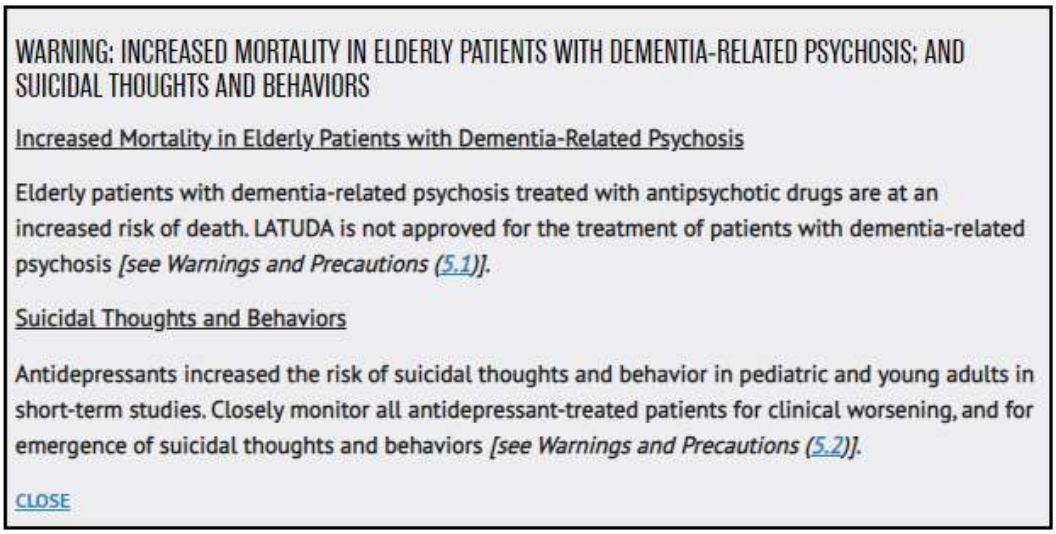
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the comparator product that is Lurisa 80mg Tablet Batch No Q003 by M/s Helix Pharma (Pvt) Ltd, by performing quality tests (Appearance, identification Assay, Dissolution, DT and average weight) against Test product Lura Tablet 80mg. Batch No21SB(A)173-01 CDP has been performed against the same brand that is Lurisa 80mg Tablet Batch No Q003 in Acid media (pH 1.0-1.2), Acetate Buffer (pH 4.5) and Phosphate Buffer (pH 6.8) against Test product Lura Tablet 80mg. Batch No21SB(A)173-01 The values for f1 and f2 are in the acceptable range.
	Analytical method validation studies of product	Method validation studies have been submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	Jiangsu Yongan Pharmaceutical Co Ltd 18 Provincial Highway 237, Huaian Economic Development zone, Jiangsu.		
API Lot No.	0200-202104001		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 3 months Accelerated: 3 months		
Frequency	Accelerated: 0, 3 (Months) Real Time: 0, 3 (Months)		
Batch No.	21SB(A)-173-01	21SB(A)-174-02	21SB(A)-175-03
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	07-2021	07-2021	07-2021

Date of Initiation		04-08-2021	04-08-2021	04-08-2021
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)		Not Provided	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.		Firm has submitted GMP certificate No JS2020921 in the name of Jiangsu Yongan Pharmaceutical Co Ltd 18 Provincial Highway 237, Huaian Economic Development zone, Jiangsu valid till 20.09.2025	
3.	Documents for the procurement of API with approval from DRAP (in case of import).		Not provided	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.		Firm has submitted all documents related to stability data i.e Chromatograms, Raw data sheets, COA, summary data sheets	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing		Provided	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)		Provided	

Remarks of Assessor (DD PEC XX):

Box warning by USFDA for approved product as follows:



WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS; AND SUICIDAL THOUGHTS AND BEHAVIORS

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. LATUDA is not approved for the treatment of patients with dementia-related psychosis *[see Warnings and Precautions (5.1)]*.

Suicidal Thoughts and Behaviors

Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adults in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors *[see Warnings and Precautions (5.2)]*.

CLOSE

S.No	Observation	Reply	Remarks

1.	The finished product specification and stability testing includes quality parameter of microbiological testing and water content as per public assessment report of innovator product while same has not been performed by the applicant. (microbial test performed at initial time point only https://www.ema.europa.eu/en/documents/assessment-report/latuda-epar-public-assessment-report_en.pdf	Water content test was performed during development study but not included in specification. Now firm has submitted revised specification wherein water content test was included. Moreover, microbiological testing will be performed at 24th month as well. As incorporated in protocol.	Complied Fee of Rs 7500/- to be submitted on account of pre-registration variation.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided	Not complied Name of API manufacturer mentioned on submitted documents is different.
3.	Stability data including summary data sheet, COA, raw data sheet and chromatograms for 6th month and onward (both accelerated and real time) to be provided.	Stability data including summary data sheet, COA, raw data sheet and chromatograms for 6th month was already submitted dated 07.06.2022	Verified

Decision: Deferred for following submissions:

- **Submission of documents for the procurement of API with approval from DRAP**
- **Submission of fee for pre-approval variation in finished product specification as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**

1065	Name, address of Applicant / Marketing Authorization Holder	M/s Sapient Pharma, 123/S, 104/S, Industrial area Kot Lakhpat, Lahore.
	Name, address of Manufacturing site.	M/s Bio-Mark Pharmaceuticals, Plot No. 527, Sunder-Industrial Estate, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5386 dated 25/02/2022
	Details of fee submitted	PKR 75,000/-: dated 20/1/2022
	The proposed proprietary name / brand name	Gosoft 20mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: - Omeprazole (as enteric coated pellets)...20mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved
	For generic drugs (me-too status)	Risek capsule 20mg by Getz Pharma Pakistan (Pvt) Ltd, Reg. No. 019364
	GMP status of the Finished product manufacturer	GMP certificate based on inspection dated 13.02.2020 valid for one year.
	Name and address of API (pellets) manufacturer.	M/s Vision Pharmaceuticals Pvt Ltd, Plot No 22-23, Industrial Triangle, Kahuta road, Islamabad
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.

	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: B#OMP065, B# OMP103, B# OMP083
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Risek Capsule 20mg Batch No 883C19 by Getz Pharma Pakistan (Pvt) Ltd, by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form and weight Variation, LOD and Assay) against Test product Helozem 20mg Capsule . CDP has been performed against the same brand that Risek Capsule 20mg in Acid media (pH 1.0-1.2), Acetate Buffer (pH 4.5) and Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API (pellets)	M/s Vision Pharmaceuticals Pvt Ltd, Plot No 22-23, Industrial Triangle, Kahuta road, Islamabad
API/Pellets Lot No.	OMP1006 and OMP1005
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×14's)
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3,6 (Months)		
Batch No.	21A505	21B506	21E525
Batch Size	561792 Capsules	138208 Capsules	420000 Capsules
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	01-03-2021	03-03-2021	05-03-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Nil
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. F.3-26/2019 Addl.Dir (QA&LT-I) dated 31.07.2019 based on inspection dated 11.02.2019 valid till 10.02.2022 issued by DRAP.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not applicable (pellets are from local source) Pellets of Batch No OMP1006 and OMP1005 have been purchased by M/s Bio Mark pharmaceuticals vide invoice no. 702111
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	CoA / Raw data sheet at each time interval to be submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Assessor (DD PEC XX):

Sr.#	Observation	Reply	Remarks

1.	Evidence for section approval (Capsule General) of M/s Bio-Mark pharmaceuticals, Lahore to be provided	Firm has provided evidence for section approval i.e Capsule General dated 12th June 2017.	Complied
2.	Valid Approval of API/ DML/GMP certificate of API manufacturer issued by DRAP.	Firm has provided copy of GMP certificate dated 22.08.2022 based on inspection dated 14.06.2022. Valid for 2 years.	Complied
3.	Analytical Method Verification studies of Drug substance including specificity, accuracy and repeatability (method precision) performed by Drug Product manufacturer to be provided	Summary report including results of parameters such as linearity, accuracy precision (repeatability and intermediate precision) has been submitted for "omeprazole capsule"	
4.	CoA at each time interval to be submitted	Provided	Complied
5.	Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.	Digital data logger for temperature and humidity monitoring is submitted	Complied

Remarks: Analytical Method Verification studies of omeprazole pellets is required.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1066	Name, address of Applicant / Marketing Authorization Holder	M/s Sapient Pharma, 123/S, 104/S, Industrial area Kot Lakhpat, Lahore.
	Name, address of Manufacturing site.	M/s Bio-Mark Pharmaceuticals, Plot No. 527, Sunder-Industrial Estate, Lahore.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)

	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5387 dated 25/02/2022
	Details of fee submitted	PKR 75,000/-: dated 20/1/2022
	The proposed proprietary name / brand name	Gosoft 40mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: - Omeprazole (as enteric coated pellets)...40mg
	Pharmaceutical form of applied drug	Capsule
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved
	For generic drugs (me-too status)	Risek capsule 40mg by Getz Pharma Pakistan (Pvt) Ltd, Reg. No. 022109
	GMP status of the Finished product manufacturer	GMP certificate based on inspection dated 13.02.2020 valid for one year.
	Name and address of API (pellets) manufacturer.	M/s Vision Pharmaceuticals Pvt Ltd, Plot No 22-23, Industrial Triangle, Kahuta road, Islamabad
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference

		standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: B#OMP065, B# OMP103, B# OMP083
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Risek Capsule 40mg Batch No 779D18 by Getz Pharma Pakistan (Pvt) Ltd,.by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form and weight Variation, LOD and Assay) against Test product Helozem 40mg Capsule . CDP has been performed against the same brand that Risek Capsule 40mg in Acid media (pH 1.0-1.2), Acetate Buffer (pH 4.5) and Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API (pellets)	M/s Vision Pharmaceuticals Pvt Ltd, Plot No 22-23, Industrial Triangle, Kahuta road, Islamabad
API/Pellets Lot No.	OMP1006 and OMP1005
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (1×14's)
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0, 3,6 (Months)

		Real Time: 0, 3,6 (Months)		
Batch No.		21A506	21D523	21E524
Batch Size		28000 Capsules	134624 Capsules	144816 Capsules
Manufacturing Date		02-2021	02-2021	02-2021
Date of Initiation		02-2021	02-2021	02-2021
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Nil		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. F.3-26/2019 Addl.Dir (QA&LT-I) dated 31.07.2019 based on inspection dated 11.02.2019 valid till 10.02.2022 issued by DRAP.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not applicable (pellets are from local source) Pellets of Batch No OMP1006 and OMP1005 have been purchased by M/s Bio Mark pharmaceuticals vide invoice no. 702111		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	CoA / Raw data sheet at each time interval to be submitted		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted		

Remarks of Assessor (DD PEC XX):

Sr.#	Observation	Reply	Remarks
1.	Evidence for section approval (Capsule General) of M/s Bio-Mark pharmaceuticals, Lahore to be provided	Firm has provided evidence for section approval i.e Capsule General dated 12th June 2017.	Complied

2.	Valid Approval of API/ DML/GMP certificate of API manufacturer issued by DRAP.	Firm has provided copy of GMP certificate dated 22.08.2022 based on inspection dated 14.06.2022. Valid for 2 years.	Complied
3.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the both Drug Substance and Drug Product manufacturer to be provided	Summary report including results of parameters such as linearity, accuracy precision (repeatability and intermediate precision) has been submitted for "omeprazole capsule"	
4.	CoA at each time interval to be submitted	Provided	Complied
5.	Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.	Digital data logger for temperature and humidity monitoring is submitted	Complied

Remarks: Analytical Method Verification studies of omeprazole pellets is required.

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1067	Name, address of Applicant / Marketing Authorization Holder	M/s Getz Pharma Pvt Ltd, Plot No 29-30, Sector 27, Korangi Industrial Area Karachi.
	Name, address of Manufacturing site.	M/s Getz Pharma Pvt Ltd, Plot No 29-30, Sector 27, Korangi Industrial Area Karachi.
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale

		☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5390 dated 27/01/2022
	Details of fee submitted	PKR 30,000/-: dated 27/1/2022
	The proposed proprietary name / brand name	Obico Tablet 5mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: - Obeticholic acid……....5mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Bile Acid and Derivatives (A05AA04)
	Reference to Finished product specifications	Not mentioned
	Proposed Pack size	10's, 20's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved
	For generic drugs (me-too status)	Abeticholic acid tablet 5mg M/s Dyson Research Lab Reg No 109521
	GMP status of the Finished product manufacturer	GMP certificate based on inspection dated 13.01.2022 valid for two years. Tablet General section has been approved vide DML renewal approval letter dated 30.10,2019
	Name and address of API (pellets) manufacturer.	M/s Zenji Pharmaceuticals (SUZHOU) Ltd No 122 Xuquin Road, Xuguan town, Suzhou, Jiangsu, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical

		form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 25°C ± 2°C / 60% ± 5%RH for 12 months Accelerated: 2-8° C for 6 months Batches: B#3A421912241, B#3A421912191, B# 3A421912131
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator product that is Ocaliva Tablet Batch No CE00030H by Intercept Pharma (Dublin Ireland) by performing quality tests (Appearance, Assay, Dissolution, weight Variation) against Test product Obico Tablet 10mg. Batch No 543DS02 CDP has been performed against the same brand that is Ocaliva Tablet Batch No CE00030H in Acid media (pH 1.0-1.2), Acetate Buffer (pH 4.5) and Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API (pellets)	M/s Zenji Pharmaceuticals (SUZHOU) Ltd No 122 Xuquin Road, Xuguan town, Suzhou, Jiangsu, China.
API Lot No.	1778-145-18
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (10's,20's and 30's)
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3,6,9,12 (Months)		
Batch No.	543DS01	543DS02	543DS03
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	07-2020	08-2020	08-2020
Date of Initiation	01-09-2020	01-09-2020	01-09-2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Nil
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML No Su 20170537 dated 07.12.2020 valid till 22.11.2025 issued by Jiangsu Drug Administration.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted documents for import of 0.75Kg of Obeticholic acid (Batch No 1778-145-18) invoice no. 20ATGZ083 dated 17.06.2020 . Attested by DRAP (I&E, Islamabad) dated 26.06.2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Provided
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor (DD PEC XX):

Sr.#	Observation	Reply	Remarks

1.	Analytical Method Verification studies of Drug Substance including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided	Provided	HPLC chromatograms for different parameters tested (specificity, accuracy and repeatability etc) during verification study have not been provided Moreover data of specificity Parameter has not been provided
2.	Complete CDP report to be provided along with calculation of f1 and f2 values	Provided	Complied CDP has been performed against the same brand that is Ocaliva Tablet Batch No CE00030H in Acid media (pH 1.0-1.2), Acetate Buffer (pH 4.5) and Phosphate Buffer (pH 6.8) against Test product i.e Batch No 543DS02
3.	Physicochemical characteristics of the active substance that impact the quality of the finished product are particle size distribution which plays a critical role in the content uniformity and dissolution of the tablets. https://www.ema.europa.eu/en/documents/assessment-report/ocaliva-epar-public-assessment-report_en.pdf However, particle size distribution of active substance has not been controlled /performed either by Drug substance or Dug product manufacturer	Updated CoA from DS manufacturer is provided wherein particle size distribution has been performed	Complied

4.	Title of Drug substance manufacturer mentioned on GMP /DML as M/s Zenji Pharmaceuticals (SUZHOU) Ltd while title of manufacturer mentioned on commercial invoice as Jiangsu Zenji Pharmaceuticals Ltd. Clarify it.	Declaration has been provided from M/s Zenji Pharmaceuticals (SUZHOU) i.e M/s Zenji Pharmaceuticals (SUZHOU) is subsidiary company of Jiangsu Zenji Pharmaceuticals Ltd. However the production site is M/s Zenji Pharmaceuticals (SUZHOU) No 122 Xuquin Road, Xuguan town, Suzhou, Jiangsu, China.	Complied

Remarks: The reply submitted against above mentioned shortcomings was found unsatisfactory

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter will be issued after submission of results of specificity Parameter under Analytical Method Verification studies of Drug Substance**

1068	Name, address of Applicant / Marketing Authorization Holder	M/s Getz Pharma Pvt Ltd, Plot No 29-30, Sector 27, Korangi Industrial Area Karachi.
	Name, address of Manufacturing site.	M/s Getz Pharma Pvt Ltd, Plot No 29-30, Sector 27, Korangi Industrial Area Karachi.
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 5391 dated 25/02/2022
	Details of fee submitted	PKR 30,000/-: dated 27/1/2022

	The proposed proprietary name / brand name	Obico Tablet 10mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: - Obeticholic acid……....10mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Bile Acid and Derivatives (A05AA04)
	Reference to Finished product specifications	Not mentioned
	Proposed Pack size	10's, 20's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved
	For generic drugs (me-too status)	Abeticholic acid tablet 10mg M/s Dyson Research Lab Reg No 109522
	GMP status of the Finished product manufacturer	GMP certificate based on inspection dated 13.01.2022 valid for two years. Tablet General section has been approved vide DML renewal approval letter dated 30.10,2019
	Name and address of API (pellets) manufacturer.	M/s Zenji Pharmaceuticals (SUZHOU) Ltd No 122 Xuquin Road, Xuguan town, Suzhou, Jiangsu, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 25°C ± 2°C / 60% ± 5%RH for 12 months Accelerated: 2-8° C for 6 months Batches: B#3A421912241, B#3A421912191, B# 3A421912131
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.

	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the innovator product that is Ocaliva Tablet Batch No CE00031J by Intercept Pharma (Dublin Ireland), by performing quality tests by performing quality tests (Appearance, Assay, Dissolution, weight Variation)) against Test product Obico Tablet 10mg. Batch No 545DS02 CDP has been performed against the same brand that is Ocaliva Tablet Batch No CE00031J in Acid media (pH 1.0-1.2), Acetate Buffer (pH 4.5) and Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API (pellets)	M/s Zenji Pharmaceuticals (SUZHOU) Ltd No 122 Xuquin Road, Xuguan town, Suzhou, Jiangsu, China.		
API Lot No.	1778-145-18		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (10's,20's and 30's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3,6,9,12 (Months)		
Batch No.	545DS01	545DS02	545DS03
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	08-2020	08-2020	08-2020
Date of Initiation	01-09-2020	01-09-2020	01-09-2020
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Nil
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML No Su 20170537 dated 07.12.2020 valid till 22.11.2025 issued by Jiangsu Drug Administration.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted documents for import of 0.75Kg of Obeticholic acid (Batch No 1778-145-18) invoice no. 20ATGZ083 dated 17.06.2020 . Attested by DRAP (I&E, Islamabad) dated 26.06.2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Provided

5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor (DD PEC XX):

Sr.#	Observation	Reply	Remarks
1.	Analytical Method Verification studies of Drug Substance including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided	Provided	HPLC chromatograms for different parameters tested (specificity, accuracy and repeatability etc) during verification study have not been provided Moreover data of specificity Parameter has not been provided
2.	Complete CDP report to be provided along with calculation of f1 and f2 values	Provided	Complied CDP has been performed against the same brand that is Ocaliva Tablet Batch No CE00031J in Acid media (pH 1.0-1.2), Acetate Buffer (pH 4.5) and Phosphate Buffer (pH 6.8) against Test product i.e Batch No Batch No 545DS02
3.	Physicochemical characteristics of the active substance that impact the quality of the finished product are particle size distribution which plays a critical role in the content uniformity and dissolution of the tablets. https://www.ema.europa.eu/en/documents/assessment-report/ocaliva-epar-public-assessment-report_en.pdf However, particle size distribution of active substance has not been controlled /performed either by Drug substance or Dug product manufacturer	Updated CoA from DS manufacturer is provided wherein particle size distribution has been performed	Complied

4.	Title of Drug substance manufacturer mentioned on GMP /DML as M/s Zenji Pharmaceuticals (SUZHOU) Ltd while title of manufacturer mentioned on commercial invoice as Jiangsu Zenji Pharmaceuticals Ltd. Clarify it.	Declaration has been provided from M/s Zenji Pharmaceuticals (SUZHOU) i.e M/s Zenji Pharmaceuticals (SUZHOU) is subsidiary company of Jiangsu Zenji Pharmaceuticals Ltd. However the production site is M/s Zenji Pharmaceuticals (SUZHOU) No 122 Xuquin Road, Xuguan town, Suzhou, Jiangsu, China.	Complied

Remarks: The reply submitted against above mentioned shortcomings was found unsatisfactory

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration letter will be issued after submission of results of specificity Parameter under Analytical Method Verification studies of Drug Substance**

1069	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceutical (Pvt) Ltd, Plot No 129, Sunder Industrial Estate, Raiwind Road, Lahore
	Name, address of Manufacturing site.	M/s Wimits Pharmaceutical (Pvt) Ltd, Plot No 129, Sunder Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales

	Dy. No. and date of submission	Dy. No. 4784 dated 21/02/2022
	Details of fee submitted	PKR 30,000/-: dated 20/1/2022
	The proposed proprietary name / brand name	Quwa 200mg XR Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each extended release tablet contains: - Quetiapine as fumarate……....200mg
	Pharmaceutical form of applied drug	Extended release tablet
	Pharmacotherapeutic Group of (API)	Atypical antipsychotic WHO ATC code: N05AH04
	Reference to Finished product specifications	USP specification
	Proposed Pack size	10's
	Proposed unit price	As per rule
	The status in reference regulatory authorities	USFDA approved Seroquel 200mg tablet Astrazeneca
	For generic drugs (me-too status)	Qusel 200mg XR tablet M/s Hilton Pharma Reg No 067500
	GMP status of the Finished product manufacturer	GMP certificate dated 08.09.2021 based on inspection dated 08.09.2021 valid for two years. Tablet General section has been approved by CLB in 233rd meeting and letter issued dated 07.02.2014.
	Name and address of API manufacturer.	M/s Hema Pharmaceutical Pvt Ltd Plot No 6201/A &B. G.I.D.C opp EWAC Alloys, Ankleshwar-393 002, Dist-Bharuch
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form,

		manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 48months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: B# 16QF006, B#17QF001, B# 17QF002
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the comparator product that is Qusel 200mg XR Tablet by M/s Hilton Pharma, Karachi by performing quality tests (Appearance, identification Assay) against Test product CDP has been performed against the same brand that is Qusel 200mg XR Tablet in Acid media (pH 1.0-1.2), Acetate Buffer (pH 4.5) and Phosphate Buffer (pH 6.8) against Test product Sample was taken after 1, 6, 12 and 20 hours The values for f1 and f2 are in the acceptable range.
	Analytical method validation studies of product	Method validation studies have been submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA	
Manufacturer of API	M/s Hema Pharmaceutical Pvt Ltd Plot No 6201/A &B. G.I.D.C opp EWAC Alloys, Ankleshwar-393 002, Dist- Bharuch
API Lot No.	20QF0013
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton

Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3,6 (Months)		
Batch No.	TQX001	TQX002	TQX003
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	05-2021	05-2021	05-2021
Date of Initiation	12-05-2021	15-05-2021	18-05-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Provided
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted GMP certificate No S-GMP/2062028 in the name of M/s Hema Pharmaceutical Pvt Ltd Plot No 6201/A &B. G.I.D.C opp EWAC Alloys, Ankleshwar-393 002, Dist- Bharuch valid till 11.06.2022
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted commercial invoice No Exp-016 dated 04/07/2020 Batch No 20QF0013for 25Kg Quetiapine fumarate from M/s Hema Pharmaceutical Pvt Ltd Approval from DRAP (I&E Lahore) dated 23.07.2020
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted all documents related to stability data i.e Chromatograms, Raw data sheets, COA, summary data sheets
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not Provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Remarks of Assessor (DD PEC XX):

S.No	Observations	Reply	Remarks
1.	Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin	Firm has provided copy of GMP certificate No 21012394 Dated 05/01/2021 valid till 04/01/2024 issued by Food and Drug Control Administration, Gujrat	Complied
2.	Batch No of comparator and Test product used in Pharmaceutical equivalence study/CDP, to be provided	Qusel 200mg XR Tablet by M/s Hilton Pharma, Karachi Batch No : 135352	Complied
3.	Compliance Record of HPLC software 21CFR & audit trail reports to be provided.	Provided	Complied

Decision: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Deferred cases:

Deferred case of 324th meeting:

1070	Name, address of Applicant / Marketing Authorization Holder	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 33 Punjab Industrial Estate Lahore.
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot no. 33 Punjab Industrial Estate Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☒ New Drug Product (NDP) ☐Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐Domestic and Export sales
	Dy. No. and date of submission	Dy. No 12205 dated 19-05-2022
	Details of fee submitted	Rs.75,000/- dated 11-05-2022
	The proposed proprietary name / brand name	Imeglu Tablet 500mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated tablet contains: Imeglimin Hydrochloride.....500mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-Diabetic
	Reference to Finished product specifications	As Per Innovator's specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Twymeeg Tablet 500mg approved by (PMDA Japan)
	For generic drugs (me-too status)	Not available
	GMP status of the Finished product manufacturer	Last inspection report dated 18.06.2020. certificate issued on 06.07.2020 concluded good level of cGMP compliance. Valid for 2 years Evidence for section approval (Tablet General section) provided dated 07.02.2014
	Name and address of API manufacturer.	AMI Life Sciences Pvt Ltd. Block No.82/B, ECP Road, At & Post: Kararkhadi- Tal- Padra, Dist: Baroda Gujrat India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to structure, general properties, Manufacturers, description of manufacturing process and controls,

<table>
<tr><td></td><td></td><td>Characterization, Impurities, Specifications, Analytical procedures, Validation of analytical procedure, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.</td></tr>
<tr><td></td><td>Module III (Drug Substance)</td><td>The firm as submitted detail of General information, General properties, Manufacturers, description of manufacturing process and process controls, Characterization, Impurities, Control of drug substance, Reference standard or materials container closure system and stability studies of drug substance.</td></tr>
<tr><td></td><td>Stability studies</td><td>Stability study conditions:
Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months
Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months

Imeglimin HCl:
<table><tr><td>Batch No</td><td>Accelerated</td><td>Long Term</td></tr><tr><td>IME/RD/30011221V</td><td>6 Months</td><td>60 Months</td></tr><tr><td>IME/RD/30021221V</td><td>6 Months</td><td>60 Months</td></tr><tr><td>IME/RD/30031221V</td><td>6 Months</td><td>60 Months</td></tr></table></td></tr>
<tr><td></td><td>Module-III (Drug Product):</td><td>The firm has submitted detail of Drug Products including Description and composition of drug product, Pharmaceutical Development, Manufacturing process development, Microbiological attribution, Manufacturer, Master formulations, Description of Manufacturing Process and Process Controls, Control of Critical Steps and Intermediates, Process Validation and/ or Evaluation, Control of Excipients with specification and Analytical methods, Control of Drug Products including Finished product specifications and test methods, validation of Analytical methods, Batch analysis , reference standard, Container closure and stabilities studies.</td></tr>
<tr><td></td><td>Pharmaceutical equivalence and comparative dissolution profile</td><td>Pharmaceutical Equivalence have been established against the brand leader that is Twymeeg Tablets 500mg by BioPharma (Batch No 1001C) by performing quality tests (Identification, Assay, DT, Hardness, weight variation and Dissolution against test product Imeglimin HCl tablet (Batch No PTIM-001)

CDP has been performed against the same brand that is in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.</td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>Method verification studies have submitted including Specificity, Accuracy, Precision, Linearity concentration and peak range.</td></tr>
<tr><td colspan="3">STABILITY STUDY DATA</td></tr>
</table>

Manufacturer of API		AMI Life Sciences Pvt Ltd.	
API Lot No.		IME/RD/30051221V	
Description of Pack (Container closure system)		Alu-Alu Blisters with aluminum foil having leaflet and packed in unit carton	
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Period		Real time: 3 months Accelerated: 3months	
Frequency		Accelerated: 0, 3 months Real Time: 0, 3 months	
Batch No.		IM-001	IM-002
Batch Size		5000 Tab	5000 Tab
Manufacturing Date		02-2022	02-2022
Date of Initiation		17-02-2022	18-02-2022
No. of Batches		02	
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product: EMPAZON 10mg Tablets, EMPAZON 25mg Tablets (Empagliflozin) Dayzol 30mg Capsules, Dayzol 60mg Capsules (Dexlansoprazole) which was conducted on 1st June, 2021 and was presented in 307th meeting of Registration Board held on 08-10th June , 2021. Registration Board decided to approve registration of EMPAZON 10mg Tablets, EMPAZON 25mg Tablets (Empagliflozin) Dayzol 30mg Capsules, Dayzol 60mg Capsules	

<table>
<tr><td></td><td></td><td>(Dexlansoprazole)</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Firm had provided valid DML (No. G/25/1704) of
AMI Life Sciences Pvt Ltd. Issued by Food and Drug Control Administration, Gujrat state India
DML Valid upto: 14- 06- 2025</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of commercial invoice attested by AD I&E DRAP, Lahore, has been submitted
<table>
<tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr>
<tr><td>IME/RD/30051221V</td><td>ALPL/Sample-00251/20-21</td><td>6.00kgs</td><td>18-01-2022
Ref No 885/2022 DRAP</td></tr>
</table></td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms,
Raw data sheets, COA, summary data sheets etc.</td><td>Submitted</td></tr>
<tr><td>5.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing</td><td>Audit trail reports have been submitted.</td></tr>
<tr><td>6.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers.</td></tr>
<tr><td colspan="3">Remarks of Assessor (AD-PECXX):
<table>
<tr><th>Sr.#</th><th>Observation</th><th>Reply</th><th>Remarks</th></tr>
<tr><td>1.</td><td>Data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc to be submitted at 6th month and onward.</td><td>Firm has provided 6th month stability data supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc to</td><td>Complied</td></tr>
</table></td></tr>
<tr><td colspan="3">Discussion & Decision: Registration Board was apprised regarding the CDP results of applied formulation from two different applicants i.e., M/s Horizon Healthcare and M/s NabiQasim Industries wherein conflicting results were reported despite of using same reference product i.e TWYMEEG Tablet 500mg.
In the CDP data presented by M/s Horizon Healthcare maximum drug release was reported in phosphate buffer of pH 6.8 while the CDP data of M/s Nabiqasim Industries reported minimum drug release in phosphate buffer of pH 6.8.</td></tr>
</table>

On basis of above cited observation Board decided to defer the instant application for justification of the reported results of CDP studies, with reference to the innovator drug product literature.

Reply:

Now M/s Horizon Healthcare, Lahore and M/s Nabiqasim Industries, Karachi have submitted reply as follows:

Comparison of Dissolution profile results of Twymeeg Tablet 500 mg

tested by Horizon Healthcare (Pvt.) Ltd. And Nabiqasim Industries (Pvt.) Ltd.

Dissolution Media (Phosphate Buffer pH 6.8)		
Time Point (min)	Twymeeg dissolution analyzed by Horizon (%)	Twymeeg dissolution analyzed by Nabiqasim (%)
5	42.11	-
10	68.32	51.57
15	86.14	67.85
20	90.71	86.62
30	97.78	97.33
45	96.99	97.59
60	96.61	97.54

Dissolution Media (Acetate Buffer pH 4.5)		
Time Point (min)	Twymeeg dissolution analyzed by Horizon (%)	Twymeeg dissolution analyzed by Nabiqasim (%)
5	24.99	-
10	45.97	46.79
15	63.50	68.07
20	74.91	80.56
30	84.27	87.32
45	93.49	88.28
60	93.47	88.51

Dissolution Media (0.1 M Hydrochloric Acid)		
Time Point (min)	Twymeeg dissolution analyzed by Horizon (%)	Twymeeg dissolution analyzed by Nabiqasim (%)
5	24.26	-
10	43.90	67.10

15	62.04	86.30
20	71.92	95.94
30	92.79	-
45	93.11	-
60	92.77	-

It is evident from above cited results that more than 80% of drug release is achieved within 30 minutes in all three dissolution medias of pH 1.2, 4.5 and 6.8, hence it could be stated that the average results comply the profile of an immediate release drug product and there is no major disparity among the release profile of innovator product submitted by both firms. The only slight variation in results at few time points of 0.1N HCl may please be attributed to the analytical variation

Remarks of Assessor (DD PECXX):

Although more than 80% of drug release is achieved within 30 minutes in all three dissolution medias of pH 1.2, 4.5 and 6.8 yet striking differences in CDP profile were observed at 15min.

Both firms may be asked to submit packs of innovator product of relevant batch no, used in performing CDP.

Submitted for consideration of Registration Board please.

Discussion & Decision: Registration Board considered the fact that the resulst of f2 similarity factor were above 50, for the Dissolution profiles of the innovator product by M/s NabiQasim Industries & M/s Horizon Laboratories, hence Board decided to approve Imeglu Tablet 500mg of M/s Horizon Healthcare.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1071.	Name, address of Applicant / Marketing Authorization Holder	M/s NABIQASIM INDUSTRIES (PVT) LTD. 17 / 24, Korangi Industrial Area, Karachi – Pakistan.
	Name, address of Manufacturing site.	M/s NABIQASIM INDUSTRIES (PVT) LTD. 17 / 24, Korangi Industrial Area, Karachi – Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 19518 dated 04.07.2022 6th month stability data submitted on 02.09.2022 (Dy No. 24945)
	Details of fee submitted	PKR 75,000/- dated 21/06/2022
	The proposed proprietary name / brand name	MEGLIM Tablets 500mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet: Imeglimin Hydrochloride…..…500mg
	Pharmaceutical form of applied drug	White color oblong shape film coated tablet one side engraved NQ and other side is plain.
	Pharmacotherapeutic Group of (API)	Drugs used in diabetes, Other blood glucose lowering drugs, excl. insulins.
	Reference to Finished product specifications	Innovator's Specs.
	Proposed Pack size	10's, 14's, 20's,28's, 30's, 50's, 56's tablets
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	TWYMEEG Tablet 500mg (Imeglimin Hydrochloride) by Sumitomo Dainippon Pharma Co., Ltd., Japan (Approved by Pharmaceutical and Medical Devices Agency, Japan).
	For generic drugs (me-too status)	Not available in Pakistan
	GMP status of the Finished product manufacturer	GMP Certificate granted on 28/05/2022 based on inspection dated 19.09.2020. Evidence for Section approval is provided dated 27.04.2020. Tablet (General) section is approved.
	Name and address of API manufacturer.	M/s Anhui Haikang Pharmaceutical Co. Ltd.

		No. 21, Hauncheng West Road Anqing Anhui 246000, China
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification / validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official Monograph of Imeglimin Hydrochloride is not available hence In-house (Manufacturer's) specifications were adopted. The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for related substances (Single impurity, Total impurities), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 9 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: (21061501, 21062201, 21062901)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is TWYMEEG Tablet 500mg (Imeglimin Hydrochloride) is being marketed by Sumitomo Dainippon Pharma Co., Ltd., Japan, (Batch No 1004F) by performing quality tests (Description, Identification, Disintegration, Dissolution, Impurities and Assay) against Meglim tablet 500mg (Batch No 538DS01) CDP has been performed against the same brand that is TWYMEEG Tablet 500mg (Imeglimin Hydrochloride) by Sumitomo Dainippon Pharma Co., Ltd., Japan, in Acid media (pH 1.2), Acetate Buffer (pH 4.5) & Phosphate Buffer (6.8). The values for f1 and f2 are in the acceptable range.

	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.		
STABILITY STUDY DATA				
Manufacturer of API		M/s Anhui Haikang Pharmaceutical Co. Ltd. No. 21, Hauncheng West Road Anqing Anhui 246000, China		
API Lot No.		21112901		
Description of Pack (Container closure system)		Alu-Alu blister of 10's, 14's, 20's & 28's, 30's, 50's & 56's tablets packed in unit carton.		
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		538DS01	538DS02	538DS03
Batch Size		650 tablets	650 tablets	650 tablets
Manufacturing Date		02-2022	02-2022	02-2022
Date of Initiation		20-02-2022	20-02-2022	20-02-2022
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Submitted.		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate issued by Anqing Biomedical Industry Association, China valid till 25/01/2025		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of invoice no WD202101004 dated 01/12/2021 duly attested by Assistant Director, DRAP, Karachi on 06/12/2021 was provided, confirming import of 2.1Kg Imeglimin HCl . Batch No 21112901		
4.	Data of stability batches will be supported by attested respective documents like	Submitted		

	chromatograms, Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Assesor (AD-PEC XX):

<table>
<tr><th>Sr.#</th><th>Observation</th><th>Reply</th><th>Remarks</th></tr>
<tr><td>1.</td><td>The proposed specification of Drug Substance includes residue on ignition as per Report on deliberation results of Twymeeg Tablets 500 mg by PMDA, same has not been tested by Drug substance manufacturer. Justify it

API</td><td>Reference to the “Report on deliberation results of Twymeeg Tablets 500mg by PMDA, we have conducted Residue on Ignition Test on retention sample of API and found below results :
<table><tr><th>S.No</th><th>Specifications</th><th>Results</th></tr><tr><td>01</td><td>Residue on ignition (NMT 0.1%)</td><td>0.07%</td></tr></table>
Revise API specifications for QC release having Residue on ignition test is provided</td><td>Complied

Firm has submitted revised analytical testing method and CoA, wherein “Residue on ignition” is tested, by Finished product manufacturer.</td></tr>
<tr><td>2.</td><td>The proposed specification of Drug Product includes uniformity of dosage units (mass variation test) as per Report on deliberation results of Twymeeg Tablets 500 mg by PMDA same has not been tested by finished product manufacturer. Justify it</td><td>We have previously submitted COAs of Imeglimin HCl Tablets 500mg at Initial testing having uniformity of dosage units by mass variation test same enclose in for ready reference.

We also conducted weight variation test as on today basis, results of the same are enclose in Annexure-B.</td><td>Complied

Uniformity of dosage units was performed at initial testing in stability studies , same was mentioned in CoA (NMT 15)</td></tr>
</table>

3.	3% overage is added to compensate water content as mentioned in batch formula, need further deliberation.	In formulation of Imeglimin HCl Tablet, there is no bulking agent used for potency adjustment so potency calculation is set on basis of results of water content as Drug substance having maximum limit of 5% water content , we have set median limit of 3% water content in our batch formula to comply the product assay results on QC release specifications i.e. 95% - 105% of label claim to assure product quality for patient compliance.	

Discussion & Decision 324th meeting : Registration Board was apprised regarding the CDP results of applied formulation from two different applicants i.e., M/s Horizon Healthcare and M/s Nabiqasim Industries wherein conflicting results were reported despite of using same reference product i.e TWYMEEG Tablet 500mg.

In the CDP data presented by M/s Horizon Healthcare maximum drug release was reported in phosphate buffer of pH 6.8 while the CDP data of M/s Nabiqasim Industries reported minimum drug release in phosphate buffer of pH 6.8.

On basis of above cited observation Board decided to defer the instant application for justification of the reported results of CDP studies, with reference to the innovator drug product literature along with scientific justification of using 3%overage of drug substance in the drug product formulation.

Reply:

Now M/s Horizon Healthcare, Lahore and M/s Nabiqasim Industries, Karachi have submitted reply as follows:

Comparison of Dissolution profile results of Twymeeg Tablet 500 mg

tested by Horizon Healthcare (Pvt.) Ltd. And Nabiqasim Industries (Pvt.) Ltd.

Dissolution Media (Phosphate Buffer pH 6.8)		
Time Point (min)	Twymeeg dissolution analyzed by Horizon (%)	Twymeeg dissolution analyzed by Nabiqasim (%)
5	42.11	-
10	68.32	51.57
15	86.14	67.85
20	90.71	86.62
30	97.78	97.33
45	96.99	97.59
60	96.61	97.54

Dissolution Media (Acetate Buffer pH 4.5)		
Time Point (min)	Twymeeg dissolution analyzed by Horizon (%)	Twymeeg dissolution analyzed by Nabiqasim (%)
5	24.99	-
10	45.97	46.79
15	63.50	68.07
20	74.91	80.56
30	84.27	87.32
45	93.49	88.28
60	93.47	88.51

Dissolution Media (0.1 M Hydrochloric Acid)		
Time Point (min)	Twymeeg dissolution analyzed by Horizon (%)	Twymeeg dissolution analyzed by Nabiqasim (%)
5	24.26	-
10	43.90	67.10
15	62.04	86.30
20	71.92	95.94
30	92.79	-
45	93.11	-
60	92.77	-

It is evident from above cited results that more than 80% of drug release is achieved within 30 minutes in all three dissolution medias of pH 1.2, 4.5 and 6.8, hence it could be stated that the average results comply the profile of an immediate release drug product and there is no major disparity among the release profile of innovator product submitted by both firms. The only slight variation in results at few time points of 0.1N HCl may please be attributed to the analytical variation.

Regarding scientific justification of using 3% overage of drug substance in the drug product formulation M/s Nabiqasim submitted that since there is no bulking agent used for potency adjustment so potency calculation is set on basis of results of water content as Drug substance having maximum limit of 5% water content , we have set median limit of 3% water content in our batch formula to comply the product assay results on QC release specifications i.e. 95% -105% of label claim to assure product quality for patient compliance.

Water content in API testing achieve is 2.94% and Assay of API calculated on As is basis found to be 97.61%. On the basis of above assay result on as is basis quantity of Imeglimin HCl is calculated for batch manufacturing as: 500 x 100/97.6 = 512mg Remarks of Assessor (DD PECXX): Although more than 80% of drug release is achieved within 30 minutes in all three dissolution medias of pH 1.2, 4.5 and 6.8 yet striking differences in CDP profile were observed at 15min. Both firms may be asked to submit packs of innovator product of relevant batch no, used in performing CDP. Submitted for consideration of Registration Board please.
Discussion & Decision: Registration Board considered the fact that the resulst of f2 similarity factor were above 50, for the Dissolution profiles of the innovator product by M/s NabiQasim Industries & M/s Horizon Laboratories, hence Board decided to approve Meglim Tablet 500mg of M/sNabiQasim Industries. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Deferred case of 324th meeting:

1072	Name, address of Applicant / Importer	M/s Lab Diagnostic Systems Pvt. Ltd. Plot No 36-A, PSIC,SIE, Taxila, Rawalpindi Pakistan
	Details of Drug Sale License of importer	License No: 01-374-0006-049485D Address: Plot No 36-A, PSIC,SIE, Taxila, Rwp Address of Godown: NA Validity: 19-01-2022. Status: License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	Actero Middle East Address: on the corner of 8th Golestan, Sarvestan Blvd., Baharestan industrial zone, Karaj, Iran,
	Name, address of manufacturer(s)	Actero Middle East Address: on the corner of 8th Golestan, Sarvestan Blvd., Baharestan industrial zone, Karaj, Iran,

	Name of exporting country	Iran
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized copy of CoPP certificate (No. 665/13174) dated 07/06/2021 issued by Food and Drug Administration Islamic Republic of Iran, for Nilotinib (as Hydrochloride Dihydrate) 200mg tablet. GMP certificate: Firm has submitted copy of GMP certificate No 665/12252 dated 1/6/2021 Grade A has been mentioned. Issued by Food and Drug Administration Islamic Republic of Iran
	Details of letter of authorization / sole agency agreement	Firm has submitted original letter of distribution certificate from Actero Middle East. The letter specifies that the manufacturer appoints M/s Lab Diagnostic Systems (SMC) Pvt Ltd. to register their product in Pakistan,
	Status of the applicant	☐ Manufacturer ☒ Importer ☐Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 2522 dated 26.01.2022
	Details of fee submitted	PKR 150,000/-: 26-01-2022
	The proposed proprietary name / brand name	Neonib 200mg capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains:

		Nilotinib (as Hydrochloride Dihydrate) ……..... 200mg
	Pharmaceutical form of applied drug	Opaque, yellow cap and yellow body, size 0, hard gelatine capsule, filled with slightly yellow to yellowish granular powder
	Pharmacotherapeutic Group of (API)	N/A
	Reference to Finished product specifications	Inhouse
	Proposed Pack size	28's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Reference Product: TASIGNA FDA approved By M/s Novartis pharmaceuticals.
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	HETERO labs limited. 7-2-A2 Industrial Estates Sanath Nagar, Hyderabad, Telangana, India
	Module-III Drug Substance:	Firm has submitted detailed of drug substance related to nomenclature, structure, Elucidation and characteristics, general properties, solubility , physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at Temperature 40 ± 2° Relative humidity 75 ±5% RH. The long-term stability study data at Temperature 25 ± 2° Relative humidity 60 ±5% RH. till 60 months.

	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. Product development data has been submitted from HETERO labs limited. 7-2-A2 Industrial Estates Sanath Nagar, Hyderabad, Telangana, India, product has been manufactured by technology transfer from HETERO labs limited.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Comparative Dissolution Profile for the applied product as follows Test Product Neonib 200mg capsule B.No NIL-H0200-F128 Reference product Tasigna 200mg capsule B.No F0034 Medium 0.1NHCl media (pH 1.0-1.2) f2 value has been calculated which was within acceptable range CDP has been performed by HETERO labs limited.7-2-A2 Industrial Estates Sanath Nagar, Hyderabad, Telangana, India
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies from HETERO labs limited.7-2-A2 Industrial Estates Sanath Nagar, Hyderabad, Telangana, India
	Container closure system of the drug product	Container: High Density Polyethylene (HDPE) Container 60 cc

		Closure: Child resistant plastic caps with pulp liners 30mm
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of drug product. The accelerated stability study data is conducted at 40oC ±2oC / 75% ± 5% RH for 6 months. The real time stability study data is conducted at 30oC ±2oC / 75% ± 5% RH. The real time stability study data of all 3 batches is submitted till 18 months. Batch size 50000 capsules Batch No C1905 C1906 C1903

Remarks by Assessor (AD-PECXX):

Product development data, CDP and analytical method validation studies has been performed by HETERO labs limited.7-2-A2 Industrial Estates Sanath Nagar, Hyderabad, Telangana, India, as submitted by manufacturer that product has been manufactured by technology transfer from HETERO labs limited hence all development research performed by this company.

USFDA approved box warning about Tasigna (Nilotinib) 200mg capsule as follows:

TASIGNA® (nilotinib) capsules, for oral use
Initial U.S. Approval: 2007

WARNING: QT PROLONGATION AND SUDDEN DEATHS

See full prescribing information for complete boxed warning.

- **Tasigna prolongs the QT interval. Prior to Tasigna administration and periodically, monitor for hypokalemia or hypomagnesemia and correct deficiencies (5.2). Obtain ECGs to monitor the QTc at baseline, seven days after initiation, and periodically thereafter, and following any dose adjustments (5.2, 5.3, 5.7, 5.15).**
- **Sudden deaths have been reported in patients receiving nilotinib (5.3). Do not administer Tasigna to patients with hypokalemia, hypomagnesemia, or long QT syndrome (4, 5.2).**
- **Avoid use of concomitant drugs known to prolong the QT interval and strong CYP3A4 inhibitors (5.8).**
- **Avoid food 2 hours before and 1 hour after taking the dose (5.9).**

----------RECENT MAJOR CHANGES----------

S.No	Observations	Reply	Remarks
1.	Firm has submitted DSL (License No: 01-374-0006-049485D) (Validity 19-01-2022). Submit valid DSL	Firm has submitted copy of valid DSL (License No: 01-374-0006-96845D) (Validity 04-08-2024)	Complied

2.	The title of importer mentioned on sole agency agreement mentioned as M/s Lab Diagnostic Systems (SMC) Pvt. Ltd while title mentioned on DSL as M/s Lab Diagnostic Systems Pvt. Ltd. Clarify it	Title mentioned on new DSL is M/s Lab Diagnostic Systems (SMC) Pvt. Ltd, same was mentioned in sole agency agreement	Verified
3.	Formulation approved in RRA (USFDA and MHRA) is Nilotinib (as Hydrochloride monohydrate) while applied formulation is Nilotinib (as Hydrochloride dihydrate). Provide reference of applied formulation.	Firm has provided declaration from Actero Middle East, Iran as follows: We, Actero Middle east Company hereby declare regarding the selection of API of Nilotinib Hydrochloride Dihydrate (Form-A), based on the Quality Target Product (QTPP) and formulation development study with the goal to develop a formulation that is similar to RLD (Tasigna®) with respect to dissolution profile. The attached IFDA approval of dissolution study (Attachment 1) confirms that the in-house formulation is similar to RLD. Meanwhile the IFDA approved In-vivo study (Attachment 2) proves that the quality and efficacy of Neonib® is similar to Tasigna® (RLD)	The attachments referred as 1 and 2 were approval letters from Iran Food and Drug Administration (IFDA) for conducting in vitro and in vivo studies rather than study performed.
4.	Provide Compatibility of the Drug Substance(s) with excipients (Dibasic calcium phosphate and Povidone K90) being qualitatively different from innovator product Tasigna 200mg capsule	Compatibility of the Drug Substance(s) with excipients (Dibasic calcium phosphate and Povidone K90) has been provided	Complied

5.	Since applied product has been manufactured by technology transfer from HETERO labs limited hence all development research was performed by this company. Agreement to be provided between HETERO labs limited and product manufacturer i.e Actero Middle East, Iran regarding technology transfer.	Agreement has been provided regarding technology transfer between HETERO labs limited, India and Actero Middle East, Iran.	Complied

Decision 324th meeting of RB: Deferred for following:

Submission of product development and method validation data from the manufacturer site i.e., M/s Actero Middle East on the corner of 8th Golestan, Sarvestan Blvd., Baharestan industrial zone, Karaj, Iran.

Scientific justification of variation of salt form of drug substance form that used in the innovator drug product formulation.

Updated submission:

S.No	Observation	Reply	Remarks
1.	Submission of product development and method validation data from the manufacturer site i.e., M/s Actero Middle East on the corner of 8th Golestan, Sarvestan Blvd., Baharestan industrial zone, Karaj, Iran.	Product development data performed at HETERO labs limited, India was again submitted. instead of product manufacturing site i.e M/s Actero Middle East on the corner of 8th Golestan, Sarvestan Blvd., Baharestan industrial zone, Karaj, Iran.	*Later on firm has provided product development data such as formulation development, Pharmaceutical equivalence/CDP, manufacturing process development and process validation protocol/report,*

			performed at manufacturing site i.e M/s Actero Middle East on the corner of 8th Golestan, Sarvestan Blvd., Baharestan industrial zone, Karaj, Iran. *However complete CDP report is required since provided document contain study performed at 0.1NHCl only.*
2.	Scientific justification of variation of salt form of drug substance form that used in the innovator drug product formulation.	The comparative In vitro and In vivo studies results confirms that our generic products meets the same requirements of innovator "Tasigna" and so it means no barriers and limitations to use Dihydrate salt instead of monohydrate salt. This can be proved by IFDA approval for Bioequivalence study (No 665/7473) dated 19.04.2020.	Both Test and Reference products were found equivalent in the result of in vitro (comparative dissolution profile) and in vivo analysis (Bio equivalence study).
Remarks	The reply submitted against above mentioned shortcomings found unsatisfactory		
Decision: Approved as per Policy for inspection of Manufacturer abroad. • **Before issuance of registration letter CDP (all three medium) to be submitted, performed at manufacturing site i.e M/s Actero Middle East on the corner of 8th Golestan, Sarvestan Blvd., Baharestan industrial zone, Karaj, Iran**			

Deferred case of 326th meeting of Registration Board:

1073	Name, address of Applicant / Importer	M/s Martin Dow Limited., Plot No. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan.
	Details of Drug Sale License of importer	License No: 565 Address: Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area, Karachi. Address of Godown: (a) 1st floor, Plot no. 211, Sector 23 Korangi Industrial Area, Karachi (b) Plot No 32, Sector 16, Korangi Industrial Area, Karachi

		Validity: 16-06-2024 Status: License to sell Drugs by way of Wholesale Renewal: Yes
	Name and address of marketing authorization holder (abroad)	EXELTIS HEALTHCARE, S.L. Av. Miralcampo 7 19200 Azuqueca de Henares (Guadalajara) España/Spain
	Name, address of manufacturer(s)	LABORATORIOS FARMALAN S.A. C/ La Vallina s/n, Edificio 2, Poligono Industrial Navatejera 24193 Villaquilambre (Leon) España/Spain
	Name of exporting country	Spain
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized copy of COPP certificate (No. 2022/02191) dated 10-07-2020 issued by AGENCIA ESPAÑOLA DEL MEDICAMENTO Y PRODUCTOS SANITARIOS, Spain. Firm has submitted second original, legalized copy of CoPP certificate (No. 5.8.1-2022-64806) dated 22-08-2022 issued by Swedish Medical Products Agency. The CoPP confirms free sale status of the product in Sweden with different marketing authorization holder. The name of importing country on CoPPs is mentioned as Pakistan.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of authorization from Chemo SA, Lugano branch. The letter specifies that Chemo SA, Lugano branch appoints M/s. Martin Dow Limited to register their products in Pakistan. The authorization letter is valid. Firm has also submitted a letter clarifying that Chemo has been entitled by the manufacturer and license holder to promote and distribute their product.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 31354 : 02-11-2022
	Details of fee submitted	PKR 150,000/-: 31-12-2021 ,Slip No.43533251754
	The proposed proprietary name / brand name	Vestant Solution for Injection in pre-filled syringe 250mg/5ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Fulvestrant…….50mg
	Pharmaceutical form of applied drug	Solution for Injection
	Pharmacotherapeutic Group of (API)	Anti-estrogens (ATC code: L02BA03)
	Reference to Finished product specifications	As per innovator
	Proposed Pack size	1's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	FASLODEX Injection of ASTRAZENECA (USFDA Approved).
	For generic drugs (me-too status)	Not available
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.

	Name, address of drug substance manufacturer	Industriale Chimica s.r.l. Address: Via E. H. Grieg 13, 21047 Saronno (Varese), Italy
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of API at accelerated as well as real time conditions. The real time stability data is conducted at 5oC ± 3oC and accelerated at 25°C ± 2°C. The real time stability study data is till 5 years.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence has been established with reference product FASLODEX Pre filled syringe 250mg/5ml by establishing comparative study of critical quality attributes.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Syringe 5mL Glass Type – I and Plunger Stopper
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 25oC ±2oC / 60% ± 5% RH for 6 months. The real time stability study data is conducted at 5oC ±3oC. The real time stability study data of 3 batches is for 36 months.

Remarks of Evaluator:

Sr. No	Observations
01	COPP section 1.4 mentioned that this product is not actually on the market in the exporting country ,i-e Spain, please clarify.

02	Sole Agency agreement between Marketing Authorization Holder of Country of Export and Applicant, is required.
03	GMP certificate of API /Drug Substance manufacturer was granted by AIFA based on GMP inspection dated 21-09-2018 valid for 3 years, which is expired, valid copy is required please.

Previous Decision (M-324-DRB): Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Firm's response against letter No. F.1-1/2020/PEC-DRAP(DD PE&R/PEC):

Sr#	Observations	Response of firm
01	COPP section 1.4 mentioned that this product is not actually on the market in the exporting country, i.e. Spain, please clarify.	The product from this same manufacturer is marketed in Sweden, for which a copy of COPP from Swedish Medical Products Agency, Box 26, Dag Hammarskjolds vag 42, 751 03 Uppsala, Sweden for Pakistan has been submitted in the dossier.
02	Sole Agency agreement between Marketing Authorization Holder of Country of Export and Applicant, is required.	Sole agency agreement between the distributor i.e., Chemo SA, Lugano branch and applicant i.e., Martin Dow Limited has been submitted along with a clarification letter that Chemo SA, Lugano Branch (Distributor), Exeltis (MA Holder) and Laboratorio Farmalan (manufacturer) belong to one Insudpharma group.
03	GMP certificate of API /Drug Substance manufacturer was granted by AIFA based on GMP inspection dated 21-09-2018 valid for 3 years, which is expired, valid copy is required please.	Firm has submitted valid copy of GMP certificate of API/Drug substance manufacturer, i.e. Industriale Chimica s.r.l. Address: Via Edvard Hangerup Grieg 13, 21047 Saronno, Italy vide certificate No. NBF /2/2022/V based on inspection conducted on 2020-12-15 was valid for three years from date of inspection.
04	Finished Product analytical method validation report conducted by Finished Product manufacturer is required.	The methods of analysis of Fulvestrant 250 mg / 5 mL Solution for Injection prefilled syringe has been validated by Ricon Pharma and then transferred to Laboratorios Farmalan. Validation transfer reports of the analytical methods used for the control of Fulvestrant 250 mg / 5 mL Solution for Injection prefilled syringe are submitted
05	Stability study data revealed that batch no. 180002 at Accelerated condition of 25 degree Celsius with 60% relative humidity have significant deviation of Assay results more than 5%. Moreover, the same batch at real time stability study at 5 degree Celsius also revealed significant change in Assay results more than 5%. Please clarify.	No clarification is submitted

Decision: Deferred for submission of following:

Sole Agency agreement between Marketing Authorization Holder of Country of Export and Applicant

Finished Product analytical method validation report conducted by Finished Product manufacturer

Clarification as stability study data revealed that batch no. 180002 at Accelerated condition of 25ºC with 60% relative humidity have significant change of Assay results i.e., more than 5%.

Remarks of Assessor (DD PEC XX):

Firm has submitted reply against above mentioned shortcomings as follows:

S.No	Observation	Reply	Remarks
1.	Sole Agency agreement between Marketing Authorization Holder of Country of Export and Applicant, is required.	Sole Agency agreement (original/legalized) between Marketing Authorization Holder i.e EXELTIS HEALTHCARE, S.L. Av. Miralcampo 7 19200 Azuqueca de Henares (Guadalajara) España/Spain and Applicant i.e M/s Martin Dow Limited., Plot No. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan.dated 03.05.2023 for authorization of Fulvestrant 250mg/5ml Pre filled syringe (brand name in Pakistan Vestant) The same has been notarized by Apostille as the embassy of Pakistan in the country of origin is no longer providing services of legalization after the accession of Pakistan in Hague Convention Abolishing the Requirement of Legalization for Foreign Public Documents (Apostille Convention) of 1961.	Complied
2.	Finished Product analytical method validation report conducted by Finished Product manufacturer is required.	Finished Product analytical method validation report conducted by Finished Product manufacturer i.e	Complied

		LABORATORIOS FARMALAN S.A.is submitted.	
3.	Clarification as stability study data revealed that batch no. 180002 at Accelerated condition of 25ºC with 60% relative humidity have significant change of Assay results i.e., more than 5%.	The out of trend result of Assay for Batch 180002 in upright position at T3 of Accelerated studies was evaluated and it was concluded that it is due to the intrinsic variability of the analytical method and not due to any degradation of product, which is also confirmed by the 97.2% assay result in horizontal position at the same conditions of accelerated T3 time point. Moreover, the assay results remained within specifications throughout the 36 months storage in long term conditions in both orientations (upright and horizontal) of syringe. Detailed clarification and discussion of OOT Results of Stability data along with signed statement given by Finished product manufacturer is provided.	Clarified The out of trend result for Batch 180002 in upright position at T3 of Accelerated studies was recorded as 91.2% (up right position) while assay result in horizontal position at the same conditions of accelerated T3 time point was recorded as 97.2%. Regarding real time stability study result for Batch 180002 in upright position at T3 was recorded as 95.1% (upright position) while assay result in horizontal position at the same conditions of real time studies T3 time point was recorded as 98.1% in horizontal position. Moreover, the assay results remained within specifications throughout the 36 months storage in long term conditions in both orientations (upright and horizontal) of syringe.

Remarks of Assessor (DD PEC XX):

The reply submitted against above mentioned shortcomings is found satisfactory

Decision: Approved as per Policy for inspection of Manufacturer abroad.

Deferred case of 326th meeting:

1074	Name, address of Applicant / Marketing Authorization Holder	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Name, address of Manufacturing site.	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No 612 dated 06.01.2023
	Details of fee submitted	PKR 30,000/- dated 30.11.2022
	The proposed proprietary name / brand name	LEVOTEL 250mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Levofloxacin as hemihydrate.....250 mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Quinolone antibiotics
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LEVOFLOXACIN Tablets 250mg" Approved by Health USFDA manufactured by TEVA
	For generic drugs (me-too status)	LEFLOX TABLETS 250mg (Reg. No.: 026164) manufactured by M/s Getz Pharma (Pvt.) Limited, Plot no. 29 – 30, Sector 27 Korangi Industrial Area, Karachi

	GMP status of the Finished product manufacturer	New DML granted on 11/11/2021 Tablet General ,Capsule General ,Oral dry powder suspension General) section approved.
	Name and address of API manufacturer.	M/s Zhejiang, East-Asia Pharmaceutical Co., Ltd ,address, Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Levofloxacin hemihydrate is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity (A, B & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: DC-004-1512001,DC-004-1512002,DC-004-1512003
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Tavanic 250 mg tablet by sanofi aventis by performing quality tests (Identification, Assay, Dissolution, disintegration time). CDP has been performed against the same brand that is Tavanic 250 Tablet by sanofi aventis (Batch no. B0029) in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8)

		against test product (Batch no. T001). The values for f1 and f2 are in the acceptable range.		
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.		
STABILITY STUDY DATA				
Manufacturer of API		M/s Zhejiang, East-Asia Pharmaceutical Co., Ltd ,address, Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, China.		
API Lot No.		Not provided		
Description of Pack (Container closure system)		Alu-Alu blister packed in unit carton		
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		T-001	T-002	T-003
Batch Size		1000 tab	1000 tab	1000 tab
Manufacturing Date		5-2022	5-2022	5-2022
Date of Initiation		23-05-2022	23-05-2022	23-05-2022
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided		
4.	Data of stability batches will be supported by attested respective documents like chromatograms,	Submitted		

	Raw data sheets, COA, summary data sheets etc.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not provided

Remarks of Assessor (DD PECXX):

1.6.5 Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin

3.2.S.4 Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture.

3.2.S.4 Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided

3.2.S.4 Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer.

3.2.P.2 Batch formula for proposed commercial batch size should be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards.

3.P.2.1.1Compatibility of the Drug Substance(s) with excipients (Crospovidone, Microcrystalline cellulose) is not provided since said excipients are not found in innovator/reference product.

3.2.P.8 Documents for the procurement of API to be submitted.

3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Remarks: Now the firm has submitted reply as follows:

Sr.#	Observation	Reply	Remarks
1.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided	Not complied
2.	Batch formula for proposed commercial batch size should be provided that includes a	Batch formula has been submitted for proposed	Complied

	list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards.	commercial batch size i.e 10,000 tablets	
3.	Compatibility of the Drug Substance(s) with excipients (Crospovidone, Microcrystalline cellulose) is not provided since said excipients are not found in innovator/reference product	Not provided	Not complied *Later on firm provided reference of USFDA approved product Levaquin wherein said excipients have been used in formulation hence Drug-excipient compatibility study is not required*
4.	Documents for the procurement of API to be submitted.	Commercial invoice has been submitted (No 156322) dated 22.04.2022 batch No DC-004-200312 2.5KG API was imported.	Approval from DRAP to be provided
5.	Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.	Provided	Compliance Record of HPLC software 21CFR & audit trail reports yet to be provided
6.	Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer	Provided	Complied
7.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture.	Provided	Complied
8.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the	Provided	HPLC chromatograms for different parameters tested (specificity, accuracy and repeatability etc) during verification study have not been provided. *Moreover results of specificity*

	Drug Product manufacturer to be provided		*parameter has not been provided*
Remarks:	The reply submitted against above mentioned shortcoming was found unsatisfactory.		

Decision: Deferred for following submissions:

- **Submission of approval from DRAP for procurement of API.**
- **Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.**
- **Results of specificity parameter under Analytical Method Verification studies of Drug substance.**

1075	Name, address of Applicant / Marketing Authorization Holder	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Name, address of Manufacturing site.	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No 613 dated 06.01.2023
	Details of fee submitted	PKR 30,000/-: dated 01.12.2022
	The proposed proprietary name / brand name	LEVOTEL 500mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Levofloxacin as hemihydrate.....500 mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Quinolone antibiotics
	Reference to Finished product specifications	USP

	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LEVOFLOXACIN Tablets 500mg" Approved by Health USFDA manufactured by TEVA
	For generic drugs (me-too status)	LEFLOX TABLETS 500mg (Reg. No.: 026163) manufactured by M/s Getz Pharma (Pvt.) Limited, Plot no. 29 – 30, Sector 27 Korangi Industrial Area, Karachi
	GMP status of the Finished product manufacturer	New DML granted on 11/11/2021 Tablet General ,Capsule General ,Oral dry powder suspension General) section approved.
	Name and address of API manufacturer.	M/s Zhejiang, East-Asia Pharmaceutical Co., Ltd ,address, Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Levofloxacin hemihydrate is present in USP. The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for impurity (A, B & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: DC-004-1512001,DC-004-1512002,DC-004-1512003
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities,

		specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Tavanic 500 mg tablet by sanofi aventis by performing quality tests (Identification, Assay, Dissolution, Disintegration time). CDP has been performed against the same brand that is Tavanic 500 Tablet by sanofi Aventis (Batch No CRD0020) in Acid media (pH 1.0-1.2) & Phosphate Buffer (pH 6.8) against Test product (Batch No T001). The values for f1 and f2 are in the acceptable range. CDP of Levotel 500mg tablet has not been performed in acetate buffer and phosphate buffer medium (instead Levotel 250mg was mentioned)
	Analytical method validation/verification of product	Method verification studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA

Manufacturer of API	M/s Zhejiang, East-Asia Pharmaceutical Co., Ltd ,address, Coastal Industrial City, Pubagang town, Sanmen county, Zhejiang, China.		
API Lot No.	Not provided		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	5-2022	5-2022	5-2022
Date of Initiation	24-05-2022	24-05-2022	24-05-2022
No. of Batches	03		

Administrative Portion		
1	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided
3	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided
4	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided
6	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not provided

Remarks of Assessor (DD PECXX):

1.6.5 Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin

3.2.S.4 Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture.

3.2.S.4 Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided

3.2.S.4 Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer.

3.2.P.2 Batch formula for proposed commercial batch size should be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards.

3.P.2.1.1Compatibility of the Drug Substance(s) with excipients (Crospovidone, Microcrystalline cellulose) is not provided since said excipients are not found in innovator/reference product.

3.2.P.2 Submit revised CDP report for Levotel tablet 500mg since CDP of Levotel 500mg tablet has not been performed in acetate buffer and phosphate buffer medium (instead Levotel 250mg was mentioned)

3.2.P.8 Documents for the procurement of API to be submitted.

3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Remarks: Now the firm has submitted reply as follows:

Sr.#	Observation	Reply	Remarks
1.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not provided	Not complied
2.	Batch formula for proposed commercial batch size should be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards.	Batch formula has been submitted for proposed commercial batch size i.e 10,000 tablets	Complied
3.	Submit revised CDP report for Levotel tablet 500mg since CDP of Levotel 500mg tablet has not been performed in acetate buffer and phosphate buffer medium (instead Levotel 250mg was mentioned)	Not provided	Not complied
4.	Compatibility of the Drug Substance(s) with excipients (Crospovidone, Microcrystalline cellulose) is not provided since said excipients are not found in innovator/reference product	Not provided	Not complied *Later on firm provided reference of USFDA approved product Levaquin wherein said excipients have been used in formulation hence Drug-excipient compatibility study is not required*
5.	Documents for the procurement of API to be submitted.	Commercial invoice has been submitted (No 156322) dated 22.04.2022 batch No DC-004-200312 2.5KG API was imported.	Approval from DRAP to be provided
6.	Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature	provided	Compliance Record of HPLC software 21CFR & audit trail reports yet to be provided

	and humidity monitoring is not submitted.		
7.	Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer	Provided	Complied
8.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture.	Provided	Complied
9.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided	Provided	HPLC chromatograms for different parameters tested (specificity, accuracy and repeatability etc) during verification study have not been provided. *Moreover results of specificity parameter has not been provided*
Remarks:	The reply submitted against above mentioned shortcoming was found unsatisfactory.		

Decision: Deferred for following submissions:

- **Submission of approval from DRAP for procurement of API.**
- **Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.**
- **Results of specificity parameter under Analytical Method Verification studies of Drug substance.**

1076	Name, address of Applicant / Marketing Authorization Holder	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Name, address of Manufacturing site.	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No 610 dated 06.01.2023
	Details of fee submitted	PKR 30,000/- dated 01.12.2022
	The proposed proprietary name / brand name	Sulvipride 25 mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Levosulpiride.....25 mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	Innovator
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LEVOPRAID 25 mg tablet by M/s TEOFARMA Srl - Via F.lli Cervi, AIFA Italy Approved
	For generic drugs (me-too status)	Vesulpid Tablets 25mg by M/s Martin Dow Pharmaceutical(Pakistan) Ltd, Reg. No. 041008
	GMP status of the Finished product manufacturer	New DML granted on 11/11/2021 Tablet General ,Capsule General ,Oral dry powder suspension General) section approved.
	Name and address of API manufacturer.	M/s Atlas Life Sciences Private Limited C-1/360-361, G.I.D.C Estate , Odhav, Ahmedabad – 382415, Gujarat,India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and

		controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Levosulpiride is not present in any official monograph. The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for related substances, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 12 months Batches:LSP0010415,LSP0020515,DC- LSP0030515
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Levopraid 25 mg tablet (Batch No AQ1801R) by Pacific pharmaceuticals by performing quality tests (Identification, Assay, Dissolution, Disintegration time and weight of tablet) against Test product i.e Sulvipride 25mg Tablet (Batch No T001) CDP has been performed against the same brand that is Levopraid 25mg Tablet by Pacific pharmaceuticals in Acid media (pH 1.0-1.2), Acetate medium (Ph 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.
STABILITY STUDY DATA		
Manufacturer of API	M/s Atlas Life Sciences Private Limited C-1/360-361, G.I.D.C Estate , Odhav, Ahmedabad – 382415, Gujarat,India.	
API Lot No.	LSP0260120	
Description of Pack	Alu-Alu blister packed in unit carton	

(Container closure system)			
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	6-2022	6-2022	6-2022
Date of Initiation	4-6-2022	4-6-2022	4-6-2022
No. of Batches	03		

Administrative Portion		
1	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.
2	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted GMP certificate No S-GMP/20021839 issued by Food and Drug Control Administration , Gujrat state India valid till 10.02.2022
3	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided
4	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided
6	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not provided
Remarks Assessor (DD PECXX):		

1.6.5 Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin

3.2.S.4 Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture.

3.2.S.4 Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided

3.2.S.4 Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer.

3.2.P.2 CDP report need to be clarified whether Test product was Sulvipride 25 mg Tablets or Sulvipride 50 mg Tablet.

3.2.P.2 Batch formula for proposed commercial batch size should be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards

3.2.P.8 Documents for the procurement of API to be submitted.

3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Now the firm has submitted reply as follows:

Sr.#	Observation	Reply	Remarks
1.	Valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided valid GMP (No S-GMP &GLP/22023124 valid till 10.02.2024 Issued by Food and Drug control administration Gujrat	Complied
2.	Batch formula for proposed commercial batch size should be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards.	Batch formula has been submitted for proposed commercial batch size i.e 10,000 tablets	Complied
3.	For Sulvipride 25 mg Tablet, CDP report need to be clarified whether Test product was Sulvipride 25 mg Tablet or Sulvipride 50 mg Tablet, since both products were mentioned in CDP report. Moreover, CDP of Sulvipride 50 mg Tablet was only performed in	Not provided	Not complied ***Later on firm has re submitted CDP report wherein name of Test product was corrected as Sulvipride 25 mg Tablet***

	phosphate buffer medium (pH 4.5) as per CDP report.		
4.	Documents for the procurement of API to be submitted.	Commercial invoice has been submitted (No AT-018/2021-22) dated 02.05.2022 batch No LSP-0260120 0.3KG API was imported.	Approval from DRAP is required
5.	Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.	provided	Compliance Record of HPLC software 21CFR & audit trail reports yet to be provided
6.	Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer	Provided	Complied
7.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture.	Provided	Complied
8.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided	Provided	HPLC chromatograms for different parameters tested (specificity, accuracy and repeatability etc) during verification study have not been provided. ***Moreover results of specificity parameter has not been provided***
Remarks	Reply submitted against above mentioned shortcomings found unsatisfactory		

Decision: Deferred for following submissions:

- **Submission of approval from DRAP for procurement of API.**
- **Results of specificity parameter under Analytical Method Verification studies of Drug substance.**

1077	Name, address of Applicant / Marketing Authorization Holder	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan

	Name, address of Manufacturing site.	M/s Med Asia Pharmaceuticals (Pvt) Limited Plot #7 Nowshera Industrial Estate Risalpur KPK Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy No 611 dated 06.01.2023
	Details of fee submitted	PKR 30,000/- dated 01.12.2022
	The proposed proprietary name / brand name	Sulvipride 50 mg Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Levosulpiride.....50mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	Innovator
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	LEVOPRAID 50 mg tablet by M/s TEOFARMA Srl - Via F.lli Cervi, AIFA Italy Approved
	For generic drugs (me-too status)	Vesulpid Tablets 50mg by M/s Martin Dow Pharmaceutical(Pakistan) Ltd, Reg. No. 041012
	GMP status of the Finished product manufacturer	New DML granted on 11/11/2021 Tablet General ,Capsule General ,Oral dry powder suspension General) section approved.
	Name and address of API manufacturer.	M/s Atlas Life Sciences Private Limited

		C-1/360-361, G.I.D.C Estate , Odhav, Ahmedabad – 382415, Gujarat,India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Levosulpiride is not present in any official monograph. The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for related substances, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 60 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 12 months Batches:LSP0010415,LSP0020515,DC- LSP0030515
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand leader that is Levopraid 50 mg tablet (Batch No AP0405R) by Pacific pharmaceuticals by performing quality tests (Identification, Assay, Dissolution, Disintegration time and weight of tablet) against Test product i.e Sulvipride 50mg Tablet (Batch No T001) CDP has been performed against the same brand that is Levopraid 50mg Tablet by Pacific pharmaceuticals in Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation/verification of product	Method validation studies have submitted including linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA				
Manufacturer of API		M/s Atlas Life Sciences Private Limited C-1/360-361, G.I.D.C Estate , Odhav, Ahmedabad – 382415, Gujarat,India.		
API Lot No.		LSP0260120		
Description of Pack (Container closure system)		Alu-Alu blister packed in unit carton		
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		T-001	T-002	T-003
Batch Size		1000 tab	1000 tab	1000 tab
Manufacturing Date		6-2022	6-2022	6-2022
Date of Initiation		13-6-2022	13-6-2022	13-6-2022
No. of Batches		03		
Administrative Portion				
1	Reference of previous approval of applications with stability study data of the firm (if any)	The firm has not submitted any document.		
2	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted GMP certificate No S-GMP/20021839 issued by Food and Drug Control Administration , Gujrat state India valid till 10.02.2022		
3	Documents for the procurement of API with approval from DRAP (in case of import).	Not provided		
4	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		

5	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not provided
6	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not provided

Remarks Assessor (DD PECXX):

1.6.5 Valid Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin

3.2.S.4 Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture.

3.2.S.4 Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided

3.2.S.4 Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer.

3.2.P.2 For Sulvipride 25 mg Tablet, CDP report need to be clarified whether Test product was Sulvipride 25 mg Tablet or Sulvipride 50 mg Tablet, since both products were mentioned in CDP report. Moreover, CDP of Sulvipride 50 mg Tablet was only performed in phosphate buffer medium (pH 4.5) as per CDP report.

3.2.P.2 Batch formula for proposed commercial batch size should be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per batch basis, and a reference to their quality standards

3.2.P.8 Documents for the procurement of API to be submitted.

3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.

Decision: Registration Board was apprised that the letter of shortcoming has been initially issued to the firm, hence Board deferred the case for submission of reply to the above cited shortcomings within six months.

Sr.#	Observation	Reply	Remarks
1.	Valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has provided valid GMP (No S-GMP &GLP/22023124 valid till 10.02.2024 Issued by Food and Drug control administration Gujrat	Complied
2.	Batch formula for proposed commercial batch size should be provided that includes a list of all components of the drug product to be used in the manufacturing process, their amounts on a per	Batch formula has been submitted for proposed commercial batch size i.e 10,000 tablets	Complied

	batch basis, and a reference to their quality standards.		
3.	For Sulvipride 25 mg Tablet, CDP report need to be clarified whether Test product was Sulvipride 25 mg Tablet or Sulvipride 50 mg Tablet, since both products were mentioned in CDP report. Moreover, CDP of Sulvipride 50 mg Tablet was only performed in phosphate buffer medium (pH 4.5) as per CDP report.	Provided	complied
4.	Documents for the procurement of API to be submitted.	Commercial invoice has been submitted (No AT-018/2021-22) dated 02.05.2022 batch No LSP-0260120 0.3KG API was imported.	Approval from DRAP is required
5.	Compliance Record of HPLC software 21CFR & audit trail reports and record of Digital data logger for temperature and humidity monitoring is not submitted.	provided	Compliance Record of HPLC software 21CFR & audit trail reports yet to be provided
6.	Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer	Provided	Complied
7.	Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (COA) of the same batch from Drug Substance / API manufacture.	Provided	Complied
8.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided	Provided	HPLC chromatograms for different parameters tested (specificity, accuracy and repeatability etc) during verification study have not been provided. ***Moreover results of specificity parameter has not been provided***
Remarks	Reply submitted against above mentioned shortcomings found unsatisfactory		

Decision: Deferred for following submissions:

- **Submission of approval from DRAP for procurement of API.**
- **Results of specificity parameter under Analytical Method Verification studies of Drug substance.**

Deferred case of 326th meeting:

1078	Name, address of Applicant / Marketing Authorization Holder	M/s Pharmadic Laboratories (Pvt) Ltd, 16 KM, Multan Road, Lahore
	Name, address of Manufacturing site.	M/s Pharmadic Laboratories (Pvt) Ltd, 16 KM, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the drug product manufacturer	Firm has submitted copy of GMP certificate No. 93/2020-DRAP(AD-2003099-790) dated 09-06-2020
	Evidence of approval of manufacturing facility	Tablet General Section
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 10710 dated 28-04-22
	Details of fee submitted	PKR30000 dated: 27.05.2022 bearing Deposit Slip No. 09713095356
	The proposed proprietary name / brand name	Darvin Forte 75mg/650mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Tramadol HCL … 75mg Paracetamol …….. 650mg
	Pharmaceutical form of applied drug	Film Coated Tablet

	Pharmacotherapeutic Group of (API)	Opioid & Non-Opioid Analgesic
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1x 10's (Alu-PVC Blisters)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CLANDERON 75 mg / 650 mg , Aristo Pharma Iberia, Madrid Spain.
	For generic drugs (me-too status)	Tonoflex-P Forte (film coated) of M/s Sami Pharmaceuticals (Pvt) Ltd, Karachi
	Name and address of API manufacturer.	Paracetamol (USP/BP): M/s Saakh Pharma (Pvt) Ltd, Karachi. GMP Certificate No. 83/2020-DRAP(K) dated 23-06-2022 Certificate No. ZJ20170049 Tramadol HCL USP : M/s S.L.R. Pharma (Pvt) Limited, Situated at Plot No. A-69, API Estate Settipalli Post, Tirupati, Chittor District, Andhra Pradesh, India. License Retention Certificate dated 05-12-2019.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for both drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions.

	(Conditions & duration of Stability studies)	The accelerated stability data is conducted at 40oC ± 2oC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30oC ± 2oC / 65% ± 5% RH for 24 months for both API's namely Paracetamol & Tramadol HCL USP .
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence have been established against the Tonoflex-P Forte Tablet 75/650 mg by M/s Sami Pharmaceuticals (Pvt) Ltd, Karachi by performing quality tests including Identification, water content, Assay, Dissolution, Disintegration. CDP has been performed against the same brand that is Tonoflex-P Forte Tablet 75/650 mg by M/s Sami Pharmaceuticals (Pvt) Ltd, Karachi in Acid media (0.1N HCl), acetate buffer pH 4.5 & Phosphate Buffer pH 6.8. The F2 values are not found satisfactory.
	Analytical method validation/verification of product	Firm has submitted report of validation studies of analytical method of drug substance. Firm has submitted report of verification of analytical method for the drug product.
STABILITY STUDY DATA		
Manufacturer of API		Paracetamol (BP): M/s Saakh Pharma (Pvt) Ltd, Karachi. GMP Certificate No. 83/2020-DRAP(K) dated 23-06-2022 Certificate No. ZJ20170049 Tramadol HCL USP : M/s S.L.R. Pharma (Pvt) Limited, Situated at Plot No. A-69, API Estate Settipalli Post, Tirupati, Chittor District, Andhra Pradesh, India. License Retention Certificate dated 05-12-2019.

API Lot No.	Paracetamol: ZPAR18-143 Tramadol HCL : TDH 0041019		
Description of Pack (Container closure system)	The proposed pack size of Darvin Forte Tablet is 1x10's in Alu—PVC Blister.		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 24 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6(Months) Real Time: 0, 3, 6,9,12,18,24(Months)		
Batch No.	ACTD-TR001	ACTD-TR002	ACTD-TR003
Batch Size	1000 TABLETS	1000 TABLETS	1000 TABLETS
Manufacturing Date	10,2019	10,2019	10,2019
Date of Initiation	10-10-2019	10-10-2019	10-10-2019
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not Provided
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Paracetamol (USP/BP): M/s Saakh Pharma (Pvt) Ltd, Karachi. GMP Certificate No. 83/2020-DRAP(K) dated 23-06-2022 Certificate No. ZJ20170049 Tramadol HCL USP : M/s S.L.R. Pharma (Pvt) Limited, Situated at Plot No. A-69, API Estate Settipalli Post, Tirupati, Chittor District, Andhra Pradesh, India. License Retention Certificate dated 05-12-2019.

3.	Documents for the procurement of API with approval from DRAP (in case of import).	Paracetamol (BP): Not Required Tramadol HCL USP : Not Provided
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail record of product testing of HPLC.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Not Provided.

Evaluation by PEC:

Evidence of approval of applied formulation in reference regulatory authorities as defined by the registration Board shall be submitted. As the applied formulation in reference regulatory authorities is approved as "uncoated" tablets while the applicant has applied as film coated tablets

Decision: Since the applied product is approved as "uncoated tablet" in reference regulatory authorities while the applicant has applied for film coated tablet. Therefore, Registration Board decided to defer the case for evidence of approval of applied formulation in reference regulatory authorities/agencies a

"film coated tablet" which were declared/approved by the Registration Board in its 275th meeting.

Reply of the firm :

Decision 322nd meeting of RB: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Sr. No	Observation	Reply	Remarks
1.	Provide certificate of analysis of relevant batch(es) of Drug Substance(s) (Paracetamol & Tramadol HCL) used in product development (By both Drug Substance and Drug Product manufacturer.	CoA are provided for different batches.	Not complied CoA to be provided for relevant batches. The CoA of Tramadol HCl batch No TDH 0480218 has been provided instead of batch no TDH 0041019 which was mentioned in import invoice.

2.	The Pharmaceutical equivalence studies and comparative dissolution Profile studies are not conducted with the innovator Product.	Pharmaceutical equivalence /CDP performed against the Tonoflex-P Forte Tablet 75/650 mg by M/s Sami Pharmaceuticals (Pvt) Ltd, Karachi Batch No 001E	Pharmaceutical equivalence /CDP performed against established brand
3.	Documents for the procurement of API with approval from DRAP (in case of import) of DS Tramadol HCL USP	Copy of invoice provided No E002 dated 06.11.2019 , attested by DRAP Lahore confirming import of 200Kg Tramadol HCl Batch No TDH 0041019	Complied
4.	As per submitted data of comparative dissolution profile following points have been observed: For Paracetamol: Value of F2 factor is 46% in Buffer Acetate pH 4.5 Value of F2 factor is 38% in Phosphate Buffer pH 6.8 For Tramadol HCl: value of F2 factor is 44% in 0.1N HCL Value of F2 factor is 46% in Phosphate buffer pH 6.8 Please justify scientifically.	Rectified CDP report has been submitted with f2 values as follows For Paracetamol: Value of F2 factor is 53% in acid medium pH 1.2 Value of F2 factor is 52% in Buffer Acetate pH 4.5 Value of F2 factor is 53% in Phosphate Buffer pH 6.8 For Tramadol HCl: Value of F2 factor is 54% in 0.1N HCL Value of F2 factor is 67% in Buffer Acetate pH 4.5 Value of F2 factor is 55% in Phosphate buffer pH 6.8	The F2 values are found satisfactory.

5.	Specificity testing in Analytical method validation has not been performed for the applied Product.	Analytical method validation study has been performed including parameter Specificity.	Complied
6.	Analytical Method for related substances /impurities testing of DS Paracetamol (BP) the HPLC testing procedure/chromatographic conditions are different from the one as specified in BP	Analytical Method for related substances /impurities testing of DS Paracetamol (BP) has been submitted wherein HPLC testing procedure/chromatographic conditions are as per BP (2019)	Complied
7.	DS manufacturer of Paracetamol has followed analytical method for testing(Assay) of API of BP while the Drug Product manufacturer has tested by USP Specs. (The analytical method by DS manufacturer is mentioned as BP but on COA of DS Assay is mentioned as USP)	Drug Product manufacturer has tested Drug Substance (Paracetamol) as per BP. CoA has been provided.	Complied
8,	The excipients being used are different from the ones used in Product Development of Innovator/Reference Product, therefore, provide compatibility studies protocol/method along with results.	Drug-Excipient compatibility study has been provided The binary study makes it clear that both API are compatible with all excipients	Complied

Decision 326th meeting: Deferred for following:

Submission of CoA of relevant batch of Tramadol HCl i.e., TDH 0041019 as mentioned in import invoice.

Scientific justification for the results reported in CDP studies with acceptable f2 value, whereas previously firm had reported different results of f2 value which were not within acceptable range, while the firm has not made any formulation change.

Remarks:

Now the firm has submitted CoA of relevant batch of Tramadol HCl i.e., TDH 0041019 from both Drug Substance and product manufacturer.

Regarding justification for disparity in CDP results, firm has submitted undertaking that there was clerical mistake in formula of excel sheet for calculation of similarity factor f2 in Darvin Forte tablet.

Decision: Authenticity of data to be verified through onsite inspection.

Agenda of Evaluator PEC-XXI

Agenda Item No. 01: Priority Applications of Human Drugs Locally Manufactured (New Section) applied on Form - 5F.

Case 01: M/s Gray's Pharmaceuticals, Plot No. 2, Street No. N-3, National Industrial Zone, Rawat was granted following Additional Section on 18-11-2021: -

i. Sachet (General)

1079.	Name, address of Applicant / Marketing Authorization Holder	M/s Gray's Pharmaceuticals, Plot No. 2, Street No. N-3, National Industrial Zone, Rawat.
	Name, address of Manufacturing site.	M/s Gray's Pharmaceuticals, Plot No. 2, Street No. N-3, National Industrial Zone, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 39371 dated 29 DEC 2022.
	Details of fee submitted	Slip No. 436545955517 PKR 30,000/- dated 16-11-2022.
	The proposed proprietary name / brand name	EPRACO 20/1680 mg Sachets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Omeprazole USP….20mg Sodium Bicarbonate…1680mg (USP Specifications)
	Pharmaceutical form of applied drug	Immediate Release Powder for Oral Suspension in Sachet.
	Pharmacotherapeutic Group of (API)	A02BC01, Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (GORD), Proton Pump Inhibitors.
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZEGERID (For Suspension; Oral) of Santarus, Inc., San Diego (USFDA Approved).
	For generic drugs (me-too status)	Risek Insta Sachet 20mg + 1680mg (Reg. No. 58547) of M/s Getz Pharma.

	GMP status of the Finished product manufacturer	GMP Certificate No. F.3-78/20118-Addl.Dir.(QA&LT-I)-34 dated 24th December , 2021.
	Name and address of API manufacturer.	Omeprazole: M/s Metrochem API Private Limited, Unit –I, Plot No. 62/C/6, Pipe Line Road, Phase-I, IDA, Jeedimetla, Hyderabad, India. Sodium Bicarbonate: CFL Chemische Fabrik Lehrke GmBH & Co. Kohthenwaldester 2-6, D-31275 Lehrte.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Omeprazole and Sodium Bicarbonate is present in USP. The firm has submitted detail of nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months Batches: Omeprazole: OMP-PMN20001, OMP-PMN20002 and OMP-PMN20003. Sodium Bicarbonate: 041717127112020, 04171712712020 and 041717127132020.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand Zegerid

		20mg/1680mg Sachet (Santarus) by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage units). CDP has been performed against the same brand that is Zegerid 20mg/1680mg Sachet (Santarus) in Acid media (pH 1.2) Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation / verification of product	Method validation studies have been submitted including linearity, range, accuracy, precision, and specificity.

STABILITY STUDY DATA				
Manufacturer of API		Omeprazole: M/s Metrochem API Private Limited, Unit –I, Plot No. 62/C/6, Pipe Line Road, Phase-I, IDA, Jeedimetla, Hyderabad, India. Sodium Bicarbonate: CFL Chemische Fabrik Lehrke GmBH & Co. Kohthenwaldester 2-6, D-31275 Lehrte.		
API Lot No.		Omeprazole: OME-P/22055 Sodium Bicarbonate: 22052020		
Description of Pack (Container closure system)		Aluminum Foil Sachet.		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real Time: 06 months Accelerated: 06 months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		T001	T002	T003
Batch Size		500 Sachets	500 Sachets	500 Sachets
Manufacturing Date		07-2022	07-2022	07-2022
Date of Initiation		22-07-2022	22-07-2022	22-07-2022
No. of Batches		03		
Administrative Portion				
43.	Reference of previous approval of applications with stability study data of the firm (if any).	Nil		
44.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 60625/TS/2021 dated 27/10/2021 issued by Drugs Control Administration, Telangana State, India is submitted for M/s Metrochem API Private Limited, Unit –I, Plot No. 62/C/6, Pipe Line Road, Phase-I, IDA, Jeedimetla, Hyderabad, India. Copy of GMP certificate No. DE_NI_02_GMP_2018_0031 dated 20 July 2021 issued by Staatliches		

		Gewerbeaufsichtsamt Hannover, Deutschland is submitted for CFL Chemische Fabrik Lehrke GmBH & Co. Kohthenwaldester 2-6, D-31275 Lehrte.
45.	Documents for the procurement of API with approval from DRAP (in case of import).	Omeprazole: Copy of Clearance Certificate No. E-1289258029515 dated 27-May-2022 is submitted. Sodium Bicarbonate: Copy of Clearance Certificate No. E-699858024569 dated 01-Apr-2022 is submitted.
46.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
47.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Audit trail reports on product testing is submitted.
48.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

The Firm vide their letter Dy. No. 9485 dated 10 APR 2023 have submitted Revised Dossier with Full Fee (PKR 30,000/-) vide Slip No. 5268032498 dated 07-04-2023 stating that the data was inadvertently not in proper order and requested for consideration of revised dossier as mentioned above.

Decision of 329th Meeting: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1080.	Name, address of Applicant / Marketing Authorization Holder	M/s Gray's Pharmaceuticals, Plot No. 2, Street No. N-3, National Industrial Zone, Rawat.
	Name, address of Manufacturing site.	M/s Gray's Pharmaceuticals, Plot No. 2, Street No. N-3, National Industrial Zone, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 39372 dated 29 DEC 2022.
	Details of fee submitted	Slip No. 47786312945 PKR 30,000/- dated 16-11-2022.
	The proposed proprietary name / brand name	EPRACO 40/1680 mg Sachets

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Omeprazole USP….40mg Sodium Bicarbonate…1680mg (USP Specifications)
	Pharmaceutical form of applied drug	Immediate Release Powder for Oral Suspension in Sachet.
	Pharmacotherapeutic Group of (API)	A02BC01, Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (GORD), Proton Pump Inhibitors.
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZEGERID (For Suspension; Oral) of Santarus, Inc., San Diego (USFDA Approved).
	For generic drugs (me-too status)	Risek Insta Sachet 40mg + 1680mg (Reg. No. 58548) of M/s Getz Pharma.
	GMP status of the Finished product manufacturer	GMP Certificate No. F.3-78/20118-Addl.Dir.(QA&LT-I)-34 dated 24th December , 2021.
	Name and address of API manufacturer.	Omeprazole: M/s Metrochem API Private Limited, Unit –I, Plot No. 62/C/6, Pipe Line Road, Phase-I, IDA, Jeedimetla, Hyderabad, India. Sodium Bicarbonate: CFL Chemische Fabrik Lehrke GmBH & Co. Kohthenwaldester 2-6, D-31275 Lehrte.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Omeprazole and Sodium Bicarbonate is present in USP. The firm has submitted detail of nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions:

		Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months Batches: Omeprazole: OMP-PMN20001, OMP-PMN20002 and OMP-PMN20003. Sodium Bicarbonate: 041717127112020, 04171712712020 and 041717127132020.
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand Zegerid 40mg/1680mg Sachet (Santarus) by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage units). CDP has been performed against the same brand that is Zegerid 40mg/1680mg Sachet (Santarus) in Acid media (pH 1.2) Acetate Buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 are in the acceptable range.
	Analytical method validation / verification of product	Method validation studies have been submitted including linearity, range, accuracy, precision, and specificity.

STABILITY STUDY DATA			
Manufacturer of API	Omeprazole: M/s Metrochem API Private Limited, Unit –I, Plot No. 62/C/6, Pipe Line Road, Phase-I, IDA, Jeedimetla, Hyderabad, India. Sodium Bicarbonate: CFL Chemische Fabrik Lehrke GmBH & Co. Kohthenwaldester 2-6, D-31275 Lehrte.		
API Lot No.	Omeprazole: OME-P/22055 Sodium Bicarbonate: 22052020		
Description of Pack (Container closure system)	Aluminum Foil Sachet.		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real Time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003

Batch Size	500 Sachets	500 Sachets	500 Sachets
Manufacturing Date	07-2022	07-2022	07-2022
Date of Initiation	25-07-2022	25-07-2022	25-07-2022
No. of Batches	03		
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any).	Nil	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 60625/TS/2021 dated 27/10/2021 issued by Drugs Control Administration, Telangana State, India is submitted for M/s Metrochem API Private Limited, Unit –I, Plot No. 62/C/6, Pipe Line Road, Phase-I, IDA, Jeedimetla, Hyderabad, India. Copy of GMP certificate No. DE_NI_02_GMP_2018_0031 dated 20 July 2021 issued by Staatliches Gewerbeaufsichtsamt Hannover, Deutschland is submitted for CFL Chemische Fabrik Lehrke GmBH & Co. Kohthenwaldester 2-6, D-31275 Lehrte.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Omeprazole: Copy of Clearance Certificate No. E-1289258029515 dated 27-May-2022 is submitted. Sodium Bicarbonate: Copy of Clearance Certificate No. E-699858024569 dated 01-Apr-2022 is submitted.	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Audit trail reports on product testing is submitted.	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted	

Remarks of Evaluator:

The Firm vide their letter Dy. No. 9484 dated 10 APR 2023 have submitted Revised Dossier with Full Fee (PKR 30,000/-) vide Slip No. 433021523791 dated 07-04-2023 stating that the data was inadvertently not in proper order and requested for consideration of revised dossier as mentioned above.

Decision of 329th Meeting: Approved.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Agenda Item No. 02: Routine Applications of Human Drugs Locally Manufactured applied on Form - 5F.

1081.	Name, address of Applicant / Marketing Authorization Holder	M/s Axis Pharmaceuticals 3-B, Value Additional City, 1.5-KM, Khurrianwala Sahianwala Road, Faisalabad
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals 3-B, Value Additional City, 1.5-KM, Khurrianwala Sahianwala Road, Faisalabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3189 dated 02-02-2022
	Details of fee submitted	Slip No. 338974300 PKR 30,000/- dated 07-12-2021
	The proposed proprietary name / brand name	Dexazole 30mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Dexlansoprazole (as DDR pellets) 30mg (Innovator's Specification)
	Pharmaceutical form of applied drug	White to grayish-white dual delayed release spherical pellets filled in hard gelatin capsule shell no.2 having transparent body and red cap packed in Alu-Alu blister
	Pharmacotherapeutic Group of (API)	A02BC06, Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (GORD), Proton Pump Inhibitors.
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dexilant 30 mg Capsules of M/s TAKEDA PHARMS USA (USFDA Approved).
	For generic drugs (me-too status)	Delanzo 30mg Capsule (Reg. No. 089145) by M/s Sami Pharma.

	GMP status of the Finished product manufacturer	GMP Certificate was issued based on Inspection conducted on 09-06-2020 which is more than 03 years old. Please provide latest GMP Inspection Report (not older than 03 years).
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Dexlansoprazole is present In-house. The firm as submitted detail of nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 06 months Batches: DLP123T, DLP124T, DLP125T,
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand Delanzo 30mg Capsule by M/s Sami Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Delanzo 30mg Capsule by M/s Sami Pharma in Acid media (pH 1.2) Acetate Buffer (pH 5.5) & Phosphate Buffer (pH 7.0).

		The values for f1 and f2 are in the acceptable range.
	Analytical method validation / verification of product	Method validation studies have been submitted including Linearity, Range, Accuracy, Precision, Specificity and System Suitability.

STABILITY STUDY DATA			
Manufacturer of API	M/s Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad		
API Lot No.	DLP665		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (3×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real Time: 06 Months Accelerated: 06 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T001	T002	T003
Batch Size	1250 Capsules	1250 Capsules	1250 Capsules
Manufacturing Date	08 – 2021	08 – 2021	08 – 2021
Date of Initiation	24 – 08 – 2021	24 – 08 – 2021	24 – 08 – 2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any).	Nil
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. F.3-26/2019-Addl.Dir. (QA&LT-I) Dated 31-07-2019 is submitted. Valid till 10th February 2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No. 60011 Dated 07-09-2021 from M/s Vision Pharmaceuticals (local source) is submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Audit trail reports on product testing is submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

The deficiencies / shortcomings were communicated to the firm and their response is received as follows: -

Sr. No.	Deficiencies / shortcomings communicated	Response of the Firm
i.	Please confirm the name of Firm as it is mentioned as "M/s Axis Pharmaceuticals (Pvt.) Ltd." on DML and on Renewal of your DML whereas the same is mentioned as "M/s Axis Pharmaceuticals" throughout your application. Please revise accordingly.	Typographic error which was later corrected. The firm have now submitted correct copy of DML (of M/s Axis Pharmaceuticals) date of issue w.e.f. 10-06-2019.
ii.	GMP Certificate was issued based on Inspection conducted on **09-06-2020** which is more than 03 years old. Please provide latest GMP Inspection Report (not older than 03 years).	The firm have now submitted a copy of valid GMP Certificate No. 100 / 2022 - DRAP (AD-51001963034) (validity till 12-06-2024) of drug product manufacturer, based upon evaluation conducted on 13-06-2022.
iii.	Please provide 06th Month (Real Time and Accelerated) Stability Study Data and relevant supporting documents for further processing of your application.	Submitted.
iv.	3.3. P.2.2.3. In Physicochemical and Biological Properties, Manufacturer (Axis Pharmaceuticals) Justification is given stating parent company having manufacturing license by way of formulation (semi-basic). Please clarify.	The firm have submitted that it was a **Typographic error**. The product is being manufactured by Axis Pharmaceuticals for registration purpose having valid manufacturing license by way of formulation and approved section.
v.	3.2. P.3.3. In Description of Manufacturing Process and Process Controls, under Process Flow Diagram, it has been mentioned that ''the maximum hold time of bulk product is NMT 10 working days''. Please justify / provide supporting evidence for the claim in terms of hold time studies.	The firm have submitted that for commercial batches they will perform manufacturing process validation as well Hold time study.
vi.	Furthermore, the same is not included in submitted Manufacturing Process Validation Protocol in 3.2.P.3.5 Process Validation and/or Evaluation. Please clarify.	The firm have submitted revised Manufacturing Process Validation Protocol and have included Hold time stability study.
vii.	The submitted GMP Certificate of API Manufacturer was issued based on Inspection conducted on 11th February 2019 and was valid until 10th February 2022. Please provide a valid GMP Certificate of API Manufacturer.	The firm have submitted a copy of valid GMP Certificate (validity: 13-06-2024) & DML of drug substance manufacturer.
viii.	Please provide Reference of previous approval of applications with stability study data of the firm (if any).	The firm have referred to their CTD applications approved in 321st, 322nd and 323rd Registration Board Meetings.
ix.	Please provide Compliance Record of HPLC software 21CFR &	Audit trail reports on product testing is submitted.

	complete audit trail reports on product testing.	
x.	Against documents for the procurement of API, copy of Invoice No. 60011 Dated 07-09-2021 from M/s Vision Pharmaceuticals (local source) is submitted whereas all the Trial Batches have been manufactured and placed for Stability Studies in 08 – 2021. Please justify.	The date mentioned on the invoice is in **month / date / year** format. Material processing timeline is tabulated below; **Sr. # / Stage / Date** 1. Invoice Generated — 9th July 2021 2. API Receiving Date — 13th July 2021 3. Sampling Date — 14th July 2021 4. Analysis Date — 27th July 2021 5. Dispensing Date — 03rd August 2021 6. Processing Date — 6th August 2021 7. Stability Start Date — 24th August 2021

Decision of 329th Meeting: Approved with Innovator's Specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration Board further decided that firm shall submit full fee of registration for revision of the data submitted in registration application and verification of firm's claim regarding format of date of Invoice No. 60011 Dated 07-09-2021 from M/s Vision Pharmaceuticals (local source) before issuance of Registration letter.**

1082.	Name, address of Applicant / Marketing Authorization Holder	M/s Axis Pharmaceuticals (Pvt.) Ltd. 3-B, Value Additional City, 1.5-KM, Khurrianwala Sahianwala Road, Faisalabad
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals (Pvt.) Ltd. 3-B, Value Additional City, 1.5-KM, Khurrianwala Sahianwala Road, Faisalabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3190 dated 02-02-2022
	Details of fee submitted	Slip No. 640973014707 PKR 30,000/- dated 07-12-2021
	The proposed proprietary name / brand name	Dexazole 60mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Dexlansoprazole (as DDR pellets) 60mg

		(Innovator's Specification)
	Pharmaceutical form of applied drug	White to grayish-white dual delayed release spherical pellets filled in hard gelatin capsule shell no.2 having transparent body and blue cap packed in Alu-Alu blister
	Pharmacotherapeutic Group of (API)	A02BC06, Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (GORD), Proton Pump Inhibitors.
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Dexilant 60 mg Capsules of M/s TAKEDA PHARMS USA (USFDA Approved).
	For generic drugs (me-too status)	Delanzo 60mg Capsule (Reg. No. 089146) by M/s Sami Pharma.
	GMP status of the Finished product manufacturer	GMP Certificate was issued based on Inspection conducted on 09-06-2020 which is more than 03 years old. Please provide latest GMP Inspection Report (not older than 03 years).
	Name and address of API manufacturer.	M/s Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Dexlansoprazole is present In-house. The firm as submitted detail of nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 06 months Batches: DLP123T, DLP124T, DLP125T,
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and

		controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand Delanzo 60mg Capsule by M/s Sami Pharma by performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Delanzo 60mg Capsule by M/s Sami Pharma in Acid media (pH 1.2) Acetate Buffer (pH 5.5) & Phosphate Buffer (pH 7.0). The values for f1 and f2 are in the acceptable range.
	Analytical method validation / verification of product	Method validation studies have been submitted including Linearity, Range, Accuracy, Precision, Specificity and System Suitability.

STABILITY STUDY DATA			
Manufacturer of API	M/s Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad		
API Lot No.	DLP665		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (3×10's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real Time: 06 Months Accelerated: 06 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-001	T-002	T-003
Batch Size	1250 Capsules	1250 Capsules	1250 Capsules
Manufacturing Date	08 – 2021	08 – 2021	08 – 2021
Date of Initiation	24 – 08 – 2021	24 – 08 – 2021	24 – 08 – 2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any).	Nil
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. F.3-26/2019-Addl.Dir. (QA&LT-I) Dated 31-07-2019 is submitted. Valid till 10th February 2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No. 60011 Dated 07-09-2021 from M/s Vision Pharmaceuticals (local source) is submitted.

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Audit trail reports on product testing is submitted.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

The deficiencies / shortcomings were communicated to the firm and their response is received as follows: -

Sr. No.	Deficiencies / shortcomings communicated	Response of the Firm
i.	Please confirm the name of Firm as it is mentioned as "M/s Axis Pharmaceuticals (Pvt.) Ltd." on DML and on Renewal of your DML whereas the same is mentioned as "M/s Axis Pharmaceuticals" throughout your application. Please revise accordingly.	Typographic error which was later corrected. The firm have now submitted correct copy of DML (of M/s Axis Pharmaceuticals) date of issue w.e.f. 10-06-2019.
ii.	GMP Certificate was issued based on Inspection conducted on **09-06-2020** which is more than 03 years old. Please provide latest GMP Inspection Report (not older than 03 years).	The firm have now submitted a copy of valid GMP Certificate No. 100 / 2022 - DRAP (AD-51001963034) (validity till 12-06-2024) of drug product manufacturer, based upon evaluation conducted on 13-06-2022.
iii.	Please provide 06th Month (Real Time and Accelerated) Stability Study Data and relevant supporting documents for further processing of your application.	Submitted.
iv.	3.3. P.2.2.3. In Physicochemical and Biological Properties, Manufacturer (Axis Pharmaceuticals) Justification is given stating parent company having manufacturing license by way of formulation (semi-basic). Please clarify.	The firm have submitted that it was a **Typographic error**. The product is being manufactured by Axis Pharmaceuticals for registration purpose having valid manufacturing license by way of formulation and approved section.
v.	3.2. P.3.3. In Description of Manufacturing Process and Process Controls, under Process Flow Diagram, it has been mentioned that ''the maximum hold time of bulk product is NMT 10 working days''. Please justify / provide supporting evidence for the claim in terms of hold time studies.	The firm have submitted that for commercial batches they will perform manufacturing process validation as well Hold time study.
vi.	Furthermore, the same is not included in submitted Manufacturing Process Validation Protocol in 3.2.P.3.5 Process Validation and/or Evaluation. Please clarify.	The firm have submitted revised Manufacturing Process Validation Protocol and have included Hold time stability study.

vii.	The submitted GMP Certificate of API Manufacturer was issued based on Inspection conducted on 11th February 2019 and was valid until 10th February 2022. Please provide a valid GMP Certificate of API Manufacturer.	The firm have submitted a copy of valid GMP Certificate (validity: 13-06-2024) & DML of drug substance manufacturer.
viii.	Please provide Reference of previous approval of applications with stability study data of the firm (if any).	The firm have referred to their CTD applications approved in 321st, 322nd and 323rd Registration Board Meetings.
ix.	Please provide Compliance Record of HPLC software 21CFR & complete audit trail reports on product testing.	Audit trail reports on product testing is submitted.
x.	Against documents for the procurement of API, copy of Invoice No. 60011 Dated 07-09-2021 from M/s Vision Pharmaceuticals (local source) is submitted whereas all the Trial Batches have been manufactured and placed for Stability Studies in 08 – 2021. Please justify.	The date mentioned on the invoice is in **month / date / year** format. Material processing timeline is tabulated below;

Sr. #	Stage	Date
1.	Invoice Generated	9th July 2021
2.	API Receiving Date	13th July 2021
3.	Sampling Date	14th July 2021
4.	Analysis Date	27th July 2021
5.	Dispensing Date	03rd August 2021
6.	Processing Date	6th August 2021
7.	Stability Start Date	24th August 2021

Decision of 329th Meeting: Approved with Innovator's Specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**
- **Registration board further decided that firm shall submit full fee of registration for revision of the data submitted in registration application and verification of firm's claim regarding format of date of Invoice No. 60011 Dated 07-09-2021 from M/s Vision Pharmaceuticals (local source) before issuance of Registration letter.**

1083.	Name, address of Applicant / Marketing Authorization Holder	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi – 74900.
	Name, address of Manufacturing site.	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi – 74900.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 3892 dated 10-02-2022

	Details of fee submitted	Slip No. 027883075 PKR 30,000/- dated 16-12-2021
	The proposed proprietary name / brand name	Vonocab Tablets 10mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet contains: Vonoprazan Fumarate equivalent to Vonoprazan 10mg (Innovator's Specification)
	Pharmaceutical form of applied drug	Faint yellow, oval, biconvex, immediate release film coated tablet engraved MD on one side and plain on other side.
	Pharmacotherapeutic Group of (API)	A02BC08, Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (GORD), Proton Pump Inhibitors.
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	7's, 14's, 28's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Takecab Tablets 10mg by Takeda Pharmaceutical Company Limited, PMDA Japan approved.
	For generic drugs (me-too status)	Vocinti Tablet 10mg (Reg. No. 108835) by M/s The Searle Company Limited.
	GMP status of the Finished product manufacturer	GMP inspection report dated 20/10/2021 states good level of cGMP compliance.
	Name and address of API manufacturer.	Jiangxi Synergy Pharmaceutical Co., Ltd. Jiangxi Fengxin Industrial Park, Jiangxi Province, 33070, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 75% ± 5%RH for 24 Months

		Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 Months Batches: 20190801BD, 20190802BD, 20190803BD.
	Module-III (Drug Product):	The firm has submitted detail of manufacturer, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Innovator product that is Takecab Tablet 10mg by Takeda Pharmaceuticals Company by performing quality tests (Identification, Disintegration, Assay, Dissolution, Related substances). CDP has been performed against the same brand that is Takecab Tablet 10mg by Takeda Pharmaceuticals Company, in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The profiles are considered similar.
	Analytical method validation / verification of product	Method validation studies have been submitted including Linearity, Range, Accuracy, Precision and Specificity.

STABILITY STUDY DATA			
Manufacturer of API	Jiangxi Synergy Pharmaceutical Co., Ltd. Jiangxi Fengxin Industrial Park, Jiangxi Province, 33070, China		
API Lot No.	2011000125 (02-YF20201021)		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2x7's)		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real Time: 06 Months Accelerated: 06 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	NPD-T-1612-S	NPD-T-1651-S	NPD-T-1652-S
Batch Size	2500 tablets	5000 tablets	5000 tablets
Manufacturing Date	25-08-2021	10-09-2021	10-09-2021
Date of Initiation	08-10-2021	08-10-2021	08-10-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any).	Firm has referred to their product Pirfedow Tablets 267mg which was approved in 297th

		Meeting of Registration Board held on 12th – 15th January 2021. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software. • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate for Jiangxi Synergy Pharmaceutical Co., Ltd. issued by Jiangxi Fengxin Market and Quality Supervision Administration & valid upto 23-08-2022 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Invoice No. JXSG200802 dated 29-10-2020 from Jiangxi Synergy Pharmaceutical Co., Ltd. cleared by DRAP Karachi office dated 17-11-2020.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted
Remarks of Evaluator: Initial Stability Study Data was provided for 03 Months along with application dossier on Form 5F, which was later on completed to 06 Months (Accelerated and Real Time) vide Dy. No. 10385 dated 23 APR 2022.		
Decision of 329th Meeting: Approved with Innovator's Specification. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		
1084.	Name, address of Applicant / Marketing Authorization Holder	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi – 74900.
	Name, address of Manufacturing site.	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi – 74900.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4305 dated 15-02-2022
	Details of fee submitted	Slip No. 7608774239 PKR 30,000/- dated 16-12-2021
	The proposed proprietary name / brand name	Vonocab Tablets 20mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet contains: Vonoprazan Fumarate equivalent to Vonoprazan 20mg (Innovator's Specification)
	Pharmaceutical form of applied drug	Pale pink, oblong, biconvex, immediate release film coated tablet engraved MD on one side and plain on other side.
	Pharmacotherapeutic Group of (API)	A02BC08, Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (GORD), Proton Pump Inhibitors.
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	7's, 14's, 28's and 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Takecab Tablets 20mg by Takeda Pharmaceutical Company Limited, PMDA Japan approved.
	For generic drugs (me-too status)	Vocinti Tablet 20mg (Reg. No. 108836) by M/s The Searle Company Limited.
	GMP status of the Finished product manufacturer	GMP inspection report dated 20/10/2021 states good level of cGMP compliance.
	Name and address of API manufacturer.	Jiangxi Synergy Pharmaceutical Co., Ltd. Jiangxi Fengxin Industrial Park, Jiangxi Province, 33070, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for

		impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 75% ± 5%RH for 24 Months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 Months Batches: 20190801BD, 20190802BD, 20190803BD.
	Module-III (Drug Product):	The firm has submitted detail of manufacturer, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Innovator product that is Takecab Tablet 20mg by Takeda Pharmaceuticals Company by performing quality tests (Identification, Disintegration, Assay, Dissolution, Related substances). CDP has been performed against the same brand that is Takecab Tablet 20mg by Takeda Pharmaceuticals Company, in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The profiles are considered similar.
	Analytical method validation / verification of product	Method validation studies have been submitted including Linearity, Range, Accuracy, Precision and Specificity.

STABILITY STUDY DATA			
Manufacturer of API	Jiangxi Synergy Pharmaceutical Co., Ltd. Jiangxi Fengxin Industrial Park, Jiangxi Province, 33070, China		
API Lot No.	2011000125 (02-YF20201021)		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (2x7's)		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real Time: 06 Months Accelerated: 06 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	NPD-T-1613-S	NPD-T-1653-S	NPD-T-1654-S
Batch Size	2500 tablets	5000 tablets	5000 tablets

Manufacturing Date	25-08-2021	13-09-2021	13-09-2021
Date of Initiation	08-10-2021	08-10-2021	08-10-2021
No. of Batches	03		
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any).	Firm has referred to their product Pirfedow Tablets 267mg which was approved in 297th Meeting of Registration Board held on 12th – 15th January 2021. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software. • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers.	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate for Jiangxi Synergy Pharmaceutical Co., Ltd. issued by Jiangxi Fengxin Market and Quality Supervision Administration & valid upto 23-08-2022 is submitted.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Invoice No. JXSG200802 dated 29-10-2020 from Jiangxi Synergy Pharmaceutical Co., Ltd. cleared by DRAP Karachi office dated 17-11-2020.	
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted	
Remarks of Evaluator: Initial Stability Study Data was provided for 03 Months along with application dossier on Form 5F, which was later on completed to 06 Months (Accelerated and Real Time) vide Dy. No. 10386 dated 23 APR 2022.			
Decision of 329th Meeting: Approved with Innovator's Specification. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**			
1085.	Name, address of Applicant / Marketing Authorization Holder	M/s Novamed Pharmaceuticals (Pvt.) Ltd ., 28km Ferozepur Road Lahore.	

	Name, address of Manufacturing site.	M/s Novamed Pharmaceuticals (Pvt.) Ltd ., 28km Ferozepur Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4644 dated 18-02-2022
	Details of fee submitted	Slip No. 95036060703 PKR 30,000/- dated 31-01-2022
	The proposed proprietary name / brand name	Vonomed 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet contains: Vonoprazan Fumarate equivalent to Vonoprazan 10mg (Innovator's Specification)
	Pharmaceutical form of applied drug	Peach color round shaped, biconvex film coated tablets, having both sides plain.
	Pharmacotherapeutic Group of (API)	A02BC08, Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (GORD), Proton Pump Inhibitors.
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	10's, 20's , 30's, & 14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Takecab Tablets 10mg by Takeda Pharmaceutical Company Limited, PMDA Japan approved.
	For generic drugs (me-too status)	Vocinti Tablet 10mg (Reg. No. 108835) by M/s The Searle Company Limited.
	GMP status of the Finished product manufacturer	DML Renewal granted vide letter No. F.1-9/2003-Lic(Vol-II) dated 14th September 2021 based on Inspection conducted on 06-08-2021.
	Name and address of API manufacturer.	Enantiotech Corporation Limited, Zhongshan Torch Hi-tech Industrial development zone, Guangdong Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference

		standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: TAK09R170801, TAK09R170301 and TAK09R171001.
	Module-III (Drug Product):	The firm has submitted detail of manufacturer, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Innovator product that is Takecab Tablet 10mg by Takeda Pharmaceuticals Company by performing quality tests (Identification, Disintegration, Assay, Dissolution, Related substances). CDP has been performed against the same brand that is Takecab Tablet 10mg by Takeda Pharmaceuticals Company, in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The profiles are considered similar.
	Analytical method validation / verification of product	Method validation studies have been submitted including Linearity, Range, Accuracy, Specificity, Repeatability and System Suitability.

STABILITY STUDY DATA	
Manufacturer of API	Enantiotech Corporation Limited, Zhongshan Torch Hi-tech Industrial development zone, Guangdong Province, China.
API Lot No.	TAK09R210401
Description of Pack (Container closure system)	Alu-Alu Blister pack, with insert in unit carton.
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH

	Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real Time: 06 Months Accelerated: 06 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD/PR21-095/T1/S1	RD/PR21-095/T1/S2	RD/PR21-095/T1/S3
Batch Size	2,000 Tablets	2,000 Tablets	2,000 Tablets
Manufacturing Date	08-2021	08-2021	08-2021
Date of Initiation	16-09-2021	16-09-2021	16-09-2021
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any).	-
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 202105010 submitted valid till 2024/04/30.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Assistant Director (Lahore) attested Invoice No. EAI20210604048 dated 2021/06/04 is submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Initial Stability Study Data was provided for 03 Months along with application dossier on Form 5F, which was later on completed to 06 Months (Accelerated and Real Time) vide Dy. No. 11695 dated 14 MAY 2022.

Decision of 329th Meeting: Approved with Innovator's Specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

1086.	Name, address of Applicant / Marketing Authorization Holder	M/s Novamed Pharmaceuticals (Pvt.) Ltd ., 28km Ferozepur Road Lahore.
	Name, address of Manufacturing site.	M/s Novamed Pharmaceuticals (Pvt.) Ltd ., 28km Ferozepur Road Lahore.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 4644 dated 18-02-2022
	Details of fee submitted	Slip No. 41607990659 PKR 30,000/- dated 31-01-2022
	The proposed proprietary name / brand name	Vonomed 20mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet contains: Vonoprazan Fumarate equivalent to Vonoprazan 20mg (Innovator's Specification)
	Pharmaceutical form of applied drug	White colored round shaped, biconvex film coated tablets, having both sides plain.
	Pharmacotherapeutic Group of (API)	A02BC08, Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (GORD), Proton Pump Inhibitors.
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	10's, 20's , 30's, & 14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Takecab Tablets 20mg by Takeda Pharmaceutical Company Limited, PMDA Japan approved.
	For generic drugs (me-too status)	Vocinti Tablet 20mg (Reg. No. 108836) by M/s The Searle Company Limited.
	GMP status of the Finished product manufacturer	DML Renewal granted vide letter No. F.1-9/2003-Lic(Vol-II) dated 14th September 2021 based on Inspection conducted on 06-08-2021.
	Name and address of API manufacturer.	Enantiotech Corporation Limited, Zhongshan Torch Hi-tech Industrial development zone, Guangdong Province, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.

	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: TAK09R170801, TAK09R170301 and TAK09R171001.
	Module-III (Drug Product):	The firm has submitted detail of manufacturer, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the Innovator product that is Takecab Tablet 20mg by Takeda Pharmaceuticals Company by performing quality tests (Identification, Disintegration, Assay, Dissolution, Related substances). CDP has been performed against the same brand that is Takecab Tablet 20mg by Takeda Pharmaceuticals Company, in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The profiles are considered similar.
	Analytical method validation / verification of product	Method validation studies have been submitted including Linearity, Range, Accuracy, Specificity, Repeatability and System Suitability.

STABILITY STUDY DATA	
Manufacturer of API	Enantiotech Corporation Limited, Zhongshan Torch Hi-tech Industrial development zone, Guangdong Province, China.
API Lot No.	TAK09R210401
Description of Pack (Container closure system)	Alu-Alu Blister pack, with insert in unit carton.
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Real Time: 06 Months Accelerated: 06 Months

Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	RD/PR21-090/T1/S1	RD/PR21-090/T1/S2	RD/PR21-090/T1/S3
Batch Size	2,000 Tablets	2,000 Tablets	2,000 Tablets
Manufacturing Date	08-2021	08-2021	08-2021
Date of Initiation	16-09-2021	16-09-2021	16-09-2021
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any).	-
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 202105010 submitted valid till 2024/04/30.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Assistant Director (Lahore) attested Invoice No. EAI20210604048 dated 2021/06/04 is submitted.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Initial Stability Study Data was provided for 03 Months along with application dossier on Form 5F, which was later on completed to 06 Months (Accelerated and Real Time) vide Dy. No. 11696 dated 14 MAY 2022.

Decision of 329th Meeting: Approved with Innovator's Specification.

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

Agenda Item No. 03: Priority applications on the basis of Export Facilitation of Locally Manufactured Drugs:

The following dossiers have been evaluated reference to the letter No. F.1-6/2019-PR-I (EFD) dated 06th October 2022 from Assistant Director (PR-I/EFD) wherein it has been stated that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical

i.e. one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm (M/s Getz Pharma (Pvt.) Limited) have achieved the benchmark of export of more than 100,000 USD (2311157.75 USD) during the fiscal year 2021-2022 and have submitted their applications for priority consideration in lieu of export facilitation for Registration Board please: -

1087.	Name, address of Applicant / Marketing Authorization Holder	M/s Getz Pharma (Pvt.) Limited 29-30, Sector 27, Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s Getz Pharma (Pvt.) Limited 29-30, Sector 27, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 18003 dated 21-06-2022.
	Details of fee submitted	Slip No. 74763446899 PKR 75,000/- dated 27-08-2021.
	The proposed proprietary name / brand name	UVF DPI Capsules 62.5mcg + 25mcg + 100mcg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each DPI capsule contains: Umeclidinium Bromide equivalent to Umeclidinium 62.5mcg Vilanterol Trifenatate equivalent to Vilanterol 25mcg Fluticasone Furoate 100mcg (Innovator's Specification)
	Pharmaceutical form of applied drug	Hydroxypropyl methylcellulose (HPMC) capsule shell containing white powder for Inhalation.
	Pharmacotherapeutic Group of (API)	R03AL08, Drugs For Obstructive Airway Diseases, Adrenergics in combination with anticholinergics incl. triple combinations with corticosteroids.
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	3 x 10's (30's)
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Trelegy Ellipta (fluticasone furoate 100 mcg, umeclidinium 62.5 mcg, and vilanterol 25 mcg) Inhalation Powder by GlaxoSmithKline (USFDA Approved).
	For generic drugs (me-too status)	Not applicable
	GMP status of the Finished product manufacturer	GMP Certificate No. 06/2022-DRAP(K) issued dated 17-01-2022.

	Name and address of API manufacturer.	**Umeclidinium Bromide:** M/s INKE, S.A. C/ Argent, 1, Área Industrial del Llobregat, 08755 CASTELLBISBAL (Barcelona) Spain. **Vilanterol Trifenatate:** M/s INKE, S.A. C/ Argent, 1, Área Industrial del Llobregat, 08755 CASTELLBISBAL (Barcelona) Spain. **Fluticasone Furoate:** M/s Aarti Industries Limited, D-53, Phase-II, Kalyan shill road, Dombivli (E.), Dombivli- 421204, District- Thane, Zone6 – India.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: **Umeclidinium Bromide** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 18 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: DS-1M, DS-2M, DS-3M **Vilanterol Trifenatate** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 18 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: PP-5M, PP-6M, PP-7M **Fluticasone Furoate** Real time: 30˚C ± 2˚C / 65% ± 5%RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: UK/1601/01/010, UK/1503/I/01/127, UK/1403/01/126.
	Module-III (Drug Product):	The firm has submitted detail of manufacturer, description of manufacturing process and controls,

		impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against innovator's product **Trelegy Ellipta 62.5mcg + 25mcg + 100mcg Inhalation Powder by M/s GlaxoSmithKline, USA** by performing quality tests (appearance, assay, deposition of emitted dose, uniformity of delivered dose, aerodynamics particle size distribution test and related substances).
	Analytical method validation / verification of product	Method validation studies have submitted including, system suitability, specificity, linearity, accuracy, precision repeatability, intermediate precision, robustness, stability of solution and range.

STABILITY STUDY DATA

Manufacturer of API	**Umeclidinium Bromide:** M/s INKE, S.A. C/ Argent, 1, Área Industrial del Llobregat, 08755 CASTELLBISBAL (Barcelona) Spain. **Vilanterol Trifenatate:** M/s INKE, S.A. C/ Argent, 1, Área Industrial del Llobregat, 08755 CASTELLBISBAL (Barcelona) Spain. **Fluticasone Furoate:** M/s Aarti Industries Limited, D-53, Phase-II, Kalyan shill road, Dombivli (E.), Dombivli- 421204, District- Thane, Zone6 – India.		
API Lot No.	Umeclidinium Bromide: PP-2M Vilanterol Trifenatate: PR-16 Fluticasone Furoate: UK/20003/01/074		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton (3 x 10's).		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real Time: 06 Months Accelerated: 06 Months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	554DS02	554DS03	554DS04
Batch Size	4,545 Capsules	4,545 Capsules	4,545 Capsules
Manufacturing Date	12.11.2020	20.11.2020	23.11.2020
Date of Initiation	04.12.2020	04.12.2020	04.12.2020
No. of Batches	03		

Administrative Portion

1.	Reference of previous approval of applications with stability study data of the firm (if any).	Firm has referred to onsite inspection report of their product Estine (Ebastine) Tablets 10mg & 20mg on 6th May, 2019. Further, the said panel inspection report was discussed in 289th Drug Registration Board meeting held on 14th – 16th May 2019.

<table>
<tr><td></td><td></td><td>The case was approved and the inspection report confirms following points:
The HPLC software is 21CFR Compliant as per record available with the firm.
Audit trail on the testing reports is available.
Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well.
Related manufacturing area, equipment, personnel and utilities are GMP compliant.</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td>Umeclidinium Bromide & Vilanterol Trifenatate:
Firm has submitted copy of GMP Certificate No. NCF-II/2123/001/CAT issued by Ministry of Health of Government Catalonia – Spain (valid till 31-12-2023).

Fluticasone Furoate:
Firm has submitted copy GMP Certificate No. 6102121 issued by Food and Drug Administration, Maharashtra State, India (valid till 29-09-2022).</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of invoice attested by AD I&E DRAP, Karachi, has been submitted as follows:

<table><tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval</th></tr><tr><td colspan="4">Umeclidinium Bromide</td></tr><tr><td>PP-2M</td><td>14602935</td><td>30g</td><td>01.04.2020</td></tr><tr><td colspan="4">Vilanterol Trifenatate</td></tr><tr><td>PR-16</td><td>14602935</td><td>15g</td><td>01.04.2020</td></tr><tr><td colspan="4">Fluticasone Furoate</td></tr><tr><td>UK/20003/ 01/074</td><td>EX/1750/ 20-21</td><td>70g</td><td>20.07.2020</td></tr></table></td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td>Firm has submitted data of stability batches along with batch manufacturing record, analytical record and attested documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td></tr>
<tr><td>5.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing</td><td>Firm has submitted compliance certificate of HPLC software and audit trail reports on product testing.</td></tr>
<tr><td>6.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated).</td></tr>
<tr><td colspan="3">Remarks of Evaluator:</td></tr>
<tr><td colspan="3">Decision of 329th Meeting: Approved with Innovator’s Specification.</td></tr>
</table>

- **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**

- **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

The following dossiers have been evaluated reference to the letter No. F.1-6/2019-PR-I (EFD) dated 29th December 2022 from Assistant Director (PR-I/EFD) wherein it has been stated that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical i.e. one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm (M/s. Sami Pharmaceuticals (Pvt.) Ltd.) have achieved the benchmark of export of more than 100,000 USD (1596135.35 USD) during the fiscal year 2021-2022 and have submitted their applications for priority consideration in lieu of export facilitation for Registration Board please: -

1088.	Name, address of Applicant / Marketing Authorization Holder	M/s. Sami Pharmaceuticals (Pvt.) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi.
	Name, address of Manufacturing site.	M/s. Sami Pharmaceuticals (Pvt.) Ltd. F-95, Off Hub River Road, S.I.T.E. Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 35340 dated 06-12-2022
	Details of fee submitted	Slip No. 664267317193 PKR 30,000/- dated 26-10-2022.
	The proposed proprietary name / brand name	DICLOREP 50mg Sachet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sachet contains: Diclofenac Potassium USP 50mg (USP Specifications)
	Pharmaceutical form of applied drug	White to off white color, free following granules.
	Pharmacotherapeutic Group of (API)	M01AB05, Anti-inflammatory and Anti-rheumatic Products, Acetic acid derivatives and related substances.
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1's & 9's
	Proposed unit price	As per SRO

	The status in reference regulatory authorities	Voltfast Sachet of Novartis Pharma (Swissmedic).
	For generic drugs (me-too status)	Diclovis-K 50mg (Reg. No. 109783) Sachet by M/s Vision Pharmaceuticals.
	GMP status of the Finished product manufacturer	GMP Certificate No. 110/2022-DRAP(K) issued dated 03-08-2022.
	Name and address of API manufacturer.	Henan Dongtai Pharm Co., Ltd. No. 2, East Kangtai Road, Tangyin County,City, Henlan Province, P.R. China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5% RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5% RH for 6 months Batches: 303210412-5, 303210413-5, 303210414-5.
	Module-III (Drug Product):	The firm has submitted detail of manufacturer, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against the brand **Voltfast 50mg powder for oral solution** by M/s Novartis by performing quality tests (appearance, identification, pH, average wt. of content, assay, dissolution, impurity profiling, dissolution & microbial enumeration).

		CDP has been performed against the same brand that is **Voltfast 50mg powder for oral solution** by M/s Novartis in Water, Phosphate Buffer (pH 6.8 & 7.5). The dissolution profile of Test and Reference Product is comparable.		
	Analytical method validation / verification of product	Method verification studies have submitted including linearity, accuracy, repeatability, solution stability and specificity.		
STABILITY STUDY DATA				
Manufacturer of API		Henan Dongtai Pharm Co., Ltd. No. 2, East Kangtai Road, Tangyin County,City, Henlan Province, P.R. China.		
API Lot No.		0303191014-5		
Description of Pack (Container closure system)		Paper Foil		
Stability Storage Condition		Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period		Real Time: 06 Months Accelerated: 06 Months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		Lab-04	Lab-05	Lab-06
Batch Size		1,500 Sachet	1,500 sachet	1,500 sachet
Manufacturing Date		Jan-2022	Jan-2022	Jan-2022
Date of Initiation		Feb-2022	Feb-2022	Feb-2022
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any).	The firm has referred to the last onsite panel inspection for instant dosage form "Recada 30mg & 10mg Sachet (Rececadotril)" conducted on 12th June, 2019 which was presented & approved in 290th Meeting of the Registration Board held on 3rd - 4th July, 2019.		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. HA20190077 issued by CFDA valid till 05/11/2024 has been submitted.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Commercial Invoice No. DT2012183F dated 10-05-2021 attested by AD (I&E) Karachi dated 01-06-2021 has been submitted.		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted		

Remarks of Evaluator:
Decision of 329th Meeting: Approved. • **Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.** • **Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**

The following dossiers have been evaluated reference to the letter No. F.1-6/2019-PR-I (EFD) dated 29th December 2022 from Assistant Director (PR-I/EFD) wherein it has been stated that DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis to the pharmaceutical i.e. one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm (M/s Indus Pharma (Pvt.) Ltd.) have achieved the benchmark of export of more than 100,000 USD (965264.88 USD) during the fiscal year 2020 - 2021 and have submitted their applications for priority consideration in lieu of export facilitation for Registration Board please.

1089.	Name, address of Applicant / Marketing Authorization Holder	M/s Indus Pharma (Pvt.) Ltd. Plot No. 26-27, 63-67, Sector-27 Korangi Industrial Area, Karachi.
	Name, address of Manufacturing site.	M/s Indus Pharma (Pvt.) Ltd. Plot No. 26-27, 63-67, Sector-27 Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 22140 dated 04-08-2022.
	Details of fee submitted	Slip No. 7682522698 PKR 30,000/- dated 03-06-2022.
	The proposed proprietary name / brand name	Parabac 500mg Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Sterile Cefoperazone Sodium & Sulbactum Sodium (1:1) … 500mg (Innovator's Specification)
	Pharmaceutical form of applied drug	A white to off-white sterile crystalline powder for Injection, filled and sealed in 8ml clear glass vial with blue colored plastic flip off seal.
	Pharmacotherapeutic Group of (API)	J01DD62, Anti-infectives for Systemic Use, Third-generation Cephalosporins.

	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Sulperazone for Intravenous Injection 0.5g (PMDA Japan Approved).
	For generic drugs (me-too status)	2Sum 500mg Injection (Reg. No. 079941) by M/s Healthtek (Pvt.) Ltd.
	GMP status of the Finished product manufacturer	GMP Certificate No. 53/2021-DRAP(K) issued dated 24-12-2021.
	Name and address of API manufacturer.	Zhuhai United Laboratories Co., Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai, China.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurity & related substances, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies	Stability study conditions: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months Batches: 319109008, 319109009 and 319109010.
	Module-III (Drug Product):	The firm has submitted detail of manufacturer, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing at acidic and buffer medium) and its validation studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against "2Sum 500mg Injection by

		M/s Healthtek (Pvt.) Ltd, Reg. No. 079941" by performing quality tests (description, pH, Assay, Microbial Limit).		
	Analytical method validation / verification of product	Method validation studies have submitted including linearity, specificity, precision, accuracy, range, robustness and system suitability.		
STABILITY STUDY DATA				
Manufacturer of API		Zhuhai United Laboratories Co., Ltd. No. 2428, Anji Road, Sanzao Town, Jinwan District, Zhuhai, China.		
API Lot No.		3192103009		
Description of Pack (Container closure system)		8ml clear glass sealed vial.		
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real Time: 06 Months Accelerated: 06 Months		
Frequency		Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.		TR-1/PB 500mg Inj	TR-2/PB 500mg Inj	TR-3/PB 500mg Inj
Batch Size		2,000 Vials	2,000 Vials	2,000 Vials
Manufacturing Date		10 – 2021	10 – 2021	10 – 2021
Date of Initiation		26-10-2021	26-10-2021	26-10-2021
No. of Batches		03		
Administrative Portion				
1.	Reference of previous approval of applications with stability study data of the firm (if any).	The firm has referred to their Inspection of Canazin 100mg & 300mg Tablets (Canagliflozin) conducted on 14th March, 2019 and discussed and approved in 289th meeting of Registration Board held on 14th – 16th May, 2019.		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate No. GD20180909 issued by China Food and Drug Administration valid till 05/12/2023 has been submitted.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Invoice No. CESU210802JZ dated 02-08-2021 cleared on 11/08/2021 by AD (I&E) DRAP Karachi for 200Kgs of Cefoperazone Sodium and Sulbactum Sodium (1:1) has been submitted.		
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted.		
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.		

Remarks of Evaluator:

The deficiencies / shortcomings were communicated to the firm and their response is received as follows: -

Sr. No.	Deficiencies / shortcomings communicated	Response of the Firm
i.	In 1.5.10 Dosage form of applied drug, b) Description of Dosage Form, it is mentioned as "A white to yellowish orange, sterile crystalline powder, filled and sealed in 20ml clear glass vial with Red color plastic flip off seal". However, the same has been mentioned as "A white to off-white sterile crystalline powder, filled and sealed in 8ml clear glass vial with blue color plastic flip off seal in rest of the dossier". Please clarify	The firm have submitted revised section 1.5.10 Dosage form of applied drug, b) Description of Dosage Form as "A white to off-white sterile crystalline powder, filled and sealed in 8ml clear glass vial with blue color plastic flip off seal in rest of the dossier".
ii.	In 2.3.S.4 Control of the Drug Substance, 2.3.S.4.1 (a) Drug Substance specifications of the Drug Product Manufacturer, the standard specification and reference number has been mentioned as "USP 43" whereas the Tests are conducted as per "In-House" Specifications. Please clarify	The firm have submitted revised section 2.3.S.4 Control of the Drug Substance, 2.3.S.4.1 (a) Drug Substance specifications of the Drug Product Manufacturer as "In-House".
iii.	In 2.3.S.4.5 Justification of Specifications, it is stated that "Cefoperazone sodium and Sulbactum sodium being In-House product is analysed as per Manufacturers Specifications", however the official monograph of Cefoperazone Sodium and Sulbactam Sodium for Injection is present in Japanese Pharmacopoeia. Please justify the reason for not adopting the same	The firm have submitted that the product mentioned in Japanese Pharmacopeia Monograph is freeze lyophilized solution while they are manufacturing product by direct filling of powder aseptically into final container hence both are considered as different products and have different product specifications.
iv.	In 2.3.P.5.4 Batch Analysis, a) Description of the Batches, date of Manufacturing of Batch "TR-3/PB 500mg Inj" is mentioned as "12 – 2019". Please clarify	The firm have submitted revised section 2.3.P.5.4 Batch Analysis, a) Description of the Batches, date of Manufacturing of Batch "TR-3/PB 500mg Inj" as "10 – 2021".
v.	Pharmaceutical Equivalence have been established against "2Sum 500mg Injection by M/s Healthtek (Pvt.) Ltd". Please justify the reason for not establishing the same against Reference / Innovator / Originator Product	The firm have submitted that the innovator Product Magnex 500mg Injection (Cefoperazone + Sulbactum) by Pfizer (Japan) was not available in Pakistan hence they have established Pharmaceutical Equivalence against "2Sum 500mg Injection by M/s Healthtek (Pvt.) Ltd".

Decision: Registration Board Referred to Expert Working Group for the review of specifications Cefoperazone Sodium & Sulbactam Sodium for Injection (JP Specifications).

- **Registration Board further decided that firm shall submit full fee of registration for revision of the data submitted in registration application before issuance of Registration letter.**

Agenda of Evaluator PEC-XXIII

Case no. 01 Registration applications for local manufacturing of (Human) drugs (Form 5)

a. New cases

1090.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	TEROD tablet 3mg
	Composition	Each tablet contains: Tegaserod ……..3mg
	Diary No. Date of R& I & fee	Dy No. 14534 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900629 dated 05-03-2019.
	Pharmacological Group	Other drugs for constipation ATC Code A06AX06
	Type of Form	Form 5
	Finished Product Specification	USP, as stated by applicant
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not found in applied composition and strength
	Me-too status	Serrod Tablets 3mg M/s Pulse Pharmaceuticals Reg. No. 049011
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Revision in finished product specifications from USP to In-house specifications along with requisite fee. • Revision in master formulation from Tegaserod Maleate to Tegaserod according to the label claim, along with requisite fee. • Evidence of approval of applied product in reference regulatory authority as approved by the Registration Board in its 275th meeting is required. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant.
	Decision: Deferred for following: • **Revision in finished product specifications from USP to In-house specifications along with fee prescribed vide S.R.O 496(I)/2023 dated 17-04-2023 (PKR 7500);** • **Revision in master formulation from Tegaserod Maleate to Tegaserod according to the label claim, along with fee prescribed vide S.R.O 496(I)/2023 dated 17-04-2023 (PKR 30,000);** • **Submission of Form-5 and annexures duly signed by the applicant instead of the qualified persons;** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
1091.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	TEROD tablet 2mg
	Composition	Each tablet contains: Tegaserod ……..2mg

	Diary No. Date of R& I & fee	Dy No. 14533 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900628 dated 05-03-2019.
	Pharmacological Group	Other drugs for constipation ATC Code A06AX06
	Type of Form	Form 5
	Finished Product Specification	USP, as stated by applicant
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Tegaserod (as maleate) tablet is discontinued by USFDA. Status could not be confirmed from PMDA Japan, Health Canada, ANSM France and TGA Australia.
	Me-too status	Tegaser 2mg Tablet M/s Nexus Pharma (Pvt) Ltd., Karachi Reg. No. 86653
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Revision in finished product specifications from USP to In-house specifications along with requisite fee. • Change in label claim from Tegacerod to Tegaserod (as maleate) according to product already/previously approved by USFDA & DRAP, along with requisite fee. • As product is discontinued in USFDA, evidence of approval of applied product in reference regulatory authority is required. Strength of 6mg was not allowed marketing authorization by EMA due to risks of use outweighting the benefits. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) alongwith Deposit Slip No. 926154083 and the Board was apprised of the same during the meeting. However, RRA status could not be confirmed.***
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
1092.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	TEROD tablet 6mg
	Composition	Each tablet contains: Tegaserod ……..6mg
	Diary No. Date of R& I & fee	Dy No. 14535 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900630 dated 05-03-2019.
	Pharmacological Group	Other drugs for constipation ATC Code A06AX06
	Type of Form	Form 5
	Finished Product Specification	USP, as stated by applicant
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	Tegaserod (as maleate) tablet is discontinued by USFDA and EMA. Not confirmed from PMDA Japan, Health Canada, ANSM France and TGA Australia
	Me-too status	Serrod Tablets 6mg M/s Pulse Pharmaceuticals Reg. No. 86654
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Revision in finished product specifications from USP to In-house specifications along with requisite fee. • Change in label claim from Tegaserod to Tegaserod (as maleate) according to product already approved by USFDA & DRAP, along with requisite fee. • As product is discontinued in USFDA & refused marketing authorization in EMA, evidence of approval of applied product in reference regulatory authority is required. (According to European Medicines Agency Post-authorisation Evaluation of Medicines for Human Use Doc.Ref. EMEA/CHMP/109088/2006 dated 23-3-2006, on 15 December 2005 the Committee for Medicinal Products for Human Use (CHMP) recommended the refusal of the marketing authorisation for the medicinal product Zelnorm (Tegaserod) 6 mg tablets. Following request from the applicant, the CHMP re-examined the opinion and confirmed its previous view on 23 March 2006. The CHMP was of the opinion that Zelnorm's benefits are not greater than its risks. Hence, the CHMP recommended that Zelnorm be refused marketing authorisation.) • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) alongwith Deposit slip No. 93081752261 and the Board was apprised of the same during the meeting. However, RRA status could not be confirmed.***
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
1093.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	ESKLON tablet 1mg
	Composition	Each film coated tablet contains: Eszopiclone(USP) ..……..1mg
	Diary No. Date of R& I & fee	Dy No. 14549 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900589 dated 05-03-2019.

	Pharmacological Group	Benzodiazepine related drugs ATC Code N05CF04
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lunesta 1mg tablet USFDA Approved
	Me-too status	Ezpik Tablet 1mg M/s Aspin Pharma (Pvt) Ltd., Karachi Reg. No. 100130
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1094.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	ESKLON tablet 2mg
	Composition	Each film coated tablet contains: Eszopiclone(USP) ..……..2mg
	Diary No. Date of R& I & fee	Dy No. 14550 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900590 dated 05-03-2019.
	Pharmacological Group	Benzodiazepine related drugs ATC Code N05CF04
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lunesta 2mg tablet USFDA Approved
	Me-too status	Ezpik Tablet 2mg M/s Aspin Pharma (Pvt) Ltd., Karachi Reg. No. 100131
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***

	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1095.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	ESKLON tablet 3mg
	Composition	Each film coated tablet contains: Eszopiclone(USP) ..……..3mg
	Diary No. Date of R& I & fee	Dy No. 14551 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900591 dated 05-03-2019.
	Pharmacological Group	Benzodiazepine related drugs ATC Code N05CF04
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lunesta 3mg tablet USFDA Approved
	Me-too status	Ezpik Tablet 3mg M/s Aspin Pharma (Pvt) Ltd., Karachi Reg. No. 100132
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1096.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	FERIDE tablet 5mg
	Composition	Each film coated tablet contains: Finasteride (USP) ..……..5mg
	Diary No. Date of R& I & fee	Dy No. 14555 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900595 dated 05-03-2019.
	Pharmacological Group	Testosterone-5-alpha reductase inhibitors ATC Code G04CB01
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Proscar 5mg tablet USFDA Approved
	Me-too status	Xebim 5mg Tablet M/s Ameer & Adnan Pharmaceuticals (Pvt) Ltd, Lahore Reg. No. 113292

	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• The Registration Board in its 307th meeting approved the manufacture of finasteride tablet in general tablet section since the drug substance is neither hormone nor steroid. However, manufacturer shall be directed to provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs, in accordance with the decision of Registration Board in its 321st meeting. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter. **Moreover the Registration Board directed the manufacturer to provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.**	
1097.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	FERIDE tablet 1mg
	Composition	Each film coated tablet contains: Finasteride (USP) ..……..1mg
	Diary No. Date of R& I & fee	Dy No. 14553 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900593 dated 05-03-2019.
	Pharmacological Group	Testosterone-5-alpha reductase inhibitors ATC Code G04CB01
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Propecia 1mg tablet USFDA Approved
	Me-too status	Finacal 1mg Tablet M/s Dyson Research Laboratories (Pvt.) Ltd, Lahore Reg. No. 112046
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• The Registration Board in its 307th meeting approved the manufacture of finasteride tablet in general tablet section since the drug substance is neither hormone nor steroid. However, manufacturer shall be directed to provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs, in

		accordance with the decision of Registration Board in its 321st meeting. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter. **Moreover the Registration Board directed the manufacturer to provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.**	
1098.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	CANDEXIL tablet 16/12.5mg
	Composition	Each tablet contains: Candestartan Cilexetil (USP)……..16mg Hydrochlorthiazide(USP) ..…….12.5mg
	Diary No. Date of R& I & fee	Dy No. 14487 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902521 dated 05-03-2019.
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics ATC Code C09DA06
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Atacand HCT USFDA Approved
	Me-too status	CST-H 16mg/12.5mg Tablet M/s Pharmasol (Pvt) Ltd
	GMP status	Last GMP inspection conducted on 10-12-2020
	Remarks of the Evaluator[xxiii].	
	Decision: Approved.	
1099.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	CANDEXIL tablet 32/25mg
	Composition	Each tablet contains: Candestartan Cilexetil (USP)……..32mg Hydrochlorthiazide(USP) ..…….25mg
	Diary No. Date of R& I & fee	Dy No. 14486 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902520 dated 05-03-2019.
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics ATC Code C09DA06
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Atacand HCT USFDA Approved
	Me-too status	CST-H 32mg/25mg Tablet M/s Pharmasol (Pvt) Ltd

		Reg. No. 102566
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1100.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	NATIDE tablet 60mg
	Composition	Each film coated tablet contains: Nateglinide(USP) ..……..60mg
	Diary No. Date of R& I & fee	Dy No. 14512 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900607 dated 05-03-2019.
	Pharmacological Group	Other blood glucose lowering drugs, excluding insulins ATC Code A10BX03
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Starlix 60mg tablet USFDA Approved
	Me-too status	Starlix Tablets 60mg M/s Novartis Pharma (Pakistan) Limited Reg. No. 27341
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1101.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	NATIDE tablet 120mg
	Composition	Each film coated tablet contains: Nateglinide(USP) ..……..120mg
	Diary No. Date of R& I & fee	Dy No. 14513 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900608 dated 05-03-2019.

	Pharmacological Group	Other blood glucose lowering drugs, excluding insulins ATC Code A10BX03
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Starlix 120mg tablet USFDA Approved
	Me-too status	Starlix Tablets 60mg M/s Novartis Pharma (Pakistan) Limited Reg. No. 27340
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1102.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	FLUVATE tablet 100mg
	Composition	Each film coated tablet contains: Fluvoxamine Maleate(USP) ..……..100mg
	Diary No. Date of R& I & fee	Dy No. 14560 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900600 dated 05-03-2019.
	Pharmacological Group	Selective serotonin reuptake inhibitors ATC Code N06AB08
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Luvox 100mg tablet USFDA Approved
	Me-too status	Fluvoxamine 100mg Tablet M/s Lisko Pakistan (Pvt.) Ltd Reg. No. 112566
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	

1103.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (Antibiotic, Non antibiotic, Steroidal Hormone)
	Brand Name +Dosage Form + Strength	FLUVATE tablet 50mg
	Composition	Each film coated tablet contains: Fluvoxamine Maleate(USP)……...……50mg
	Diary No. Date of R& I & fee	Dy No. 14558 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900598 dated 05-03-2019.
	Pharmacological Group	Antidepressants, Selective serotonin reuptake Inhibitors ATC code: N06AB08
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved PL 29831/0096
	Me-too status	Voxamine 50 mg Tablet M/s PharmEvo (Pvt) Ltd Reg. No. 029165
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued for tablets (antibiotic, non antibiotic, steroidal hormones).
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1104.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	RANATE tablet 75mg
	Composition	Each film coated tablet contains: Risedronate Sodium as Hemi Pentahydrate(USP)……...75mg
	Diary No. Date of R& I & fee	Dy No. 14521 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900616 dated 05-03-2019.
	Pharmacological Group	Bisphosphonates ATC Code M05BA07
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Actonel 75mg tablet USFDA Approved
	Me-too status	Freal Tablets M/s Genix Pharma Reg. No. 61252

	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1105.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	RANATE tablet 150mg
	Composition	Each film coated tablet contains: Risedronate Sodium as Hemi Pentahydrate(USP)…….150mg
	Diary No. Date of R& I & fee	Dy No. 14522 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900617 dated 05-03-2019.
	Pharmacological Group	Bisphosphonates ATC Code M05BA07
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Actonel 150mg tablet USFDA Approved
	Me-too status	Udro-150mg Tablets M/s Genome Pharmaceuticals (Pvt.) Ltd Reg. No. 80979
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1106.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	TRIDINE tablet 35mg
	Composition	Each film coated modified release tablet contains: Trimetazine dihydrochloride (BP)…… 35mg
	Diary No. Date of R& I & fee	Dy No. 14492 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902527 dated 05-03-2019.
	Pharmacological Group	Other cardiac preparations

		ATC Code C01EB15 (Trimetazidine)
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed Innovator's Specifications; Trimetazidine hydrochloride tablets monograph is available in JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Trimetazidine biogaran 35 mg, film-coated tablet with modified release ANSM approved
	Me-too status	Ofimta MR tablet 35mg High-Q Pharmaceuticals
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Change in specifications from innovator's specifications to JP is required along with prescribed fee (Rs.7500) as per S.R.O 496(I)/2023 dated 17-04-2023. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) alongwith Deposit Slip No. 50399721291 and the Board was apprised of the same during the meeting.***
	Decision: Approved with JP Specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5 and drug product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1107.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	OLME PLUS tablet 10mg/40mg
	Composition	Each film coated tablet contains: Amlodipine Besylate eq. to Amlodipine…….10mg Olmesartan Medoxomil ……..40mg
	Diary No. Date of R& I & fee	Dy No. 14514 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900609 dated 05-03-2019.
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and calcium channel blockers ATC Code C09DB02
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Sevikar 40 mg/10 mg film-coated tablets MHRA Approved
	Me-too status	Baritec-A 40/10mg Tablet M/s Barrett Hodgson Pakistan (Pvt) Ltd., Karachi. Reg. No. 81445
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Change in specifications from innovator's specifications to USP is required along with

		prescribed fee (Rs.7500) as per S.R.O 496(I)/2023 dated 17-04-2023. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) alongwith Deposit Slip No. 88232115534 and the Board was apprised of the same during the meeting.***
	Decision: Approved with USP Specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5 and drug product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1108.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	XCLUDE tablet 1mg
	Composition	Each film coated tablet contains: Entecavir as Monohydrate (USP) ..……1mg
	Diary No. Date of R& I & fee	Dy No. 14548 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900588 dated 05-03-2019.
	Pharmacological Group	Direct acting antivirals, Nucleoside and nucleotide reverse transcriptase inhibitors ATC Code J05AF10
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Entecavir 1.0mg film-coated tablets MHRA Approved PL 08828/0277
	Me-too status	Livose-C 1mg Tablets M/s Wilson's Pharmaceuticals Reg. No. 77832
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1109.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	ELITEN tablet 40mg
	Composition	Each film coated tablet contains: Eletriptan (In-house) ..…….40mg

	Diary No. Date of R& I & fee	Dy No. 14541 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900581 dated 05-03-2019.
	Pharmacological Group	Antimigraine preparations ATC Code N02CC06
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Relpax 40 mg film coated tablets MHRA Approved PL 50622/0054
	Me-too status	Relpax 40 mg tablets M/s Pfizer Pakistan Ltd Reg. No. 39809
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Change in label claim from "Each film coated tablet contains: Eletriptan (In-house)…… 40mg" To "Each film coated tablet contains: Eletriptan (as hydrobromide)…… 40mg", according to composition approved in MHRA, along with relevant fee (full fee) is required as per S.R.O 496(I)/2023 dated 17-04-2023. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) alongwith fee of Rs. 30,000/- vide Deposit Slip No. 3370916376 and the Board was apprised of the same during the meeting.***
	Decision: Approved with following label claim: **"Each film coated tablet contains: Eletriptan (as hydrobromide)…… 40mg"**	
1110.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	EZOVAST tablet 10/40mg
	Composition	Each film coated tablet contains: Ezetimibe……..……..10mg Atorvastatin Calcium eq. to Atorvastatin……40mg
	Diary No. Date of R& I & fee	Dy No. 14554 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900594 dated 05-03-2019.
	Pharmacological Group	Combinations of various lipid modifying agents ATC Code C10BA05
	Type of Form	Form 5
	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Liptruzet 10/40mg USFDA Approved
	Me-too status	Lipiget EZ Tablets 40mg/10mg M/s Getz Pharma (Pvt) Limited Reg. No. 73715

	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1111.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	FOSRIL tablet 10mg
	Composition	Each tablet contains: Fosinopril Sodium(USP) ..……..10mg
	Diary No. Date of R& I & fee	Dy No. 14559 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900599 dated 05-03-2019.
	Pharmacological Group	ACE inhibitors, plain ATC Code C09AA09
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fosinopril sodium 10 mg tablets MHRA Approved
	Me-too status	Aksopril Tablets 10mg M/s Akson Pharmaceuticals (Pvt) Ltd Reg. No. 23747
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1112.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	PIOGLIDE tablet 30mg/2mg
	Composition	Each tablet contains: Pioglitazone as Hydrochloride(USP) ..…….30mg Glimepride (USP)……..2mg
	Diary No. Date of R& I & fee	Dy No. 14515 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900610 dated 05-03-2019.

	Pharmacological Group	Combinations of oral blood glucose lowering drugs ATC Code A10BD06
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Duetact 30/2mg tablet USFDA Approved
	Me-too status	Plugax-G 30/2mg Tablet M/s Axis Pharmaceuticals Reg. No. 108484
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1113.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	PIOGLIDE tablet 30mg/4mg
	Composition	Each tablet contains: Pioglitazone as Hydrochloride(USP) ..…….30mg Glimepride (USP)……..4mg
	Diary No. Date of R& I & fee	Dy No. 14516 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900611 dated 05-03-2019.
	Pharmacological Group	Combinations of oral blood glucose lowering drugs ATC Code A10BD06
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Duetact 30/4mg tablet USFDA Approved
	Me-too status	Plugax-G 30/4mg Tablet M/s Axis Pharmaceuticals Reg. No. 109285
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***

	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1114.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	ABORT-MM tablet 200mg/800mcg
	Composition	Combination pack consisting of: 1 Mifepristone oral tablet Each tablet contains: Mifepristenol (In-House)……..…..200mg 4 Misoprostol tablets Each tablet contains: Misoprostol (USP)…….200mcg
	Diary No. Date of R& I & fee	Dy No. 14564 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902544 dated 06-03-2019.
	Pharmacological Group	Progesterone receptor modulators ATC Code G03XB51
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Medabon Combipack of Mifepristone 200 mg tablet and Misoprostol 4 x 0.2 mg vaginal tablets MHRA Approved
	Me-too status	Mifepristone tablet is not registered in Pakistan. Misoprostol vaginal tablet is registered in Pakistan but not in applied strength.
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• The Registration Board in its 316th meeting, considering an application for registration of Mifepristone 200mg tablet (Agenda item 79) had decided as follows: *"Registration Board deliberated the case in detail regarding the clinical indications and potential abuse of the product. The Board after thread bare deliberations decided to refer the case to DRAP Authority with submission that drug qualifies criteria for grant of Registration. However, Registration Board referred the case to DRAP Authority whether Registration Board should proceed for grant of registration or otherwise due to its potential for abuse. Director DTL Sindh opined not to register the product due to its potential abuse as abortifacient drug."* Decision of Authority, if any, may be considered prior to decision of instant case otherwise the case may once again be referred to DRAP Authority for consideration. • If allowed for registration by Authority, application is required on Form 5D instead of Form 5 for Mifepristone as me-too is not available.

		• Revision of label to mention oral tablet and vaginal tablet in label of Mifepristone and Misoprostol tablets, respectively. • Change in specifications of Misoprostol tablets from Innovator's specifications to Pharmacopoeial Specifications along with relevant fee is required. • Evidence of applied strength of Misoprostol (200mcg) vaginal tablet already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant.
	Decision: The Board decided to refer the case to Expert Working Group on human drugs to review the therapeutic requirements keeping in view the safety, quality and efficacy parameters.	
1115.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	GRAZIT tablet 1mg
	Composition	Each tablet contains: Granisetron as hydrochloride(USP)……..1mg
	Diary No. Date of R& I & fee	Dy No. 14507 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900602 dated 05-03-2019.
	Pharmacological Group	Antiemetics and antinauseants ATC Code A04AA02
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Granisetron 1 mg Film-coated Tablets PL 36687/0295 MHRA Approved
	Me-too status	Graniset Tablets 1mg M/s CCL Pharmaceuticals (Pvt.) Ltd Reg. No. 48026
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1116.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	TAXOFIN tablet 10mg
	Composition	Each film coated tablet contains:

		Tamoxifen as Citrate Salt (USP)..……..10mg
	Diary No. Date of R& I & fee	Dy No. 14530 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900625 dated 05-03-2019.
	Pharmacological Group	Hormone antagonists and related agents Anti-estrogens ATC Code L02BA01
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Tamoxifen 10mg film-coated Tablets MHRA Approved PL 29831/0194
	Me-too status	Shamoxifen Tablet 10mg M/s Shaheen Pharmaceuticals, Swat Reg. No. 97088
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued for tablet.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1117.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	TAXOFIN tablet 20mg
	Composition	Each film coated tablet contains: Tamoxifen as Citrate Salt (USP)..……..20mg
	Diary No. Date of R& I & fee	Dy No. 14531 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900626 dated 05-03-2019.
	Pharmacological Group	Hormone antagonists and related agents Anti-estrogens ATC Code L02BA01
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Tamoxifen 20mg film-coated Tablets MHRA Approved PL 00142/0272
	Me-too status	Shamoxifen Tablet 20mg M/s Shaheen Pharmaceuticals, Swat Reg. No. 97089
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant.

		• ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1118.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	ALOSIN tablet 10mg
	Composition	Each uncoated sustained release tablet contains: Alfuzosin Hydrochloride (USP)..……..5mg
	Diary No. Date of R& I & fee	Dy No. 14480 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902512 dated 05-03-2019.
	Pharmacological Group	Drugs used in benign prostatic hypertrophy, Alpha-adrenoreceptor antagonists ATC Code G04CA01
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Taurazil SR 5mg tablets (Prolonged release uncoated) MHRA Approved PL 04569/0773
	Me-too status	Zostat SR Tablets M/s The Searle Company Limited Reg. No. 34491
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1119.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	ALOSIN tablet 10mg
	Composition	Each uncoated sustained release tablet contains: Alfuzosin Hydrochloride (USP)..……..10mg
	Diary No. Date of R& I & fee	Dy No. 14479 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902511 dated 05-03-2019.
	Pharmacological Group	Drugs used in benign prostatic hypertrophy, Alpha-adrenoreceptor antagonists ATC Code G04CA01
	Type of Form	Form 5
	Finished Product Specification	USP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Taurazil XL 10 mg tablets (Prolonged release uncoated) MHRA Approved PL 04569/0774
	Me-too status	Ztrol-XL extended release tablet M/s Noa Hemis Pharmaceuticals, Karachi Reg. No. 74964
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1120.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	RAMIDE tablet 2.5mg/12.5mg
	Composition	Each tablet contains: Ramipril (USP)……..…….2.5mg Hydrochlorthiazide(USP)…….12.5mg
	Diary No. Date of R& I & fee	Dy No. 14518 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900613 dated 05-03-2019.
	Pharmacological Group	ACE inhibitors and diuretics ATC Code C09BA05
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	ALTACE HCT tablets Health Canada Approved
	Me-too status	Ramipace D 2.5/12.5 Tablet M/s PHARMEVO (PVT) LTD Reg. No. 76091
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Approved in Health Canada with following boxed warning: "When used in pregnancy, angiotensin converting enzyme (ACE) inhibitors can cause injury or even death of the developing fetus. When pregnancy is detected, Ramipril/hydrochlorothiazide should be discontinued as soon as possible." • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated***

		02-06-2023) and the Board was apprised of the same during the meeting.
	Decision: Approved with boxed warning as under: **"When used in pregnancy, angiotensin converting enzyme (ACE) inhibitors can cause injury or even death of the developing fetus. When pregnancy is detected, Ramipril/hydrochlorothiazide should be discontinued as soon as possible."** **The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
1121.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	RAMIDE tablet 5mg/12.5mg
	Composition	Each tablet contains: Ramipril (USP)……..……5mg Hydrochlorthiazide(USP)……12.5mg
	Diary No. Date of R& I & fee	Dy No. 14519 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900614 dated 05-03-2019.
	Pharmacological Group	ACE inhibitors and diuretics ATC Code C09BA05
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	ALTACE HCT tablets Health Canada Approved
	Me-too status	Ramipace D 5/12.5 Tablet M/s PHARMEVO (PVT) LTD Reg. No. 70406
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Approved in Health Canada with following boxed warning: "When used in pregnancy, angiotensin converting enzyme (ACE) inhibitors can cause injury or even death of the developing fetus. When pregnancy is detected, Ramipril/hydrochlorothiazide should be discontinued as soon as possible." • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved with boxed warning as under: **"When used in pregnancy, angiotensin converting enzyme (ACE) inhibitors can cause injury or even death of the developing fetus. When pregnancy is detected, Ramipril/hydrochlorothiazide should be discontinued as soon as possible."** **The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	

1122.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	RAMIDE tablet 10mg/12.5mg
	Composition	Each tablet contains: Ramipril (USP)……..…….10mg Hydrochlorthiazide(USP)…….12.5mg
	Diary No. Date of R& I & fee	Dy No. 14520 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900615 dated 05-03-2019.
	Pharmacological Group	ACE inhibitors and diuretics ATC Code C09BA05
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	ALTACE HCT tablets Health Canada Approved
	Me-too status	Ramipace D 10/12.5 Tablet M/s PHARMEVO (PVT) LTD Reg. No. 73818
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Approved in Health Canada with following boxed warning: "When used in pregnancy, angiotensin converting enzyme (ACE) inhibitors can cause injury or even death of the developing fetus. When pregnancy is detected, Ramipril/hydrochlorothiazide should be discontinued as soon as possible." • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved with boxed warning as under: **"When used in pregnancy, angiotensin converting enzyme (ACE) inhibitors can cause injury or even death of the developing fetus. When pregnancy is detected, Ramipril/hydrochlorothiazide should be discontinued as soon as possible."** **The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
1123.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	STAZIL tablet 50mg
	Composition	Each tablet contains: Cilostazol(USP)…...……..50mg
	Diary No. Date of R& I & fee	Dy No. 14483 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902517 dated 05-03-2019.
	Pharmacological Group	Platelet aggregation inhibitors excluding heparin ATC Code B01AC23

	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cilostazol 50mg tablets MHRA Approved PL 24837/0047
	Me-too status	Zatocil 50 mg Tablets M/s Global Pharmaceuticals Pvt Ltd Reg. No. 94357
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1124.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	STAZIL tablet 100mg
	Composition	Each tablet contains: Cilostazol(USP)…..……..100mg
	Diary No. Date of R& I & fee	Dy No. 14482 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902516 dated 05-03-2019.
	Pharmacological Group	Platelet aggregation inhibitors excluding heparin ATC Code B01AC23
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cilostazol 100mg tablets MHRA Approved PL 04569/1427
	Me-too status	Zatocil 100 mg Tablets M/s Global Pharmaceuticals Pvt Ltd Reg. No. 94356
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	

1125.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	AROPRIL tablet 10mg/8mg
	Composition	Each tablet contains: Amlodipine as Besylate……..…….10mg Perindopril tert-butylamine/ erbumine……..8mg
	Diary No. Date of R& I & fee	Dy No. 14470 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902502 dated 05-03-2019.
	Pharmacological Group	ACE inhibitors and calcium channel blockers ATC Code C09BB04
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Perindopril/Amlodipine 8 mg/10 mg tablets MHRA Approved PL 01656/0117
	Me-too status	Coversam 8/10mg Tablet M/s Servier Research and Pharmaceuticals Pakistan (Pvt) Ltd., Lahore. Reg. No. 65960
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1126.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	AROPRIL tablet 5mg/8mg
	Composition	Each tablet contains: Amlodipine as Besylate…….. ……..…….. 5mg Perindopril tert-butylamine/erbumine ……8mg
	Diary No. Date of R& I & fee	Dy No. 14471 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902503 dated 05-03-2019.
	Pharmacological Group	ACE inhibitors and calcium channel blockers ATC Code C09BB04
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Perindopril/Amlodipine 8 mg/10 mg tablets MHRA Approved PL 01656/0116
	Me-too status	Coversam 8/5mg Tablet M/s Servier Research and Pharmaceuticals Pakistan (Pvt) Ltd., Lahore.

		Reg. No. 65961
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1127.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610)
	Brand Name +Dosage Form + Strength	EXETIN tablet 25mg
	Composition	Each tablet contains: Exemestane (USP)……25mg
	Diary No. Date of R& I & fee	Dy No. 14552 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900592 dated 05-03-2019.
	Pharmacological Group	Aromatase inhibitors ATC Code L02BG06
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Exemestane 25 mg coated tablets MHRA Approved PL 00057/1202
	Me-too status	Aromasin Tablet 25mg M/s Pfizer Pakistan Ltd Reg. No. 28359
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued for tablet (antibiotic, non antibiotic and steroidal hormone).
	Remarks of the Evaluator[xxiii].	• The Registration Board in its 324th meeting decided to defer similar application of M/s Ameer and & Adnan Pharmaceutical Pvt Ltd, Lahore for deliberation regarding the classification of applied formulation whether it is a steroidal drug or otherwise. Clarification is required from the firm. • The applicant holds valid GMP certificate for tablet (non-antibiotic) and tablet (steroidal hormones). Evidence of approval of section for manufacturing steroids and GMP status is required in case the instant drug is considered to be a steroid. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm submitted requisite signed Form 5 and annexures vide Letter No. Nil dt 01-06-2023***

		(Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.
	Decision: The Board decided to refer the application to Expert Working Group on human drugs for deliberation regarding the classification of applied formulation whether it is considered to be a steroidal and/or hormonal drug or otherwise. Accordingly, section requirement may be confirmed from CLB after the comments from the EWG.	
1128.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (Anti-cancer)
	Brand Name +Dosage Form + Strength	SONIB tablet 200mg
	Composition	Each film coated tablet contains: Sorafenib (as tosylate)……..……200mg
	Diary No. Date of R& I & fee	Dy No. 14494 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902529 dated 05-03-2019.
	Pharmacological Group	Protein Kinase inhibitors ATC Code L01EX02
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved PL 04569/1817
	Me-too status	Soranix 200mg Tablet M/s Himmel Pharmaceuticals (Pvt) Ltd, Lahore. Reg. No. 103784
	GMP status	Not available for tablet anti-cancer section.
	Remarks of the Evaluator[xxiii].	• Evidence of required manufacturing facility (i.e. tablet anticancer section) along with approval letter from Licensing Division and current GMP status. • Applied product is available in BP. Change in finished product specifications is required from Innovator's Specifications to BP along with prescribed fee (Rs.7500) as per S.R.O 496(I)/2023 dated 17-04-2023. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant.
	Decision: Deferred for following: • **Submission of evidence of approval of required manufacturing facility of "Tablet (Anti-cancer) section" from CLB.** • **Change in finished product specifications is required from Innovator's Specifications to BP along with prescribed fee (Rs.7500) as per S.R.O 496(I)/2023 dated 17-04-2023.** • **Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant.**	
1129.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	ESTINE tablet 20mg
	Composition	Each film coated tablet contains: Ebastine(BP)……..……20mg
	Diary No. Date of R& I & fee	Dy No. 14540 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900580 dated 05-03-2019.
	Pharmacological Group	Other antihistamines for systemic use ATC Code R06AX

	Type of Form	Form 5
	Finished Product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	CBGMEB (Netherland) approved
	Me-too status	Kestine 20mg Tablet M/s Highnoon Laboratories Ltd Reg. No. 25432
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1130.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	ALIKEN tablet 150mg
	Composition	Each film coated tablet contains: Aliskiren as Hemifumarate……..……150mg
	Diary No. Date of R& I & fee	Dy No. 14478 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902510 dated 05-03-2019.
	Pharmacological Group	Renin inhibitor ATC Code C09XA02
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Tekturna tablet 150mg USFDA Approved
	Me-too status	Yahtin 150mg Tablet Martin Dow Limited Reg. No. 81122
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1131.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610)

		Tablet section (General)
	Brand Name +Dosage Form + Strength	ALIKEN tablet 300mg
	Composition	Each film coated tablet contains: Aliskiren as Hemifumarate……..……300mg
	Diary No. Date of R& I & fee	Dy No. 14477 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902509 dated 05-03-2019.
	Pharmacological Group	Renin inhibitor ATC Code C09XA02
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Tekturna tablet 300mg USFDA Approved
	Me-too status	Yahtin 300mg Tablet Martin Dow Limited Reg. No. 81123
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1132.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	ALISOZID tablet 150/12.5mg
	Composition	Each film coated tablet contains: Aliskiren as Hemifumarate……..……150mg Hydrochlorthiazide……..12.5mg
	Diary No. Date of R& I & fee	Dy No. 14476 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902508 dated 05-03-2019.
	Pharmacological Group	Renin inhibitor ATC Code C09XA52
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Discontinued in USFDA (not due to safety or efficacy reasons)
	Me-too status	Yahtin-H 150/12.5 Tablet Martin Dow Limited Reg. No. 81127
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.

	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1133.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	ALISOZID tablet 300/12.5mg
	Composition	Each film coated tablet contains: Aliskiren as Hemifumarate……..……300mg Hydrochlorthiazide…….12.5mg
	Diary No. Date of R& I & fee	Dy No. 14474 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902506 dated 05-03-2019.
	Pharmacological Group	Renin inhibitor ATC Code C09XA52
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Discontinued in USFDA (not due to safety or efficacy reasons)
	Me-too status	Yahtin-H 300/12.5 Tablet Martin Dow Limited Reg. No. 81126
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1134.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	ALISOZID tablet 150/25mg
	Composition	Each film coated tablet contains: Aliskiren as Hemifumarate……..……150mg Hydrochlorthiazide…….25mg
	Diary No. Date of R& I & fee	Dy No. 14475 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902507 dated 05-03-2019.
	Pharmacological Group	Renin inhibitor ATC Code C09XA52

	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Discontinued in USFDA(not due to safety or efficacy reasons)
	Me-too status	Yahtin-H 150/25 Tablet Martin Dow Limited Reg. No. 81124
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Evidence of approval of applied product in reference regulatory authority is required. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1135.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (General)
	Brand Name +Dosage Form + Strength	ALISOZID tablet 300/25mg
	Composition	Each film coated tablet contains: Aliskiren as Hemifumarate……..……300mg Hydrochlorthiazide…….25mg
	Diary No. Date of R& I & fee	Dy No. 14473 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902505 dated 05-03-2019.
	Pharmacological Group	Renin inhibitor ATC Code C09XA52
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Discontinued in USFDA(not due to safety or efficacy reasons)
	Me-too status	Yahtin-H 300/25 Tablet Martin Dow Limited Reg. No. 81125
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Evidence of approval of applied product in reference regulatory authority is required. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***

	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1136.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (Antibiotic, Non antibiotic, Steroidal Hormone)
	Brand Name +Dosage Form + Strength	LANIDO tablet 1mg
	Composition	Each film coated tablet contains: Lercanidipine Hydrochloride…...……10mg
	Diary No. Date of R& I & fee	Dy No. 14568 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900603 dated 05-03-2019.
	Pharmacological Group	Selective calcium channel blockers with mainly vascular effects- Dihydropyridine derivatives ATC Code: C08CA13
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved PL 04569/1097
	Me-too status	Leradip 10 mg Tablet M/s Himont Pharmaceuticals, Lahore. Reg. No. 025007
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued for tablets (antibiotic, non antibiotic, steroidal hormones).
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1137.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (Antibiotic, Non antibiotic, Steroidal Hormone)
	Brand Name +Dosage Form + Strength	L-PRIDE tablet 100mg
	Composition	Each tablet contains: Levosulpiride…...…….100mg
	Diary No. Date of R& I & fee	Dy No. 14569 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900604 dated 05-03-2019.
	Pharmacological Group	Antipsychotics ATC code: N05AL07
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Levosulpiride 100 mg tablet AIFA Italy Approved
	Me-too status	Sulvo tablet 100mg

		M/s Medisure Reg. No. 31749
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued for tablets (antibiotic, non antibiotic, steroidal hormones).
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1138.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (Antibiotic, Non antibiotic, Steroidal Hormone)
	Brand Name +Dosage Form + Strength	FUSIA tablet 250mg
	Composition	Each film coated tablet contains: Sodium Fusidate (BP)……..……250mg
	Diary No. Date of R& I & fee	Dy No. 14526 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900621 dated 05-03-2019.
	Pharmacological Group	Steroid Antibacterials ATC code: J01XC01
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved PL 00043/5000R
	Me-too status	Bacusid 250mg Tablet M/s SAMI Pharmaceuticals Pvt. Ltd Reg. No. 090778
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued for tablets (antibiotic, non antibiotic, steroidal hormones).
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Defferred for the confirmation of steroidal section from licencing division.	
1139.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (Antibiotic, Non antibiotic, Steroidal Hormone)
	Brand Name +Dosage Form + Strength	PREGIL tablet 10mg

	Composition	Each Film Coated Tablet Contains: Prasugrel as hydrochloride (USP)…….10mg
	Diary No. Date of R& I & fee	Dy No. 14517 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900612 dated 05-03-2019.
	Pharmacological Group	Platelet aggregation inhibitors excl. heparin ATC code: B01AC22
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Prisa 10mg Tablet M/s Getz Pharma (Pvt) Ltd., Karachi. Reg. No. 066942
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued for tablets (antibiotic, non antibiotic, steroidal hormones).
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1140.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (Antibiotic, Non antibiotic, Steroidal Hormone)
	Brand Name +Dosage Form + Strength	AMLOPRIL tablet 5/10mg
	Composition	Each tablet contains: Amlodipine as Besylate (USP)…..……5mg Lisinopril as dihydrate (USP)……10mg
	Diary No. Date of R& I & fee	Dy No. 14472 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902504 dated 05-03-2019.
	Pharmacological Group	ACE inhibitors and calcium channel blockers ATC code: C09BB03
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Ampril 5/10 Tablet M/s Nabiqasim Industries (Pvt) Ltd., Karachi Reg. No. 086872
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued for tablets (antibiotic, non antibiotic, steroidal hormones).
	Remarks of the Evaluator[xxiii].	• Evidence of approval of applied product in reference regulatory authority as approved by the Registration Board in its 275th meeting is required.

		• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
1141.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (Antibiotic, Non antibiotic, Steroidal Hormone)
	Brand Name +Dosage Form + Strength	SOMEX tablet 1mg
	Composition	Each film coated tablet contains: Sirolimus ……..……..……..1mg
	Diary No. Date of R& I & fee	Dy No. 14525 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900620 dated 05-03-2019.
	Pharmacological Group	Selective immunosuppressants Inhibitors ATC code: L04AA10
	Type of Form	Form 5
	Finished Product Specification	USP, as claimed by the applicant
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved PLGB 00057/1613
	Me-too status	Rapammune Tablet M/s Wyeth Pakistan Limited Reg. No. 0 31376
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued for tablets (antibiotic, non antibiotic, steroidal hormones).
	Remarks of the Evaluator[xxiii].	• Finished product monograph is not available in USP. Change of specifications from USP to Innovator's Specifications is required along with relevant fee (PKR 7500/-) as per S.R.O 496(I)/2023 dated 17-04-2023. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) alongwith fee of Rs. 7,500/- Deposit slip No.98504981 and the Board was apprised of the same during the meeting.***
	Decision: Approved with Innovator's Specifications.	
1142.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Tablet section (Non-antibiotic)
	Brand Name +Dosage Form + Strength	Myfolate tablet 500mg
	Composition	Each film coated tablet contains: Mycophenolate Mofetil (USP)…….……500mg

	Diary No. Date of R& I & fee	Dy No. 14511 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900606 dated 05-03-2019.
	Pharmacological Group	Immunosuppresants ATC code L04AA06
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Myfenax 500 mg film-coated tablets MHRA approved
	Me-too status	Micocept Film Coated Tablets M/s Novartis Pharma (Pakistan) Limited Reg. No. 84629
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued for tablet (anti-biotic, non-antibiotic & steroidal hormone section).
	Remarks of the Evaluatorxxiii.	• Registration Board in its 296th meeting approved registration of Mycophenolate Mofetil capsules in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1143.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Capsule section (Steroidal)
	Brand Name +Dosage Form + Strength	Tamsorid 0.4/0.5mg Capsule
	Composition	Each capsule contains: Tamsulosin HCl……...0.4mg (as modified release pellets) Dutasteride……...0.5mg (as soft gel capsule)
	Diary No. Date of R& I & fee	Dy No.14532 dated 07-03-2019 Fee paid PKR 20,000/-vide Deposit Slip No. 1900627 dated 05-03-2019.
	Pharmacological Group	Alpha-adrenoreceptor antagonists ATC code G04CA52
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Combodart 0.5 mg / 0.4 mg hard capsules MHRA Approved
	Me-too status	Duodart Capsule M/s GSK, Karachi Reg. No. 69515
	GMP status	Not available for capsule steroidal section.

	Remarks of the Evaluator[xxiii].	• The product approved in reference country contains Tamsulosin HCl MR pellets and Soft gel capsule of Dutasteride filled in hard gelatin capsule shell. • As the firm intends to manufacture dutasteride capsules in-house, evidence of required manufacturing facility (i.e. soft gel capsule steroidal section) along with section approval letter from Licensing Division and current GMP status is required. • Firm intends to use semi-automatic capsule filling machine for filling soft gel capsules in hard gel capsules. IQ, OQ and proper functioning of the machine for the purpose of filling capsule in capsule may be ascertained by Area FID at the time of manufacturing of first batch. • Source of Tamsulosin Pellets, GMP certificate of pellet manufacturer, Certificate of analysis, stability study data of 3 batches according to the climatic conditions of Zone IV-A are required, alongwith fee in case of imported pellets. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant.
	Decision: Deferred for following: • **Source of pellets along with COA, stability study data of 3 batches of pellets, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets).** • **Evidence of approval of required required manufacturing facility of "Soft gel capsule (steroid) section or source of Dutasteride soft gel capsules, along with COA, stability study data of 3 batches, GMP certificate of soft gel capsule manufacturer and differential fee (in case of imported pellets** • **Evidence of availability of required manufacturing facility of "Capsule in Capsule filling machine".**	
1144.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Capsule section (Anti-cancer)
	Brand Name +Dosage Form + Strength	HEDROX Capsule 500mg
	Composition	Each Capsule Contains: Hydroxyurea……500mg
	Diary No. Date of R& I & fee	Dy No. 14495 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902530 dated 05-03-2019.
	Pharmacological Group	Other antineoplastic agents ATC Code L01XX05
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Hydrea 500mg capsule MHRA Approved PL 45043/0113
	Me-too status	Hydroxa Capsule 500mg M/s Pharmasol (Pvt) Ltd, Lahore Reg. No. 91813
	GMP status	Not available for anti-cancer capsule section

	Remarks of the Evaluator[xxiii].	• Evidence of required manufacturing facility (i.e. capsule anticancer section) along with approval letter from Licensing Division and current GMP status. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant.
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Capsule (anticancer) section" from CLB.	
1145.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Capsule section (General)
	Brand Name +Dosage Form + Strength	DUXAFIT capsule 60mg
	Composition	Each capsule contains: Duloxetine enteric coated pellets 17% (USP)…….60mg (Source of pellets is M/s Vision Pharma, Islamabad)
	Diary No. Date of R& I & fee	Dy No. 14539 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900579 dated 05-03-2019.
	Pharmacological Group	Other antidepressants ATC code N06AX21
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Duloxetine Dr. Reddy's 60 mg Gastro-Resistant Capsules MHRA Approved
	Me-too status	Hepretin 60mg capsule M/s Hygeia Pharmaceuticals, Islamabad Reg. No. 081201
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Following are required: GMP certificate of source of pellets Stability studies of three batches of pellets according to the climatic conditions of Zone IV-A Certificate of analysis of pellets • Revision of formulation from "Duloxetine enteric coated pellets 17% (USP)……60mg" To "Duloxetine (as hydrochloride) enteric coated pellets 17% …….60mg", as approved by MHRA, along with full fee of registration. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) alongwith fee of Rs. 30.000/- vide Deposit Slip No. 1921931556 and the Board was apprised of the same during the meeting.***
	Decision: Approved with following label claim: **"Duloxetine (as hydrochloride) enteric coated pellets ……. 60mg"**	

	Source of Pellets: M/s Vision Pharmaceuticals (Pvt) Ltd, Plot no. 22-23, Industrial Triangle, Kahuta Road, Islamabad.	
1146.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Capsule section (General)
	Brand Name +Dosage Form + Strength	DUXAFIT capsule 30mg
	Composition	Each capsule contains: Duloxetine enteric coated pellets 17% (USP)…….30mg (Source of pellets is M/s Vision Pharma, Islamabad)
	Diary No. Date of R& I & fee	Dy No. 14538 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900578 dated 05-03-2019.
	Pharmacological Group	Other antidepressants ATC code N06AX21
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Duloxetine Dr. Reddy's 30 mg Gastro-Resistant Capsules MHRA Approved
	Me-too status	Hepretin 30mg capsule M/s Hygeia Pharmaceuticals, Islamabad Reg. No. 081202
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Following are required: GMP certificate of source of pellets Stability studies of three batches of pellets according to the climatic conditions of Zone IV-A Certificate of analysis of pellets • Revision of formulation from "Duloxetine enteric coated pellets 17% (USP)……60mg" To "Duloxetine (as hydrochloride) enteric coated pellets 17% …….60mg", as approved by MHRA, along with full fee of registration. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) alongwith fee of Rs. 30.000/- vide Deposit Slip No. 578636180927 and the Board was apprised of the same during the meeting.***
	Decision: Approved with following label claim: **"Duloxetine (as hydrochloride) enteric coated pellets …….30mg"** **Source of Pellets: M/s Vision Pharmaceuticals (Pvt) Ltd, Plot no. 22-23, Industrial Triangle, Kahuta Road, Islamabad.**	
1147.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Capsule section (General)
	Brand Name +Dosage Form + Strength	CASILAT capsule 500mg
	Composition	Each Capsule Contains:

		Calcium dobesilate monohydrate (BP)……500mg
	Diary No. Date of R& I & fee	Dy No. 14488 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902523 dated 05-03-2019.
	Pharmacological Group	Antivaricose Therapy ATC Code C05BX01
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Doxium 500mg capsule Swissmedic Approved
	Me-too status	Dobrid Capsule 500mg M/s Pharmasol (Pvt) Ltd, Lahore Reg. No. 99686
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1148.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Capsule section (General)
	Brand Name +Dosage Form + Strength	STIGMA capsule 1.5mg
	Composition	Each Capsule Contains: Rivastigmine as Hydrogen Tartrate Eq. to Rivastigmine……1.5mg
	Diary No. Date of R& I & fee	Dy No. 14523 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900618 dated 05-03-2019.
	Pharmacological Group	Anticholinesterases ATC code N06DA03
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved PL 36687/0121
	Me-too status	Riveme 1.5mg Capsule M/s Genix Pharma (Pvt) Ltd., Karachi Reg. No. 079951
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated***

		02-06-2023) and the Board was apprised of the same during the meeting.
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1149.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Capsule section (General)
	Brand Name +Dosage Form + Strength	STIGMA capsule 4.5mg
	Composition	Each Capsule Contains: Rivastigmine as Hydrogen Tartrate Eq. to Rivastigmine……4.5mg
	Diary No. Date of R& I & fee	Dy No. 14524 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900619 dated 05-03-2019.
	Pharmacological Group	Anticholinesterases ATC code N06DA03
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved PL 36687/0123
	Me-too status	Riveme 4.5mg Capsule M/s Genix Pharma (Pvt) Ltd., Karachi Reg. No. 079953
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1150.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Capsule section (Non-antibiotic)
	Brand Name +Dosage Form + Strength	Myfolate capsule 250mg
	Composition	Each Capsule contains: Mycophenolate Mofetil (USP)…….……250mg
	Diary No. Date of R& I & fee	Dy No. 14510 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900605 dated 05-03-2019.
	Pharmacological Group	Immunosuppresants ATC code L04AA06
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	CELLCEPT®(mycophenolate mofetil) capsules 250mg, USFDA approved
	Me-too status	Micocept Capsule M/s Novartis Pharma (Pak)

		Reg. No. 087079
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued for Capsule (anti-biotic, non-antibiotic & cephalosporin section).
	Remarks of the Evaluator[xxiii].	• Registration Board in its 296th meeting approved registration of similar product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1151.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Capsule section (General)
	Brand Name +Dosage Form + Strength	Aprewin capsule 125mg
	Composition	Each Capsule contains: Aprepitant (USP)…….……250mg
	Diary No. Date of R& I & fee	Dy No. 14469 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902501 dated 05-03-2019.
	Pharmacological Group	Other antiemetics ATC code A04AD12
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved
	Me-too status	Apritus 125mg Capsule M/s S.J&G Karachi Reg. No. 074887
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued for Capsule (anti-biotic, non-antibiotic & cephalosporin section).
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	

1152.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Capsule section (General)
	Brand Name +Dosage Form + Strength	Etifowin capsule 50mg
	Composition	Each Capsule contains: Etifoxine hydrochloride…….……50mg
	Diary No. Date of R& I & fee	Dy No. 14501 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902535 dated 05-03-2019.
	Pharmacological Group	Other Anxiolytics ATC code N05BX03
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Stresam capsule ANSM, France approved
	Me-too status	Etifox Capsule M/s Genix Pharma (Pvt) Ltd., Karachi Reg. No. 81452
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued for Capsule (anti-biotic, non-antibiotic & cephalosporin section).
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1153.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Capsule section (Non-antibiotic)
	Brand Name +Dosage Form + Strength	NT- Fungal capsule 200mg
	Composition	Each Capsule contains: Fluconazole (BP)….……..…….200mg
	Diary No. Date of R& I & fee	Dy No. 14556 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900596 dated 05-03-2019.
	Pharmacological Group	Triazole and tetrazole derivatives ATC code J02AC01
	Type of Form	Form 5
	Finished Product Specification	International Pharmacopoeia
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fluconazole 200mg Capsules - PL29831/0305 MHRA Approved
	Me-too status	Mycol Capsule 200mg M/s CCL Pharmaceuticals (Pvt.) Ltd Reg. No. 31681
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued for Capsule (anti-biotic, non-antibiotic & cephalosporin section)

	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1154.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) **contract manufacturing** from M/s Weather Folds Pharmaceuticals Plot No.69/2, Phase II, Industrial Area, Hattar (DML No. 000644) Liquid syrup section (General)
	Brand Name +Dosage Form + Strength	DOXYLINE syrup 100/5ml
	Composition	Each 5ml contains: Doxofylline …….100mg
	Diary No. Date of R& I & fee	Dy No. 14564 dated 07-03-2019 Fee paid PKR 50,000/- vide Deposit Slip No. 1902538 dated 05-03-2019.
	Pharmacological Group	Xanthines ATC Code R03DA11
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	60ml, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not found
	Me-too status	Unifyline Syrup M/s Platinum Pharmaceuticals, Karachi Reg. No. 047180
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued to M/s Wnsfeild Pharmceuticals. Last GMP inspection conducted on 12-10-2022 on the basis of which Certificate No. F.3-12/2022-DRAP-179 dated 28-10-2022 was issued to M/s WeatherFolds Pharmaceuticals.
	Remarks of the Evaluator[xxiii].	• Evidence of approval of applied product in reference regulatory authority as approved by the Registration Board in its 275th meeting is required. • Contract manufacturing agreement is required • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm provided duly signed Form 5 and contract manufacturing agreement vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	

1155.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) **contract manufacturing** from M/s Weather Folds Pharmaceuticals Plot No.69/2, Phase II, Industrial Area, Hattar (DML No. 000644) Liquid syrup section (General)
	Brand Name +Dosage Form + Strength	WIPROATE syrup 250mg/5ml
	Composition	Each 5ml contains: Doxofylline …….100mg
	Diary No. Date of R& I & fee	Dy No. 14563 dated 07-03-2019 Fee paid PKR 50,000/- vide Deposit Slip No. 1902537 dated 05-03-2019.
	Pharmacological Group	Xanthines R03DA11
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	60ml, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not found
	Me-too status	Unifyline Syrup M/s Platinum Pharmaceuticals, Karachi Reg. No. 047180
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued to M/s Wnsfeild Pharmceuticals. Last GMP inspection conducted on 12-10-2022 on the basis of which Certificate No. F.3-12/2022-DRAP-179 dated 28-10-2022 was issued to M/s WeatherFolds Pharmaceuticals.
	Remarks of the Evaluator[xxiii].	• Name of applied product on cover letter is Wiproate 250mg/5ml syrup. On challan the product name is Valproic acid 250mg/5ml. Name of product on Form 5 and annexed documents is Doxofylline 100mg/5ml syrup. Doxofylline 100mg/5ml syrup has already been applied for registration vide Dy No. 14564 dated 07-03-2019 (Fee paid PKR 50,000/- vide Deposit Slip No. 1902538 dated 05-03-2019). As the name on Form 5 is same, hence, this may be considered as duplicate application of Doxofylline Syrup 100mg/5ml.
	Decision: The Registration Board while considering the fact that firm had already applied for the formulation of Doxofylline 100mg/5ml syrup for registration vide Dy No. 14564 dated 07-03-2019 (Fee paid PKR 50,000/- vide Deposit Slip No. 1902538 dated 05-03-2019) which has been considered above, decided to declare the instant application as disposed of.	
1156.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Dry Powder Suspension section (Cephalosporin)
	Brand Name +Dosage Form + Strength	CEFOZIL dry suspension 125mg/5ml
	Composition	Each 5ml suspension contains: Cefprozil as Monohydrate (USP)…….125mg
	Diary No. Date of R& I & fee	Dy No. 14485 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902519 dated 05-03-2019.
	Pharmacological Group	Second generation Cephalosporin ATC Code: J01DC10
	Type of Form	Form 5

	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Vegapro 125mg dry powder suspension M/s Vega Pharmaceuticals, Lahore Reg No.078765
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1157.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Dry Powder Suspension section (Cephalosporin)
	Brand Name +Dosage Form + Strength	CEFOZIL dry suspension 250mg/5ml
	Composition	Each 5ml suspension contains: Cefprozil as Monohydrate (USP)…….250mg
	Diary No. Date of R& I & fee	Dy No. 14484 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902518 dated 05-03-2019.
	Pharmacological Group	Second generation Cephalosporin ATC Code: J01DC10
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Vegapro 250mg dry powder suspension M/s Vega Pharmaceuticals, Lahore Reg No.078764
	GMP status	Last GMP inspection conducted on 10-12-2020 on the basis of which Certificate No. F.11-195/2021-DRAP-32 dated 06-05-2021 was issued.
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1158.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Dry powder injection (general)

	Brand Name +Dosage Form + Strength	ARENATE 120mg injection
	Composition	Each 2ml vial contains: Artesunate ……120mg
	Diary No. Date of R& I & fee	Dy No. 14481 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902515 dated 05-03-2019.
	Pharmacological Group	Anti-malarials ATC code: P01BE03
	Type of Form	Form 5
	Finished Product Specification	International Pharmacopoeia Specifications
	Pack size & Demanded Price	Transparent vial along with Sodium bicarbonate 2ml glass ampule packed in unit carton; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Applied component is included in WHO approved formulation
	Me-too status	Gen-M 120mg Injection M/s Genix Pharma, Karachi Reg. No. 076073 (Inclusion of solvent not confirmed)
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Applicant has submitted master formulation and packaging details for combo pack having following two components: Artesunate 120mg in 2ml vial along with 5% Sodium Bicarbonate Solution in Water for Injection packed in 2ml ampule. WHO approved formulation is as follows "Each vial contains: Artesunate powder 120 mg Each ampoule of solvent contains: Sodium bicarbonate 50 mg/ml, 2 ml (5%) Each ampoule of diluent contains: Sodium chloride 9 mg/ml, 10 ml (0.9%)"; According to the International Pharmacopoeia, the reconstituted injection is a sterile solution of Artesunate in 5% sodium bicarbonate intravenous infusion. It is prepared by dissolving Artesunate for injection in the requisite amount of 5% sodium bicarbonate intravenous infusion immediately before use. This solution is diluted further with a suitable diluent for injection in accordance with the manufacturer's instructions. Accordingly, separate application for registration of solvent for Artesunate (5% sodium bicarbonate solution in Water for Injection) is required along with full fee of registration. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm submitted requisite signed Form 5, and master formulation without sodium bicabonate solution alongwith Deposit Slip No. 775169097 (PKR 7500) vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.***

	Decision: Approved	
1159.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Liquid injection (general)
	Brand Name +Dosage Form + Strength	WINWATER 10ml injection
	Composition	Each 10ml contains: Water for Injection……10ml
	Diary No. Date of R& I & fee	Dy No. 14493 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902528 dated 05-03-2019.
	Pharmacological Group	Other injection solutions/infusions ATC code K4D
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	1x10ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Water for injection of Martin Dow
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Applicant has stated that container is 100mL vial. Clarification is required regrading type (ampule or vial) and volume of container (10ml or 100ml). If volume is changed, full fee of registration is also required as per S.R.O 496(I)/2023 dated 17-04-2023. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) alongwith Deposit slip No. 1162106584 (PKR 7500) and the Board was apprised of the same during the meeting.***
	Decision: Approved with fill volume of 10ml. The firm shall submit differential fee of Rs. 22,500/- for correction/pre-approval change in product fill volume as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1160.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610)
	Brand Name +Dosage Form + Strength	GRAZIT 1mg/ml injection
	Composition	Each 3mL contains: Granisetron as Hydrochloride (USP) ……3mg
	Diary No. Date of R& I & fee	Dy No. 14506 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 190601 dated 05-03-2019.
	Pharmacological Group	Anti-emetics ATC code: A04AA02
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1x3mL; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Granisetron 3mg/3ml concentrate for solution for infusion or injection; Granisetron, 1mg/ml, solution for injection MHRA Approved
	Me-too status	Graniset Injection 3mg/3ml (3ml amoule) M/s CCL Pharmaceuticals (Pvt.) Ltd Reg. No. 048027
	GMP status	Same as above

	Remarks of the Evaluator[xxiii].	• Packaging on Form 5 is 3mL vial, type of container/packaging is given as 3mL transparent ampule. Clarification is required regarding primary container type (ampule or vial). • Composition of inactive ingredients is given for 10mL injection. Pre-approval change in composition regrading inactives is required along with prescribed fee (PKR 7500/-) as per S.R.O 496(I)/2023 dated 17-04-2023. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) alongwith Deposit slip No. 4401710408 (PKR 7500) and the Board was apprised of the same during the meeting.***
	Decision: Approved with following label claim: **"Each 3mL ampule contains:** **Granisetron as Hydrochloride (USP) ……3mg"**	
1161.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Liquid Injection (General)
	Brand Name +Dosage Form + Strength	FESOTIN 150mg/2ml injection
	Composition	Each 2mL contains: Fosphenytoin Sodium (equivalent to 100mg Phenytoin Sodium)……150mg
	Diary No. Date of R& I & fee	Dy No. 14562 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902536 dated 05-03-2019.
	Pharmacological Group	Antiepileptics ATC code: N03AB05
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1x2mL, 1x10mL ; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Pro-Epanutin 75 mg/mL, Concentrate for solution for infusion/Solution for injection (2mL & 10mL vial) MHRA Approved
	Me-too status	Pro-Eputin Injection M/s Atco Laboratories (Pvt) Ltd, Karachi. Reg. No. 053358
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Composition of Fosphenytoin Sodium (active) is given as 100mg/2mL whereas it should be 150mg/2mL. Composition of inactive ingredients (WFI) is given as q.s 10mL for 2mL vial. Pre-approval change in composition regarding active and inactives is required along with full fee of registration prescribed as per S.R.O 496(I)/2023 dated 17-04-2023. • Revision of label claim is required according to product approved by MHRA, as follows: *Each mL contains fosphenytoin sodium……75 mg (equivalent to 50 mg of phenytoin sodium)*

		• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) alongwith deposit slip No. 5105851669 and the Board was apprised of the same during the meeting.***
	Decision: Approved with following label claim: **"Each mL contains Fosphenytoin sodium……75 mg** **(equivalent to 50 mg of phenytoin sodium)"**	
1162.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Liquid Injection (General)
	Brand Name +Dosage Form + Strength	BAVOKIN injection 10mg/2ml
	Composition	Each 20mL vial contains: Bupivacaine Hydrochloride ……100mg
	Diary No. Date of R& I & fee	Dy No. 14490 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902525 dated 05-03-2019.
	Pharmacological Group	Anaesthetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1x20mL; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Bupivacaine-Baxter, solution for injection 100 mg/20 mL. Glass vial. TGA approved
	Me-too status	Bucan 0.5% Injection M/s Bosch Pharmaceutical Karachi Reg. No. 39196 (Pack size and container closure, whether ampule or vial, is not confirmed)
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Change strength to read as 5mg/ml • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) alongwith deposit slip No. 3736921475 (PKR 7500) and the Board was apprised of the same during the meeting.***
	Decision: Approved with following label claim: **"Each mL contains:** **Bupivacaine Hydrochloride ……5mg";** **Pack size 20mL vial.**	
1163.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Liquid Injection (General)
	Brand Name +Dosage Form + Strength	BAVOKIN injection 5mg/ml
	Composition	Each 10mL vial contains: Bupivacaine Hydrochloride ……50mg
	Diary No. Date of R& I & fee	Dy No. 14489 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902524 dated 05-03-2019.

	Pharmacological Group	Anaesthetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1x10mL; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Bupivacaine-Baxter, solution for injection 50 mg/10 mL. Glass vial.
	Me-too status	Bucan 0.5% Injection M/s Bosch Pharmaceutical Karachi Reg. No. 39196 (Pack size and container closure, whether ampule or vial, is not confirmed)
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Revise label claim as follows: "Each ml contains: Bupivacaine HCl as monohydrate……5mg" • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 01-06-2023 (Dy No. 13787 dated 02-06-2023) alongwith deposit slip No. 77991948600 (PKR 7500) and the Board was apprised of the same during the meeting.***
	Decision: Approved with following label claim: **"Each mL contains:** **Bupivacaine Hydrochloride ……5mg";** **Pack size 10mL vial.**	
1164.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Liquid Injection (General)
	Brand Name +Dosage Form + Strength	FINZINE injection 25mg
	Composition	Each 1mL ampule contains: Fluphenazine Decanoate ……25mg
	Diary No. Date of R& I & fee	Dy No. 14557 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900597 dated 05-03-2019.
	Pharmacological Group	Antipsychotics ATC code: N05AB02
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1mL ; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Saviget Injection 25mg ICI Pakistan Limited Reg. No. 69745
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Evidence of approval of applied product in reference regulatory authority is required. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm submitted requisite signed Form 5 and annexures vide Letter No. Nil dt 01-06-2023***

		(Dy No. 13787 dated 02-06-2023) and the Board was apprised of the same during the meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
1165.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Injectable section (Biopharmaceutical)
	Brand Name +Dosage Form + Strength	Tressin Injection 2mg
	Composition	Each vial of lyophilized powder contains: Terlipressin acetate (in-house)……..2mg (equivalent to Terlipressin 1.72mg)
	Diary No. Date of R& I & fee	Dy No. 14565 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902539 dated 05-03-2019.
	Pharmacological Group	Vasopressin and analogues ATC Code H01BA04
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not found for 2mg lyophilized powder for injection
	Me-too status	Not found
	GMP status	Not available for lyophilized powder for injection (biopharmaceutical).
	Remarks of the Evaluator[xxiii].	• Evidence of required manufacturing facility i.e. lyophilized powder for injection (biopharmaceutical) section along with section approval letter from Licensing Division of DRAP and current GMP status. Comments may be taken from technical members whether biopharmaceuticals require pharmaceutical or biological facility for manufacturing. • Terlipressin acetate is available as monograph in BP so specifications of raw material may be changed from In-house to BP. • Evidence of approval of applied product in reference regulatory authority is required. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required. • Pack size is not mentioned in application • Volume and type of container closure system (vial/ampule) for lyophilized powder and solvent is required • Details of solvent including name, method of manufacturing, source and pack size are required and application for registration is required for solvent on Form 5 along with fee. • Strength of reconstituted solution is required as part of label claim.

		• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant.
	Decision: The Registration Board referred the application to Biological Evaluation & Research Division, since applied product is Biological formulation.	
1166.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals Plot No. 122, Block A, Phase-V, Industrial Estate Hattar, Pakistan. (DML No. 000610) Injectable section (Biological)
	Brand Name +Dosage Form + Strength	Tressin Injection 1mg
	Composition	Each vial of lyophilized powder contains: Terlipressin acetate (in-house)……..1mg (equivalent to Terlipressin 0.86mg)
	Diary No. Date of R& I & fee	Dy No. 14491 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1902526 dated 05-03-2019.
	Pharmacological Group	Vasopressin and analogues ATC Code H01BA04
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Novapressin parenteral injection M/s Ferozsons laboratories Reg. No. 028416
	GMP status	Not available for lyophilized powder for injection (biopharmaceutical).
	Remarks of the Evaluator[xxiii].	• Evidence of required manufacturing facility i.e. lyophilized powder for injection (biopharmaceutical) section along with section approval letter from Licensing Division of DRAP and current GMP status. Comments may be taken from technical members whether biopharmaceuticals require pharmaceutical or biological facility for manufacturing. • Terlipressin acetate is available as monograph in BP so specifications of raw material may be changed from In-house to BP. • Label claim may be revised according to product approved in MHRA as follows: "Each vial of powder contains: 1 mg terlipressin acetate equivalent to 0.85 mg terlipressin. 1 ml of reconstituted solution contains 0.2 mg terlipressin acetate". • Pack size is not mentioned in application • Volume and type of container closure system for lyophilized powder and solvent is required. • Details of solvent including name, method of manufacturing, source and pack size are required and application for registration is required for solvent on Form 5 along with fee. • Strength of reconstituted solution is required as part of label claim.

		• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant.
	Decision: The Registration Board referred the application to Biological Evaluation & Research Division, since applied product is Biological formulation.	
1167.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet (general) section
	Brand Name +Dosage Form + Strength	FENTAP tablet 250mg
	Composition	Each film coated tablet contains: Sodium Fusidate (BP)……..……250mg
	Diary No. Date of R& I & fee	Dy No. 14142 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900145 dated 06-03-2019.
	Pharmacological Group	Steroid Antibacterials ATC code: J01XC01
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved PL 00043/5000R
	Me-too status	Bacusid 250mg Tablet M/s SAMI Pharmaceuticals Pvt. Ltd Reg. No. 090778
	GMP status	GMP inspection conducted on 15-06-2022 on the basis of which Certificate No. F.3-15/2018-Addl. Dir. (QA &LT-I)-40 was issued for the following sections: Tablet (General) Capsule (General) Capsule (Cephalosporin) Sachet (General) Oral Dry powder (Suspension) (General) Oral Dry powder (Suspension) (Cephalosporin) Injectable (Dry Powder) (General) (Vial) Injectable (Dry Powder) (Cephalosporin) Liquid Ampule SVP (General)
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Deffered for clarification of steroidal section from licencing division. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1168.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet section (general)
	Brand Name +Dosage Form + Strength	MYNOLATE tablet 500mg
	Composition	Each film coated tablet contains: Mycophenolate Mofetil (USP)…….……500mg
	Diary No. Date of R& I & fee	Dy No. 14134 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 840065 dated 05-03-2019.
	Pharmacological Group	Immunosuppresants

		ATC code L04AA06
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Myfenax 500 mg film-coated tablets MHRA approved
	Me-too status	Micocept Film Coated Tablets M/s Novartis Pharma (Pakistan) Limited Reg. No. 84629
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Registration Board in its 296th meeting approved registration of Mycophenolate Mofetil capsules in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1169.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet (general) section
	Brand Name +Dosage Form + Strength	ENVIR tablet 0.5mg
	Composition	Each film coated tablet contains: Entecavir as Monohydrate (USP) ..…….0.5mg
	Diary No. Date of R& I & fee	Dy No. 14130 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 840061 dated 05-03-2019.
	Pharmacological Group	Direct acting antivirals, Nucleoside and nucleotide reverse transcriptase inhibitors ATC Code J05AF10
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Entecavir 0.5mg film-coated tablets MHRA Approved PL 25258/0233
	Me-too status	Livose-C 0.5mg Tablets M/s Wilson's Pharmaceuticals Reg. No. 77831
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated***

		02-06-2023) and the Board was apprised of the same during the meeting.
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1170.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet (general) section
	Brand Name +Dosage Form + Strength	FITER tablet 5mg
	Composition	Each film coated tablet contains: Finasteride (USP) ..……..5mg
	Diary No. Date of R& I & fee	Dy No. 14133 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0840064 dated 05-03-2019.
	Pharmacological Group	Testosterone-5-alpha reductase inhibitors ATC Code G04CB01
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Proscar 5mg tablet USFDA Approved
	Me-too status	Xebim 5mg Tablet M/s Ameer & Adnan Pharmaceuticals (Pvt) Ltd, Lahore Reg. No. 113292
	GMP status	Same as above.
	Remarks of the Evaluator[xxiii].	• Manufacturer shall be directed to provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs, in accordance with the decision of Registration Board in its 321st meeting • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter. **Moreover the Registration Board directed the manufacturer to provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.**	
1171.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet (general) section
	Brand Name +Dosage Form + Strength	OLMIXIL tablet 20mg
	Composition	Each film coated tablet contains: Olmesartan Medoxomil……..……20mg
	Diary No. Date of R& I & fee	Dy No. 14096 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0840068 dated 05-03-2019.
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) ATC code: C09CA08
	Type of Form	Form 5

	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Benicar tablets 20mg & 40mg USFDA Approved
	Me-too status	Olmisan 20mg tablets M/s Highnoon Laboratories Reg. no. 092273
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1172.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet (general) section
	Brand Name +Dosage Form + Strength	OLMIXIL tablet 40mg
	Composition	Each film coated tablet contains: Olmesartan Medoxomil……..……40mg
	Diary No. Date of R& I & fee	Dy No. 14097 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0840069 dated 05-03-2019.
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) ATC code: C09CA08
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Benicar tablets 20mg & 40mg USFDA Approved
	Me-too status	Olmisan 40mg tablets M/s Highnoon Laboratories Reg. no. 092274
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1173.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet (general) section
	Brand Name +Dosage Form + Strength	WEROM tablet 1.25mg
	Composition	Each tablet contains: Ramipril (USP)……..……..1.25mg

	Diary No. Date of R& I & fee	Dy No. 14138 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900128 dated 06-03-2019.
	Pharmacological Group	ACE Inhibitors, plain, ATC Code: C09AA05
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ramipril 1.25 mg Tablets MHRA Approved
	Me-too status	Mevlon 1.25mg Tablet M/s Helix Pharma (Pvt) Ltd., Karachi Reg. No. 045336
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1174.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet (general) section
	Brand Name +Dosage Form + Strength	WEROM tablet 2.5mg
	Composition	Each tablet contains: Ramipril (USP)……...……..2.5mg
	Diary No. Date of R& I & fee	Dy No. 14139 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900129 dated 06-03-2019.
	Pharmacological Group	ACE Inhibitors, plain, ATC Code: C09AA05
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ramipril 2.5 mg Tablets MHRA Approved
	Me-too status	Tritace 2.5mg Tablet M/s Sanofi-Aventis Pakistan Limited Reg. No. 019564
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1175.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790)

		Tablet (general) section
	Brand Name +Dosage Form + Strength	WEROM tablet 5mg
	Composition	Each tablet contains: Ramipril (USP)……..……..5mg
	Diary No. Date of R& I & fee	Dy No. 14140 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900130 dated 06-03-2019.
	Pharmacological Group	ACE Inhibitors, plain, ATC Code: C09AA05
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ramipril 1.25 mg Tablets MHRA Approved
	Me-too status	Mevlon 1.25mg Tablet M/s Helix Pharma (Pvt) Ltd., Karachi Reg. No. 045338
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1176.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet (general) section
	Brand Name +Dosage Form + Strength	WEETOR tablet 10mg
	Composition	Each film coated tablet contains: Atorvastatin as Calcium salt ……..……..……10mg
	Diary No. Date of R& I & fee	Dy No. 14143 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900133 dated 06-03-2019.
	Pharmacological Group	HMG CoA reductase inhibitors ATC Code: C10AA05
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Atorvastatin 10 mg Film-coated Tablets PL 36687/0258 MHRA Approved
	Me-too status	Lipiget 10mg Tablet M/s Getz Pharma Reg. No. 029956
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Revision of label claim and master formulation is required as follows according to product approved in MHRA, along with submission of full fee of registration: *"Each Film Coated Tablet Contains:* *Atorvastatin (as Calcium trihydrate)……..10mg"*

		• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) alongwith fee for Rs. 30,000/- vide Deposit Slip No. 327943881 and the Board was apprised of the same during the meeting.***
	Decision: Approved with following label claim: **"Each Film Coated Tablet Contains:** **Atorvastatin (as Calcium trihydrate)……..10mg"**	
1177.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet (general) section
	Brand Name +Dosage Form + Strength	WEETOR tablet 20mg
	Composition	Each film coated tablet contains: Atorvastatin as Calcium salt ……...……...…….20mg
	Diary No. Date of R& I & fee	Dy No. 14144 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900134 dated 06-03-2019.
	Pharmacological Group	HMG CoA reductase inhibitors ATC Code: C10AA05
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Atorvastatin 20 mg Film-coated Tablets PL 50805/0002 MHRA Approved
	Me-too status	Lipiget 20mg Tablet M/s Getz Pharma Reg. No. 029957
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Revision of label claim and master formulation is required as follows according to product approved in MHRA, along with submission of full fee of registration: *"Each Film Coated Tablet Contains:* • *Atorvastatin (as Calcium trihydrate)……..20mg"* • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) alongwith fee for Rs. 30,000/- Deposit Slip No. 64407672307 and the Board was apprised of the same during the meeting.***
	Decision: Approved with following label claim: **"Each Film Coated Tablet Contains:** **Atorvastatin (as Calcium trihydrate)……..20mg"**	
1178.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet (general) section
	Brand Name +Dosage Form + Strength	KOMAOR 1mg tablet
	Composition	Each tablet contains:

		Cinitapride as Hydrogen Tartarate……1mg
	Diary No. Date of R& I & fee	Dy No. 14150 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900141 dated 06-03-2019.
	Pharmacological Group	Propulsives ATC Code: A03FA08
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	CIMA, Spain Approved
	Me-too status	Cidine Tablets 1mg M/s Highnoon Laboratories Ltd Reg. No. 052940
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1179.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet (general) section
	Brand Name +Dosage Form + Strength	WENOLOM 400mg tablet
	Composition	Each film coated tablet contains: Lomefloxacin as hydrochloride……400mg
	Diary No. Date of R& I & fee	Dy No. 14141 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900131 dated 06-03-2019.
	Pharmacological Group	Floroquinolones ATC Code: J01MA07
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	TGA Australia Approved
	Me-too status	Lomerox 400mg Tablets M/s Rock Pharmaceutical Laboratories (Pvt)Ltd Reg. No. 064228
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	

1180.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet (general) section
	Brand Name +Dosage Form + Strength	AMOSIDE 400mg tablet
	Composition	Each tablet contains: Amisulpride…….400mg
	Diary No. Date of R& I & fee	Dy No. 14126 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0840057 dated 05-03-2019.
	Pharmacological Group	Antipsychotics ATC Code: N05AL05
	Type of Form	Form 5
	Finished Product Specification	USP, as claimed by applicant. Monograph is not available in USP.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved PL 16363/0148
	Me-too status	Amis 400mg Tablet M/s Genome Pharmaceuticals (Pvt.) Ltd Reg. No. 080873
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Evidence of product approved in reference regulatory authority (MHRA) is of film coated tablets, applied product is uncoated. However, applicant has included coating agents in master formulation and also included coating process in the manufacturing process. Therefore, change in formulation from uncoated to film coated tablet as approved by MHRA is required, along with PKR 7500/- fee prescribed vide S.R.O 496(I)/2023 dated 17-04-2023. • Change in specifications from USP to BP Specifications along with prescribed fee is required. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) alongwith Deposit slip No. 21805309151 and the Board was apprised of the same during the meeting.***
	Decision: Approved with BP Specifications alongwith following label claim: ***"Each film coated tablet contains:*** ***Amisulpride……400mg".***	
1181.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet (general) section
	Brand Name +Dosage Form + Strength	FAMOVIR 500mg tablet
	Composition	Each film coated tablet contains: Famciclovir(USP) …….500mg
	Diary No. Date of R& I & fee	Dy No. 14132 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0840063 dated 05-03-2019.
	Pharmacological Group	Antivirals ATC Code: J05AB09
	Type of Form	Form 5

	Finished Product Specification	Innovator's Specifications, USP monograph is available
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Famcilo 500mg Tablet M/s Bio-Labs(Pvt) Ltd Reg. No. 112977
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Change in specifications from Innnovator's Specifications to USP is required along with prescribed fee (PKR 7500/-) fee vide S.R.O 496(I)/2023 dated 17-04-2023. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) alongwith Deposit slip No. 8187064911 and the Board was apprised of the same during the meeting.***
	Decision:Approved with USP specifications.	
1182.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet (general) section
	Brand Name +Dosage Form + Strength	FAMOVIR 250mg tablet
	Composition	Each film coated tablet contains: Famciclovir(USP) …….250mg
	Diary No. Date of R& I & fee	Dy No. 14131 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0840062 dated 06-03-2019.
	Pharmacological Group	Antivirals ATC Code: J05AB09
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications, USP monograph is available
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Famcilo 500mg Tablet M/s Bio-Labs(Pvt) Ltd Reg. No. 112976
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Change in specifications from Innnovator's Specifications to USP is required along with prescribed fee (PKR 7500/-) fee vide S.R.O 496(I)/2023 dated 17-04-2023. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) alongwith Deposit slip No. 692073017539 and the Board was apprised of the same during the meeting.***
	Decision: Approved with USP specifications.	

1183.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet (general) section
	Brand Name +Dosage Form + Strength	TYNOXIL 300mg tablet
	Composition	Each film coated tablet contains: Tenofovir Disoproxil Fumarate ……300mg (Equivalent to 245mg of Tenofovir Disoproxil)
	Diary No. Date of R& I & fee	Dy No. 14106 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900105 dated 05-03-2019.
	Pharmacological Group	Direct acting antivirals ATC Code: J05AF07
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed Innovator's Specifications whereas product monograph is available in International Pharmacopeia.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	VIREAD® (tenofovir disoproxil fumarate) film coated tablets, USFDA approved
	Me-too status	Tenastra 300mg Tablets Hamaz Pharmaceuticals Reg. No. 085023
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved with International Pharmacopoeia specifications. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in product specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1184.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet (general) section
	Brand Name +Dosage Form + Strength	WECLOZ 100mg tablet
	Composition	Each tablet contains: Clozapine (USP)……..100mg
	Diary No. Date of R& I & fee	Dy No. 14120 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900127 dated 06-03-2019.
	Pharmacological Group	Diazepines, oxazepines, thiazepines and oxepines ATC Code: N05AH02
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Clozaril tablets USFDA Approved
	Me-too status	Lozapa 100mg Tablet M/s Trigon Pharmaceuticals (Private) Ltd Reg. No. 110882
	GMP status	Same as above

	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1185.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet (general) section
	Brand Name +Dosage Form + Strength	ANZOLE 1mg tablet
	Composition	Each tablet contains: Anastrazole (USP)…….……1mg
	Diary No. Date of R& I & fee	Dy No. 14127 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0840058 dated 05-03-2019.
	Pharmacological Group	Aromatase inhibitors ATC Code: L02BG03
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Arimidex Anastrozole 1mg film coated tablets TGA approved
	Me-too status	Arimisol 1mg Tablet M/s Swiss Pharmaceuticals (Pvt) Ltd., Karachi Reg. No. 091125
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• For manufacturing in general manufacturing area, the manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of this drugs • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1186.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet (general) section
	Brand Name +Dosage Form + Strength	NOVOMATE 200mg tablet
	Composition	Each film coated tablet contains: Topiramate (USP)……200mg
	Diary No. Date of R& I & fee	Dy No. 14116 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900123 dated 06-03-2019.
	Pharmacological Group	Other antiepileptics

		ATC Code: N03AX11
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved PL 25258/0063
	Me-too status	Hitop 200mg Tablet M/s Hilton Pharma (Pvt) Limited Reg. No. 037683
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1187.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet (general) section
	Brand Name +Dosage Form + Strength	DYROX 250mg tablet
	Composition	Each dispersible tablet contains: Deferasirox……250mg
	Diary No. Date of R& I & fee	Dy No. 14129 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0840060 dated 05-03-2019.
	Pharmacological Group	Iron chelating agents ATC Code V03AC03
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed Innovator's Specifications, product monograph is available in European Pharmacopoeia
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Health Canada Approved
	Me-too status	Obsarox dispersible tablet M/s Aspin Pharma (Pvt) Ltd., Karachi
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Change of finished product specifications from Innovator's Specifications to EP Specifications along with relevant fee is required. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) alongwith Deposit slip No. 701587009 and the Board was apprised of the same during the meeting.***
	Decision: Approved with EP Specifications.	
1188.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet (general) section

	Brand Name +Dosage Form + Strength	WENDEF/DYROX 500mg tablet
	Composition	Each dispersible tablet contains: Deferasirox……500mg
	Diary No. Date of R& I & fee	Dy No. 14113 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900119 dated 06-03-2019.
	Pharmacological Group	Iron chelating agents ATC Code V03AC03
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed Innovator's Specifications, product monograph is available in European Pharmacopoeia
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Health Canada Approved
	Me-too status	Obsarox dispersible tablet M/s Aspin Pharma (Pvt) Ltd., Karachi
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Change of finished product specifications from Innovator's Specifications to EP Specifications along with relevant fee is required. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) alongwith Deposit slip No. 4934671416 and the Board was apprised of the same during the meeting.***
	Decision: Approved with EP Specifications.	
1189.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet (general) section
	Brand Name +Dosage Form + Strength	REDOF 10/40mg tablet
	Composition	Each tablet contains: Ezetimibe ……..10mg Simvastatin…….40mg
	Diary No. Date of R& I & fee	Dy No. 14146 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900136 dated 06-03-2019.
	Pharmacological Group	HMG CoA reductase inhibitors in combination with other lipid modifying agents
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Limitrol-EZ 10/40 Tablet M/s PHARMEVO (PVT) LTD. Reg. No. 42402
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-***

		06-2023) and the Board was apprised of the same during the meeting.
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1190.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet (general) section
	Brand Name +Dosage Form + Strength	REDOF 10/80mg tablet
	Composition	Each tablet contains: Ezetimibe ……..10mg Simvastatin…….80mg
	Diary No. Date of R& I & fee	Dy No. 14145 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900135 dated 06-03-2019.
	Pharmacological Group	HMG CoA reductase inhibitors in combination with other lipid modifying agents
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Survive Plus 10mg/80mg Tablets M/s Werrick Pharmaceuticals Reg. No. 47196
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1191.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet (general) section
	Brand Name +Dosage Form + Strength	WENOTRAM 1000mg tablet
	Composition	Each film coated tablet contains: Levetiracetam……..1000mg
	Diary No. Date of R& I & fee	Dy No. 14115 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900122 dated 06-03-2019.
	Pharmacological Group	Other anti-epileptics ATC Code: N03AX14
	Type of Form	Form 5
	Finished Product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Lumark tablet 1000mg M/s The Searle Company Limited
	GMP status	Same as above

	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1192.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet (general) section
	Brand Name +Dosage Form + Strength	WENOTRAM 750mg tablet
	Composition	Each film coated tablet contains: Levetiracetam……..750mg
	Diary No. Date of R& I & fee	Dy No. 14114 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900121 dated 06-03-2019.
	Pharmacological Group	Other anti-epileptics ATC Code: N03AX14
	Type of Form	Form 5
	Finished Product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Lumark tablet 750mg M/s The Searle Company Limited
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1193.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet (general) section
	Brand Name +Dosage Form + Strength	WEMBAR 5mg tablet
	Composition	Each film coated tablet contains: Solifenacin succinate ……..5mg
	Diary No. Date of R& I & fee	Dy No. 14119 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900126 dated 06-03-2019.
	Pharmacological Group	Drugs for urinary frequency and incontinence ATC Code: G04BD08
	Type of Form	Form 5
	Finished Product Specifications	Innovators Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved

	Me-too status	Solif Tablet by M/s Global
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1194.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet (general) section
	Brand Name +Dosage Form + Strength	WEMBAR 10mg tablet
	Composition	Each film coated tablet contains: Solifenacin succinate ……..10mg
	Diary No. Date of R& I & fee	Dy No. 14118 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900125 dated 06-03-2019.
	Pharmacological Group	Drugs for urinary frequency and incontinence ATC Code: G04BD08
	Type of Form	Form 5
	Finished Product Specifications	Innovators Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Solif Tablet by M/s Global
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1195.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790)
	Brand Name +Dosage Form + Strength	WENOVER 5mg tablet
	Composition	Each tablet contains: Everolimus ……..5mg
	Diary No. Date of R& I & fee	Dy No. 14111 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900117 dated 06-03-2019.
	Pharmacological Group	Antineoplastic agents ATC Code L01EG02 Immunosuppressants ATC Code L04AA18
	Type of Form	Form 5
	Finished Product Specifications	Innovator's Specifications
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Afinitor 5mg Tablets M/s Novartis Pharma (Pakistan) Limited Reg. No. 69519
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Evidence of approval of required manufacturing facility of "Cytotoxic/Oncology Tablet section" from Central Licensing Board, since the applied formulation falls in both L01 and L04 categories as per WHO ATC classification. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm submitted requisite signed Form 5 and annexures vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Deferred for following: • **Deferred for submission of evidence of approval of required manufacturing facility of "Tablet (Oncology) section" from CLB.** • **Submission of fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
1196.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790)
	Brand Name +Dosage Form + Strength	WENOVER 10mg tablet
	Composition	Each tablet contains: Everolimus ……..10mg
	Diary No. Date of R& I & fee	Dy No. 14112 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900118 dated 06-03-2019.
	Pharmacological Group	Antineoplastic agents ATC Code L01EG02 Immunosuppressants ATC Code L04AA18
	Type of Form	Form 5
	Finished Product Specifications	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Afinitor 10mg Tablets M/s Novartis Pharma (Pakistan) Limited Reg. No. 69520
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Evidence of approval of required manufacturing facility of "Cytotoxic/Oncology Tablet section" from Central Licensing Board, since the applied formulation falls in both L01 and L04 categories as per WHO ATC classification.

		• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm submitted requisite signed Form 5 and annexures vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Deferred for following: • **Deferred for submission of evidence of approval of required manufacturing facility of "Tablet (Oncology) section" from CLB.** • **Submission of fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
1197.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790)
	Brand Name +Dosage Form + Strength	WENOVER 0.25mg tablet
	Composition	Each tablet contains: Everolimus ……..0.25mg
	Diary No. Date of R& I & fee	Dy No. 14109 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900115 dated 06-03-2019.
	Pharmacological Group	Antineoplastic agents ATC Code L01EG02 Immunosuppressants ATC Code L04AA18
	Type of Form	Form 5
	Finished Product Specifications	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Certican Tablets M/s Novartis Pharma (Pakistan) Limited
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Evidence of approval of required manufacturing facility of "Cytotoxic/Oncology Tablet section" from Central Licensing Board, since the applied formulation falls in both L01 and L04 categories as per WHO ATC classification. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm submitted requisite signed Form 5 and annexures vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Deferred for following: • **Deferred for submission of evidence of approval of required manufacturing facility of "Tablet (Oncology) section" from CLB.** • **Submission of fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	

	The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
1198.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790)
	Brand Name +Dosage Form + Strength	WENOVER 0.75mg tablet
	Composition	Each tablet contains: Everolimus ……..0.75mg
	Diary No. Date of R& I & fee	Dy No. 14110 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900116 dated 06-03-2019.
	Pharmacological Group	Antineoplastic agents ATC Code L01EG02 Immunosuppressants ATC Code L04AA18
	Type of Form	Form 5
	Finished Product Specifications	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Certican Tablets M/s Novartis Pharma (Pakistan) Limited
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Evidence of approval of required manufacturing facility of "Cytotoxic/Oncology Tablet section" from Central Licensing Board, since the applied formulation falls in both L01 and L04 categories as per WHO ATC classification. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm submitted requisite signed Form 5 and annexures vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Deferred for following: • **Deferred for submission of evidence of approval of required manufacturing facility of "Tablet (Oncology) section" from CLB.** • **Submission of fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
1199.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet (anticancer/cytotoxic) section
	Brand Name +Dosage Form + Strength	METWEN 2.5mg tablet
	Composition	Each tablet contains: Methotrexate ……..2.5mg
	Diary No. Date of R& I & fee	Dy No. 14107 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900113 dated 06-03-2019.

	Pharmacological Group	Antineoplastic agents ATC Code: L01BA01 Immunosuppressant ATC Code: L04AX03
	Type of Form	Form 5
	Finished Product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Methotrexate tablet 2.5mg M/s Pak China International (Reg No. 066007)
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Evidence of approval of required manufacturing facility of "Cytotoxic/Oncology Tablet section",from Central Licensing Board, since the applied formulation falls in both L01 and L04 categories as per WHO ATC classification. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm submitted requisite signed Form 5 and annexures vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Deferred for following: • **Deferred for submission of evidence of approval of required manufacturing facility of "Tablet (Oncology) section" from CLB.** • **Submission of fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.** **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
1200.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Tablet (anticancer/cytotoxic) section
	Brand Name +Dosage Form + Strength	METWEN 10mg tablet
	Composition	Each tablet contains: Methotrexate ……..10mg
	Diary No. Date of R& I & fee	Dy No. 14108 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900114 dated 06-03-2019.
	Pharmacological Group	Antineoplastic agents ATC Code: L01BA01 Immunosuppressant ATC Code: L04AX03
	Type of Form	Form 5
	Finished Product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Methotrexate tablet 10mg M/s Pak China International

		(Reg No. 066009)
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Evidence of approval of required manufacturing facility of "Cytotoxic/Oncology Tablet section",from Central Licensing Board, since the applied formulation falls in both L01 and L04 categories as per WHO ATC classification. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm submitted requisite signed Form 5 and annexures vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Deferred for following: • **Deferred for submission of evidence of approval of required manufacturing facility of "Tablet (Oncology) section" from CLB.** **Submission of fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.**	
1201.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Capsule (General)
	Brand Name +Dosage Form + Strength	TACROWEN capsule 0.5mg
	Composition	Each capsule contains: Tacrolimus as monohydrate ..……0.5mg
	Diary No. Date of R& I & fee	Dy No. 14103 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900101 dated 05-03-2019.
	Pharmacological Group	Immunosuppressants ATC code: L04AD02
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Vivadex 0.5mg, 1mg, 5mg hard capsules (tacrolimus) - PL 23022/0018-20; UK/H/2179/01-03/DC MHRA Approved
	Me-too status	Tacrosan 0.5mg Capsule M/s Novartis Karachi Reg. No. 078163
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Above product may be manufactured in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***

	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1202.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Capsule (General)
	Brand Name +Dosage Form + Strength	TACROWEN capsule 1mg
	Composition	Each capsule contains: Tacrolimus as monohydrate ..……1mg
	Diary No. Date of R& I & fee	Dy No. 14104 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900103 dated 05-03-2019.
	Pharmacological Group	Immunosuppressants ATC code: L04AD02
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Vivadex 0.5mg, 1mg, 5mg hard capsules (tacrolimus) - PL 23022/0018-20; UK/H/2179/01-03/DC MHRA Approved
	Me-too status	Tacrosan 1mg Capsule M/s Novartis Karachi Reg. No. 078164
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Above product may be manufactured in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1203.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Capsule (General)
	Brand Name +Dosage Form + Strength	TACROWEN capsule 5mg
	Composition	Each capsule contains: Tacrolimus as monohydrate ..……5mg
	Diary No. Date of R& I & fee	Dy No. 14105 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900104 dated 05-03-2019.
	Pharmacological Group	Immunosuppressants ATC code: L04AD02
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Vivadex 0.5mg, 1mg, 5mg hard capsules (tacrolimus) - PL 23022/0018-20; UK/H/2179/01-03/DC

		MHRA Approved
	Me-too status	Tacrosan 5mg Capsule M/s Novartis Karachi Reg. No. 078165
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Above product may be manufactured in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1204.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Capsule (Cephalosporin)
	Brand Name +Dosage Form + Strength	WENTOCEF capsule 400mg
	Composition	Each capsule contains: Ceftibuten as dihydrate ……...……400mg
	Diary No. Date of R& I & fee	Dy No. 14117 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900124 dated 06-03-2019.
	Pharmacological Group	Third-generation cephalosporins ATC code: J01DD14
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not confirmed. Marketing status declared as Discontinued in USFDA
	Me-too status	Xigris 400mg Capsule M/s Wilshire Laboratories (Private) Limited Reg. No. 053635
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm submitted requisite signed Form 5 and annexures vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023).***
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
1205.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Capsule (General)

	Brand Name +Dosage Form + Strength	CHICOWEN capsule 4mg
	Composition	Each capsule contains: Thiocolchicoside ……4mg
	Diary No. Date of R& I & fee	Dy No. 14186 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900106 dated 05-03-2019.
	Pharmacological Group	Muscle relaxants, centrally acting agents ATC code: M03BX05
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MIOREL 4 mg, capsule ANSM Approved
	Me-too status	Muscolin 4mg Capsule M/s Saffron Pharmaceuticals (Pvt) Ltd., Faisalabad Reg. No. 060348
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1206.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790)
	Brand Name +Dosage Form + Strength	POMEGA 50,000IU Injection
	Composition	Each soft gel capsule contains: Vitamin D3 (Cholecalciferol) BP……..50,000IU
	Diary No. Date of R& I & fee	Dy No. 14149 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900140 dated 06-03-2019.
	Pharmacological Group	Vitamins ATC Code: A11CC05
	Type of Form	Form 5
	Finished Product Specification	Firm has stated Innovator's Specifications. Monograph of capsule dosage form is available in USP.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved DELTIUS 50,000 IU capsules, hard (containing oily solution) (PL 27827/0048) Choli-D3 50,000 IU Capsules, soft(containing clear transparent liquid) (PL 48836/0013)
	Me-too status	Not confirmed as clarification is required for dosage form & strength
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Product name on cover letter and challan is Pomega 50,000IU Injection. Product name on Form 5 is Pomega soft gel capsule 50,000IU. Finished product composition is given as 20,000IU Cholecalciferol in each hard gel capsule. Method of manufacturing is given for hard gel capsules. Clarification is required

		from firm regarding the applied dosage form (injectable, hard gel capsule or soft gel capsule) and submission of Form 5 and supporting documents accordingly along with full fee of registration as per S.R.O 496(I)/2023 dated 17-04-2023. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant.
	Decision: Registration Board while considering the variations in the submitted Form 5 regarding applied dosage form and strength of the formulation decided to reject the application	
1207.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Capsule section (general)
	Brand Name +Dosage Form + Strength	PREGAVO capsule 50mg
	Composition	Each capsule contains: Pregabalin ……...……...……..50mg
	Diary No. Date of R& I & fee	Dy No. 14121 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0840419 dated 05-03-2019.
	Pharmacological Group	Gabapentinoids ATC Code: N02BF02
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed Innovator's Specifications; finished product monograph is available in BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Gabica 50mg Capsules M/s Getz Pharma Reg. No. 048725
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Change in specifications from innovator's specifications to BP is required along with prescribed fee (Rs.7500) as per S.R.O 496(I)/2023 dated 17-04-2023. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) alongwith Deposit Slip No. 25353537 and the Board was apprised of the same during the meeting.***
	Decision: Approved with BP Specifications.	
1208.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Capsule section (general)
	Brand Name +Dosage Form + Strength	PREGAVO capsule 150mg
	Composition	Each capsule contains: Pregabalin ……...……...……..150mg
	Diary No. Date of R& I & fee	Dy No. 14123 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0840053 dated 05-03-2019.
	Pharmacological Group	Gabapentinoids

		ATC Code: N02BF02
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed Innovator's Specifications; finished product monograph is available in BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Gabica 150mg Capsules M/s Getz Pharma Reg. No. 048724
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Change in specifications from innovator's specifications to BP is required along with prescribed fee (Rs.7500) as per S.R.O 496(I)/2023 dated 17-04-2023. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) alongwith Deposit Slip No. 7615373284 and the Board was apprised of the same during the meeting.***
	Decision: Approved with BP Specifications.	
1209.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Capsule (general) section
	Brand Name +Dosage Form + Strength	WENKAM 60mg capsule
	Composition	Each capsule contains: Orlistat ……..60mg
	Diary No. Date of R& I & fee	Dy No. 14147 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900138 dated 06-03-2019.
	Pharmacological Group	Peripherally acting antiobesity products ATC Code: A08AB01
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Vetnor 60mg Capsule M/s Amarant Pharamceuticals (Pvt) Ltd., Karachi. Reg. No. 80348
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • Previously, inadvertently, the approval status of product in Reference Regulatory Authorities was written as "USFDA Approved powder filled capsules" and Me-too status was given as "OSKER 60mg Capsule, M/s Genix Pharma, Karachi, Reg. No. 66787 (Powder or pellet filling not confirmed)". However, later on both the entries were updated.

		Accordingly, following details are required from the applicant: Source of pellets (PKR 150,000 fee in case of imported pellets) GMP certificate of source of pellets Stability study of 3 batches of pellets Certificate of analysis of pellets.
	Decision: Deferred for submission of following: • **Form-5 and annexures duly signed by the applicant;** • **Source of pellets (PKR 150,000 fee in case of imported pellets);** • **GMP certificate of source of pellets;** • **Stability studies of the pellets at real time conditions i.e., 30°C ± 2°C/65% RH ± 5% RH alongwith quantification of degradation products throughout the stability studies / assigned shelf life** • **Certificate of analysis of pellets.**	
1210.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Capsule (general) section
	Brand Name +Dosage Form + Strength	WENKAM 120mg capsule
	Composition	Each capsule contains: Orlistat ……..120mg
	Diary No. Date of R& I & fee	Dy No. 14148 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900139 dated 06-03-2019.
	Pharmacological Group	Peripherally acting antiobesity products ATC Code: A08AB01
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved (pellet filled capsules)
	Me-too status	Orslim Capsule 120mg (pellet filled) M/s PHARMEVO (PVT) LTD. Reg.No. 42334
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • Previously, inadvertently, the approval status of product in Reference Regulatory Authorities was written as "USFDA Approved powder filled capsules" and Me-too status was given as "Xenical Capsule M/s Martin Dow Marker Limited Reg. No. 42142 (Powder or pellet filling not confirmed)". However, later on both the entries were updated. Accordingly, following details are required from the applicant: Source of pellets (PKR 150,000 fee in case of imported pellets) GMP certificate of source of pellets Stability study of 3 batches of pellets Certificate of analysis of pellets.
	Decision: Deferred for submission of following: • **Form-5 and annexures duly signed by the applicant;**	

	• **Source of pellets (PKR 150,000 fee in case of imported pellets);** • **GMP certificate of source of pellets;** • **Stability studies of the pellets at real time conditions i.e., 30°C ± 2°C/65% RH ± 5% RH alongwith quantification of degradation products throughout the stability studies / assigned shelf life** • **Certificate of analysis of pellets.**	
1211.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Capsule (general) section
	Brand Name +Dosage Form + Strength	ZEENOWO 40mg capsule
	Composition	Each capsule contains: Ziprasidone Hydrochloride Monohydrate eq. to Ziprasidone……40mg
	Diary No. Date of R& I & fee	Dy No. 14124 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0840054 dated 05-03-2019.
	Pharmacological Group	Antipsychotic ATC Code: N05AE04
	Type of Form	Form 5
	Finished Product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Geodon capsule USFDA Approved.
	Me-too status	Ziprox 20mg capsule M/s Nabiqasim Industries Reg.No.055650
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1212.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Capsule (general) section
	Brand Name +Dosage Form + Strength	ZEENOWO 60mg capsule
	Composition	Each capsule contains: Ziprasidone Hydrochloride Monohydrate eq. to Ziprasidone……60mg
	Diary No. Date of R& I & fee	Dy No. 14125 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0840056 dated 05-03-2019.
	Pharmacological Group	Antipsychotic ATC Code: N05AE04
	Type of Form	Form 5
	Finished Product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Geodon capsule USFDA Approved.
	Me-too status	Ziprox 60mg capsule

		M/s Nabiqasim Industries Reg.No.055652
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1213.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Liquid Ampule Injectable (General)
	Brand Name +Dosage Form + Strength	COLSIDE 4mg injection
	Composition	Each 2ml ampule contains: Thiocolchicoside ……4mg
	Diary No. Date of R& I & fee	Dy No. 14137 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900144 dated 06-03-2019.
	Pharmacological Group	Muscle relaxants, centrally acting agents ATC code: M03BX05
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MIOREL 4 mg/2 ml, solution for injection (IM) in ampoule ANSM France Approved
	Me-too status	Chicowel Injection 4mg/2ml M/s Welmark Pharmaceuticals Reg. No. 107680
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) and the Board was apprised of the same during the meeting.***
	Decision: Approved. The firm shall submit fee of Rs. 7,500/- for correction/pre-approval change in Form 5, as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.	
1214.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Injectable (dry powder) (vial)
	Brand Name +Dosage Form + Strength	ARTEWEN 120mg injection
	Composition	Each 2ml vial contains: Artesunate ……120mg
	Diary No. Date of R& I & fee	Dy No. 14128 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 0840059 dated 05-03-2019.
	Pharmacological Group	Anti-malarials ATC code: P01BE03
	Type of Form	Form 5

	Finished Product Specification	International Pharmacopoeia Specifications
	Pack size & Demanded Price	Transparent vial along with Sodium bicarbonate 2ml glass ampule packed in unit carton, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Applied component is included in WHO approved formulation
	Me-too status	Gen-M 120mg Injection M/s Genix Pharma, Karachi Reg. No. 076073 (Inclusion of solvent not confirmed)
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Applicant has submitted master formulation and packaging details for combo pack having following two components: Artesunate 120mg in 2ml vial along with 5% Sodium Bicarbonate Solution in Water for Injection packed in 2ml ampule. WHO approved formulation is as follows "Each vial contains: Artesunate powder 120 mg Each ampoule of solvent contains: Sodium bicarbonate 50 mg/ml, 2 ml (5%) Each ampoule of diluent contains: Sodium chloride 9 mg/ml, 10 ml (0.9%)"; According to the International Pharmacopoeia, the reconstituted injection is a sterile solution of Artesunate in 5% sodium bicarbonate intravenous infusion. It is prepared by dissolving Artesunate for injection in the requisite amount of 5% sodium bicarbonate intravenous infusion immediately before use. This solution is diluted further with a suitable diluent for injection in accordance with the manufacturer's instructions. Accordingly, separate application for registration of solvent for Artesunate (5% sodium bicarbonate solution in Water for Injection) is required along with full fee of registration.
	Decision: Approved.	
1215.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Liquid Ampule Injectable (General)
	Brand Name +Dosage Form + Strength	Sojana 10mg injection
	Composition	Each one ml ampule contains: Nalbuphine as Hydrochloride…….....10mg
	Diary No. Date of R& I & fee	Dy No. 14136 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900143 dated 06-03-2019.
	Pharmacological Group	Opioids, Morphinan derivatives ATC code: N02AF02
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	1ml ampule packed in unit carton containing 5 ampules; As per SRO
	Approval status of product in Reference Regulatory Authorities.	NUBAIN (10.0 mg/mL) 1 mL Ampoule Health Canada Approved

	Me-too status	Nalfy Injection 10mg/ml (1 mL Ampoule) M/s Vision Pharmaceuticals Pvt Ltd Reg. No. 081912
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Label claim in reference regulatory authority (Health Canada) is as follows: *"Each mL contains 10.0 mg nalbuphine hydrochloride"* Pre-approval change for equivalency and adjustment of weight as per salt factor and change in label claim is required in accordance with product approved by reference regulatory authority, along with full fee of registration as per S.R.O 496(I)/2023 dated 17-04-2023. • Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) alongwith Deposit slip No.153249936 and the Board was apprised of the same during the meeting.***
	Decision: Approved with following label claim: "Each mL contains 10.0 mg nalbuphine hydrochloride".	
1216.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. (DML No. 000790) Liquid Ampule Injectable (General)
	Brand Name +Dosage Form + Strength	Sojana 20mg injection
	Composition	Each one ml ampule contains: Nalbuphine as Hydrochloride…….....20mg
	Diary No. Date of R& I & fee	Dy No. 14135 dated 07-03-2019 Fee paid PKR 20,000/- vide Deposit Slip No. 1900142 dated 06-03-2019.
	Pharmacological Group	Opioids, Morphinan derivatives ATC code: N02AF02
	Type of Form	Form 5
	Finished Product Specification	Innovator's Specifications
	Pack size & Demanded Price	1ml ampule packed in unit carton containing 5 ampules; As per SRO
	Approval status of product in Reference Regulatory Authorities.	NUBAIN (20.0 mg/mL) 1 mL Ampoule Health Canada Approved
	Me-too status	Nalfy Injection 20mg/ml (1 mL Ampoule) M/s Vision Pharmaceuticals Pvt Ltd Reg. No. 081911
	GMP status	Same as above
	Remarks of the Evaluator[xxiii].	• Label claim in reference regulatory authority (Health Canada) is as follows: *"Each mL contains 20.0 mg nalbuphine hydrochloride"* Pre-approval change for equivalency and adjustment of weight as per salt factor and change in label claim is required in accordance with product approved by reference regulatory authority, along with full fee of registration as per S.R.O 496(I)/2023 dated 17-04-2023.

		• Form-5 and annexures are signed by Qualified personnel (Production Incharge and Quality Control Incharge) but not signed by applicant. • ***Later on, the firm rectified the shortcomings vide Letter No. Nil dt 02-06-2023 (Dy No. 13794 dated 02-06-2023) alongwith Deposit slip No.0479521201 and the Board was apprised of the same during the meeting.***
	Decision: Approved with following label claim: "Each mL contains: Nalbuphine hydrochloride …….20mg".	

Agenda of Deputy Director (PE&R) (Mr. Salateen Waseem Philip)

1217.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals (Pvt.) Ltd. ***(DML # 000517)*** Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	LORVIN Injection 8 mg
	Composition	Each vial contains *(lyophilized powder for reconstitution)*: Lornoxicam ……..8 mg (4mg/ml)
	Diary No. Date of R& I & fee	Dy.No 13953 dated 06-03-2019 Rs. 20,000/-
	Pharmacological Group	NSAID /Analgesic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in Manufacture specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	EMAE approved xefo injection by Nycomed UK
	Me-too status	Viltaz by M/s Wilshire
	GMP status	GMP valid up to 12-01-2025
	Remarks of the Evaluator[3].	
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Lyophilized injectable (General) section" from CLB.	
1218.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals (Pvt.) Ltd. ***(DML # 000517)*** Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	LORVIN Tablet 8 mg
	Composition	Each film coated tablet contains: Lornoxicam ……..8 mg
	Diary No. Date of R& I & fee	Dy.No 13954 dated 06-03-2019 Rs. 20,000/-
	Pharmacological Group	NSAID /Analgesic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in Manufacture specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	EMAE approved xefo tablet by Nycomed UK
	Me-too status	Viltaz by M/s Wilshire
	GMP status	GMP valid up to 12-01-2025
	Remarks of the Evaluator[3].	
	Decision: Approved with Innovator's Specifications. Registration Board further decided that registration letter will be issued after submission of applicable fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1219.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals (Pvt.) Ltd. ***(DML # 000517)*** Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	DIVIS Tablet 40mg/320mg
	Composition	Each film coated tablet contains: Dihydroartemisinin ……. 40 mg

		Piperaquine Phosphate ……. 320 mg
	Diary No. Date of R& I & fee	Dy.No 13957 dated 06-03-2019 Rs. 20,000/-
	Pharmacological Group	Antimalarial
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in Manufacture specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	For treatment of Malaria, WHO prequalified **Eurartesim** film-coated tablets manufactured at Sigma-Tau Industrie Farmaceutiche Riunite SpA,
	Me-too status	Armikin Tablet by M/s PharmEvo
	GMP status	GMP valid up to 12-01-2025
	Remarks of the Evaluator[3].	
	Decision: Approved with Innovator's Specifications. Registration Board further decided that registration letter will be issued after submission of applicable fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1220.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals (Pvt.) Ltd. ***(DML # 000517)*** Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	DIVIS Sachet 15mg/120mg
	Composition	Each Sachet contains: Dihydroartemisinin ……. 15 mg Piperaquine Phosphate ……. 120 mg
	Diary No. Date of R& I & fee	Dy.No 13958 dated 06-03-2019 Rs. 20,000/-
	Pharmacological Group	Antimalarial
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in Manufacture specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	No reference provided
	Me-too status	Diphos Sachet by M/s Genix
	GMP status	GMP valid up to 12-01-2025
	Remarks of the Evaluator[3].	• Provide Reference Regulatory authorities approval for dosage form
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
1221.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals (Pvt.) Ltd. ***(DML # 000517)*** Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Nitavin Tablet 500 mg
	Composition	Each film coated tablet contains: Nitazoxanide ……. 500 mg
	Diary No. Date of R& I & fee	Dy.No 13955 dated 06-03-2019 Rs. 20,000/-
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in Manufacture specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Alinia 500mg film coated tablet by M/s Romark, USFDA Approved.
	Me-too status	Nizonide 500mg Tablet by M/s AGP PvtLtd.Reg. No. 81101
	GMP status	GMP valid up to 12-01-2025
	Remarks of the Evaluator[3].	
	Decision: Approved with Innovator's Specifications. Registration Board further decided that registration letter will be issued after submission of applicable fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1222.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals (Pvt.) Ltd. ***(DML # 000517)*** Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Nitavin suspension 100 mg/5 ml

	Composition	Each 5 ml reconstituted suspension contains: Nitazoxanide ……. 100 mg
	Diary No. Date of R& I & fee	Dy.No 13956 dated 06-03-2019 Rs. 20,000/-
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in Manufacture specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Alinia 100mg/5ml suspension by M/s Romark, USFDA Approved.
	Me-too status	Nitazert by M/s Hilton
	GMP status	GMP valid up to 12-01-2025
	Remarks of the Evaluator[3].	
	Decision: Approved with Innovator's Specifications. Registration Board further decided that registration letter will be issued after submission of applicable fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1223.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals (Pvt.) Ltd. ***(DML # 000517)*** Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Walgan Tablet 450 mg
	Composition	Each film coated tablet contains: Valganciclovir HCl eq. to Valganciclovir ……. 450 mg
	Diary No. Date of R& I & fee	Dy.No 13948 dated 06-03-2019 Rs. 20,000/-
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved tablets by Glenmark UK
	Me-too status	Valcyte Tablets 450mg of M/s Roche (Reg. # 052253)
	GMP status	GMP valid up to 12-01-2025
	Remarks of the Evaluator[3].	
	Decision: Approved	

1224.	Name and address of manufacturer / Applicant	M/s Polyfine Chempharma ***(DML # 000216)*** 51 – Industrial Estate, Hayattabad, Peshawar.
	Brand Name +Dosage Form + Strength	PROFOX Tablet 60 mg
	Composition	Each tablet contains: Loxoprofen Sodium dihydrate 68.1 mg equivalent to Loxoprofen Sodium (as anhydrate) ……..60 mg
	Diary No. Date of R& I & fee	Dy.No 13587 dated 07-03-2019 Rs. 20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	JP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	PMDA Japan approved Loxonin® by Daiichi Sankyo
	Me-too status	Loxfen 60 mg Tablet by M/s Medisure
	GMP status	Firm submitted renewal inspection report conducted on 23-03-2023 & 26-05-2023 wherein firm is considered to be operating at **"Good"** level of cGMP guidelines.
	Remarks of the Evaluator.	
	Decision: Approved	
1225.	Name and address of manufacturer / Applicant	M/s Polyfine Chempharma ***(DML # 000216)*** 51 – Industrial Estate, Hayattabad, Peshawar.
	Brand Name +Dosage Form + Strength	RIFIN Tablet 250 mg

	Composition	Each tablet contains: Terbinafine HCl ……..250 mg
	Diary No. Date of R& I & fee	Dy.No 13586 dated 07-03-2019 Rs. 20,000/-
	Pharmacological Group	Antifungal for systemic use
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Lamisil® by Novartis
	Me-too status	Funge 250 mg Tablet by M/s Wilshire
	GMP status	Firm submitted renewal inspection report conducted on 23-03-2023 & 26-05-2023 wherein firm is considered to be operating at **"Good"** level of cGMP guidelines.
	Remarks of the Evaluator.	
	Decision: Approved	
1226.	Name and address of manufacturer / Applicant	M/s Polyfine Chempharma ***(DML # 000216)*** 51 – Industrial Estate, Hayattabad, Peshawar.
	Brand Name +Dosage Form + Strength	ETOROX Tablet 60 mg
	Composition	Each film coated tablet contains: Etoricoxib ……..60 mg
	Diary No. Date of R& I & fee	Dy.No 13582 dated 07-03-2019 Rs. 20,000/-
	Pharmacological Group	Selective COX-2 inhibitor
	Type of Form	Form 5
	Finished Product Specification	Manufacture Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	HPRA Ireland approved ARCOXIA® by of Merck Sharp & Dohme.
	Me-too status	Etoxib 60 mg Tablet by M/s Hiranis
	GMP status	Firm submitted renewal inspection report conducted on 23-03-2023 & 26-05-2023 wherein firm is considered to be operating at **"Good"** level of cGMP guidelines.
	Remarks of the Evaluator.	
	Decision: Approved with Innovator's Specifications. Registration Board further decided that registration letter will be issued after submission of applicable fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.	
1227.	Name and address of manufacturer / Applicant	M/s Polyfine Chempharma ***(DML # 000216)*** 51 – Industrial Estate, Hayattabad, Peshawar.
	Brand Name +Dosage Form + Strength	SOPROL Tablet 10mg
	Composition	Each film coated tablet contains: Bisoprolol Fumarate USP ……..10 mg
	Diary No. Date of R& I & fee	Dy.No 13583 dated 07-03-2019 Rs. 20,000/-
	Pharmacological Group	$Beta_1$-selective (cardio selective) adrenoceptor blocking agent
	Type of Form	Form 5
	Finished Product Specification	USP specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Zebeta® by Duramed Pharmaceuticals.
	Me-too status	Tablet Monitor 10mg by M/s Werrick
	GMP status	Firm submitted renewal inspection report conducted on 23-03-2023 & 26-05-2023 wherein firm is considered to be operating at **"Good"** level of cGMP guidelines.
	Remarks of the Evaluator[3].	
	Decision: Approved	

1228.	Name and address of manufacturer / Applicant	M/s Polyfine Chempharma ***(DML # 000216)*** 51 – Industrial Estate, Hayattabad, Peshawar.
	Brand Name +Dosage Form + Strength	SOPROL Tablet 5 mg
	Composition	Each film coated tablet contains: Bisoprolol Fumarate USP ……..5 mg
	Diary No. Date of R& I & fee	Dy.No 13585 dated 07-03-2019 Rs. 20,000/-
	Pharmacological Group	$Beta_1$-selective (cardio selective) adrenoceptor blocking agent
	Type of Form	Form 5
	Finished Product Specification	USP specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Zebeta® by Duramed Pharmaceuticals.
	Me-too status	Tablet Monitor 5 mg by M/s Werrick
	GMP status	Firm submitted renewal inspection report conducted on 23-03-2023 & 26-05-2023 wherein firm is considered to be operating at **"Good"** level of cGMP guidelines.
	Remarks of the Evaluator[3].	
	Decision: Approved	
1229.	Name and address of manufacturer / Applicant	M/s Polyfine Chempharma ***(DML # 000216)*** 51 – Industrial Estate, Hayattabad, Peshawar.
	Brand Name +Dosage Form + Strength	SOPROL Tablet 2.5 mg
	Composition	Each film coated tablet contains: Bisoprolol Fumarate USP ……..2.5 mg
	Diary No. Date of R& I & fee	Dy.No 13584 dated 07-03-2019 Rs. 20,000/-
	Pharmacological Group	$Beta_1$-selective (cardio selective) adrenoceptor blocking agent
	Type of Form	Form 5
	Finished Product Specification	USP specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved formulation by Accord Health .
	Me-too status	Tablet Monitor 2.5 mg by M/s Werrick
	GMP status	Firm submitted renewal inspection report conducted on 23-03-2023 & 26-05-2023 wherein firm is considered to be operating at **"Good"** level of cGMP guidelines.
	Remarks of the Evaluator[3].	
	Decision: Approved	
1230.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals Plot # 02, St # S-9, National Industrial Estate , Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	MATHO Tablet 500 mcg
	Composition	Each sugar coated tablet contains: Mecobalamin ……..500 mcg
	Diary No. Date of R& I & fee	Dy.No 15567 dated 07-03-2019 Rs. 20,000/-
	Pharmacological Group	Vitamin B12 (cyanocobalamin and analogues)
	Type of Form	Form 5
	Finished Product Specification	**Firm has claimed in Manufacture specification**
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	PMDA Japan approved Methycobal tablet
	Me-too status	Methycobal Tablet 500 mcg by M/s Hilton
	GMP status	**Latest GMP inspection report yet to be submitted**

	Remarks of the Evaluator[3].	• FPP Manufacture Specification are not acceptable, please follow Japanese Pharmacopeia's FPP specification for **Sugar Coated formulation** and submit fee of Rs. 7500/- • Please submit latest / fresh GMP inspection report which should be valid within last 03 months
	Decision: Approved with JP specifications. • **Registration letter will be issued after submission of updated GMP certificate / inspection report conducted within a period of last 3 years.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1231.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals Plot # 02, St # S-9, National Industrial Estate , Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	ARTI-M Tablet 20/120 mg
	Composition	Each tablet contains: Artemether …….20 mg Lumefantrine ……..120 mg
	Diary No. Date of R& I & fee	Dy.No 15618 dated 07-03-2019 Rs. 20,000/-
	Pharmacological Group	Antimalarial
	Type of Form	Form 5
	Finished Product Specification	**Firm has claimed in Manufacture specification**
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Coartem tablet by Novartis
	Me-too status	Arceva Tablet 20/120 by M/s Sami
	GMP status	**Latest GMP inspection report yet to be submitted**
	Remarks of the Evaluator[3].	• FPP Manufacture Specification are not acceptable, please submit & follow International Pharmacopeia's FPP specification and submit fee of Rs. 7500/- • Please submit latest / fresh GMP inspection report which should be valid within last 03 months
	Decision: Approved with International Pharmacopeia specifications. • **Registration letter will be issued after submission of updated GMP certificate / inspection report conducted within a period of last 3 years.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1232.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals Plot # 02, St # S-9, National Industrial Estate, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	DIQ Tablet 10 mg
	Composition	Each tablet contains: Domperidone maleate BP equivalent to domperidone … 10mg
	Diary No. Date of R& I & fee	Dy. No 15566 dated 07-03-2019 - Rs. 20,000/-
	Pharmacological Group	Antiemetic / Peripheral Dopamine receptor antagonist.
	Type of Form	Form 5
	Finished Product Specification	BP specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved Domperidone 10 mg tablets
	Me-too status	Domotin Tablet by M/s Benson
	GMP status	**Latest GMP inspection report yet to be submitted**
	Remarks of the Evaluator[3].	• Please submit latest / fresh GMP inspection report which should be valid within last 03 months

	Decision: Approved with BP specifications. • **Registration letter will be issued after submission of updated GMP certificate / inspection report conducted within a period of last 3 years.**	
1233.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals Plot # 02, St # S-9, National Industrial Estate, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	BRODIL Tablet 30 mg
	Composition	Each tablet contains: Ephedrine HCl … 30mg
	Diary No. Date of R& I & fee	Dy. No 15564 dated 07-03-2019 - Rs. 20,000/-
	Pharmacological Group	Bronchodilators
	Type of Form	Form 5
	Finished Product Specification	BP specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved Domperidone 10 mg tablets
	Me-too status	Domotin Tablet by M/s Benson
	GMP status	**Firm has Tablet (Psychotropic) Section however Latest GMP inspection report yet to be submitted.**
	Remarks of the Evaluator[3].	• Please submit latest / fresh GMP inspection report which should be valid within last 03 months
	Decision: Approved:	
1234.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals Plot # 02, St # S-9, National Industrial Estate , Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	ARTI-M Tablet 40/240 mg
	Composition	Each tablet contains: Artemether …….40 mg Lumefantrine ……..240 mg
	Diary No. Date of R& I & fee	Dy.No 15619 dated 07-03-2019 Rs. 20,000/-
	Pharmacological Group	Antimalarial
	Type of Form	Form 5
	Finished Product Specification	**Firm has claimed in Manufacture specification**
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Coartem tablet by Novartis
	Me-too status	Arceva Tablet 40/240 by M/s Sami
	GMP status	**Latest GMP inspection report yet to be submitted**
	Remarks of the Evaluator[3].	• FPP Manufacture Specification are not acceptable, please submit & follow **International Pharmacopeia's FPP** specification and submit fee of Rs. 7500/- • Please submit latest / fresh GMP inspection report which should be valid within last 03 months
	Decision: Approved with International Pharmacopeia specifications. • **Registration letter will be issued after submission of updated GMP certificate / inspection report conducted within a period of last 3 years.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1235.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals Plot # 02, St # S-9, National Industrial Estate , Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	KLARIQ Tablet 250 mg
	Composition	Each film coated tablet contains:

		Clarithromycin ……. 250 mg
	Diary No. Date of R& I & fee	Dy.No 15570 dated 07-03-2019 Rs. 20,000/-
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Biaxin tablet by Abbott
	Me-too status	Claramed Tablet 250mg by M/s Globals
	GMP status	**Latest GMP inspection report yet to be submitted**
	Remarks of the Evaluator[3].	• Please submit latest / fresh GMP inspection report which should be valid within last 03 months
	Decision: Approved with USP specifications. • **Registration letter will be issued after submission of updated GMP certificate / inspection report conducted within a period of last 3 years.**	
1236.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals Plot # 02, St # S-9, National Industrial Estate , Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	ARTI-M Tablet 20/120 mg
	Composition	Each tablet contains: Artemether …….80 mg Lumefantrine ……..480 mg
	Diary No. Date of R& I & fee	Dy.No 15518 dated 07-03-2019 Rs. 20,000/-
	Pharmacological Group	Antimalarial
	Type of Form	Form 5
	Finished Product Specification	**Firm has claimed in Manufacture specification**
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Coartem tablet by Novartis
	Me-too status	Arceva Tablet 80/480 by M/s Sami
	GMP status	**Latest GMP inspection report yet to be submitted**
	Remarks of the Evaluator[3].	• FPP Manufacture Specification are not acceptable, please submit & follow International Pharmacopeia's FPP specification and submit fee of Rs. 7500/- • Please submit latest / fresh GMP inspection report which should be valid within last 03 months
	Decision: Approved with International Pharmacopeia specifications. • **Registration letter will be issued after submission of updated GMP certificate / inspection report conducted within a period of last 3 years.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1237.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals Plot # 02, St # S-9, National Industrial Estate, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	KLARIQ Tablet 500 mg
	Composition	Each film coated tablet contains: Clarithromycin ……. 500 mg
	Diary No. Date of R& I & fee	Dy.No 15570 dated 07-03-2019 Rs. 20,000/-
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	USFDA approved Biaxin tablet by Abbott
	Me-too status	Claramed Tablet 500mg by M/s Globals
	GMP status	**Latest GMP inspection report yet to be submitted**
	Remarks of the Evaluator[3].	• Please submit latest / fresh GMP inspection report which should be valid within last 03 months
	Decision: Approved with USP specifications. • **Registration letter will be issued after submission of updated GMP certificate / inspection report conducted within a period of last 3 years.**	
1238.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals Plot # 02, St # S-9, National Industrial Estate , Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	AIR MAX Tablet 10 mg
	Composition	Each film coated tablet contains: Montelukast Sodium equivalent to Montelukast …. 10 mg
	Diary No. Date of R& I & fee	Dy.No 15617 dated 07-03-2019 Rs. 20,000/-
	Pharmacological Group	Leukotriene receptor antagonist
	Type of Form	Form 5
	Finished Product Specification	----------
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Singulair 10mg tablet by Merck Sharp & Dohme
	Me-too status	Montair Tablet 10mg by M/s CCL
	GMP status	**Latest GMP inspection report yet to be submitted**
	Remarks of the Evaluator[3].	• Please submit latest / fresh GMP inspection report which should be valid within last 03 months • Firm needs to clarify FPP specifications which should be from anyone of official Pharmacopeias. Please submit FPP specifications mentioning all tests along with limits, as mentioned in official monograph, along with requisite fee of Rs. 7500/-
	Decision: Approved with Pharmacopeia specifications. • **Registration letter will be issued after submission of updated GMP certificate / inspection report conducted within a period of last 3 years.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1239.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals Plot # 02, St # S-9, National Industrial Estate , Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	FODIQ Tablet 120 mg
	Composition	Each film coated tablet contains: Fexofenadine HCl ……. 120 mg
	Diary No. Date of R& I & fee	Dy.No 15580 dated 07-03-2019 Rs. 20,000/-
	Pharmacological Group	Anti-allergic / Anti Histamines
	Type of Form	Form 5
	Finished Product Specification	BP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Allerga tablet by Aventis
	Me-too status	Fexet Tablet 120 mg by M/s Getz
	GMP status	**Latest GMP inspection report yet to be submitted**

	Remarks of the Evaluator[3].	• Please submit latest / fresh GMP inspection report which should be valid within last 03 months.
	Decision **Approved with BP specifications.** • **Registration letter will be issued after submission of updated GMP certificate / inspection report conducted within a period of last 3 years.**	
1240.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals Plot # 02, St # S-9, National Industrial Estate , Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	DESET Tablet 5 mg
	Composition	Each film coated tablet contains: Desloratadine ……. 5 mg
	Diary No. Date of R& I & fee	Dy.No 15515 dated 07-03-2019 Rs. 20,000/-
	Pharmacological Group	Anti-histamines / anti-allergic
	Type of Form	Form 5
	Finished Product Specification	**Manufacture Specification**
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Clarinex tablet by Merck Sharp & Dohme
	Me-too status	Alenor Tablet 5mg by M/s Macter
	GMP status	**Latest GMP inspection report yet to be submitted**
	Remarks of the Evaluator[3].	• Please submit latest / fresh GMP inspection report which should be valid within last 03 months • FPP Manufacture Specification are not acceptable, please submit & follow one of Pharmacopeial monograph for FPP specification and submit requisite fee of Rs. 7500/-
	Decision **Approved with Pharmacopeia specifications.** • **Registration letter will be issued after submission of updated GMP certificate / inspection report conducted within a period of last 3 years.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1241.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals Plot # 02, St # S-9, National Industrial Estate , Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	PILZIDE Tablet 400 mg
	Composition	Each film coated tablet contains: Linezolid ……. 400 mg
	Diary No. Date of R& I & fee	Dy.No 15572 dated 07-03-2019 Rs. 20,000/-
	Pharmacological Group	Oxazolidinone , anti-infective
	Type of Form	Form 5
	Finished Product Specification	**Manufcature Specification**
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Zyvox tablet by Pharmacia UK
	Me-too status	Ecasil Tablet 400 mg by M/s Macter
	GMP status	**Latest GMP inspection report yet to be submitted**
	Remarks of the Evaluator[3].	• Please submit latest / fresh GMP inspection report which should be valid within last 03 months • FPP Manufacture Specification are not acceptable, please submit & follow USP NF 2023 Pharmacopeia monograph for

		FPP specification and submit along with requisite fee of Rs. 7500/-
	Decision **Approved with USP specifications.** • **Registration letter will be issued after submission of updated GMP certificate / inspection report conducted within a period of last 3 years.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	

1242.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Capozide Tablet 50/25
	Composition	Each tablet contains: Captopril …… 50 mg Hydrochlorthiazide …… 25 mg
	Diary No. Date of R& I & fee	Dy.No 15831 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Antihypertensive agent
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved formulation (ANDA 074896) EMAE approved Ecazide 50/25
	Me-too status	Capozide by M/s GSK
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: Approved.	
1243.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Daviquin Cream
	Composition	Each gram contains: Hydroquinone …… 40 mg (4% w/w)
	Diary No. Date of R& I & fee	Dy.No 15914 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Ultraviolet Blocking agent
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Corrector 4% Cream by M/s VIVIER CANADA INCORPORATED (Health Canada approved) Status of the product on the website of Health Canada is ***"Cancelled Post Market"***
	Me-too status	Cosmoquin by M/s Pacific
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	**[4/19/2022]** FDA issued warning letters to 12 companies for selling over-the-counter (OTC) skin lightening products containing hydroquinone that do not meet the requirements to be legally sold as OTC drugs. The warning letters explain that these OTC skin lightening products containing the active drug ingredient hydroquinone are unapproved drugs and are not generally recognized as safe and effective (not GRASE). FDA has received reports of serious side effects including skin rashes, facial swelling, and ochronosis (discoloration of skin) from the use of skin lightening products containing hydroquinone. FDA advises consumers not to use these

		products due to the potential harm they may cause, including ochronosis which may be permanent. Consumers should talk to their health care professional about treatment options for certain skin conditions including aged or dark spots. FDA is alerting consumers there are no FDA-approved or otherwise legally marketed OTC skin lightening products. Some manufacturers and distributors have already removed their OTC skin lightening products from the marketplace, and FDA plans to take action against those continuing to market these potentially harmful and illegal OTC products. Currently, Tri-Luma is the only FDA-approved drug containing hydroquinone. Tri-Luma is a prescription product approved for the short-term treatment of dark spots associated with moderate-to-severe melasma of the face. Tri-Luma should only be used under the supervision of a licensed health care professional. In addition to the COVID-19 response efforts, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) included important reforms that modernized the way certain OTC drugs are regulated. This reform finalized the legal status of products with certain active ingredients or other conditions that had been pending under the previous rulemaking framework, including finalizing the status of OTC skin lightening products. As a result, since enactment of the CARES Act, **OTC skin lightening products containing hydroquinone are deemed to be new drugs and are misbranded. All OTC skin lightening products require an FDA approved new drug application before they can be legally marketed.** As a result of CARES Act, effective September 23, 2020, manufacturers and distributors of OTC skin lightening products that do not have FDA approval must remove the products from the marketplace. The warning letters FDA issued today are to companies still marketing OTC skin lightening products containing hydroquinone without an FDA approved new drug application. FDA has asked the companies receiving warning letters to take prompt action to correct any violations outlined in the respective warning letters and respond to FDA within 15 days with what they have done to address any violations and prevent their recurrence. FDA is taking a comprehensive approach to protect consumers from the risks posed by skin lightening products containing hydroquinone. The agency is notifying companies that have listed these drugs with FDA, but may not actively be distributing them, of the current legal status of these drugs to prevent companies from distributing these illegal products. FDA is also adding certain skin lightening product manufacturers to an import alert to help stop their products from entering the U.S. Many of FDA's safety concerns regarding the use of hydroquinone in OTC skin lightening drug products also apply to the use of hydroquinone in cosmetic products. FDA reminds manufacturers and distributors it is their responsibility to comply with all requirements of federal law and FDA regulations, and to ensure their drugs meet federal

		standards for safety and effectiveness. Those who fail to comply with the law are subject to FDA action. The Ministry of Health and Prevention in the UAE has previously issue advice about unregistering whitening creams sold online, and explained that, **"while <u>hydroquinone is an active ingredient in therapeutic creams, very long-term use of these type of creams could lead to skin cancer</u>."**
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
1244.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Lefomid Tablet 10 mg
	Composition	Each film coated tablet contains: Leflunomide …… 10 mg
	Diary No. Date of R& I & fee	Dy.No 15872 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Anti-rheumatic
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved formulation
	Me-too status	Easy load by M/s Rotex Medica
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: Approved	
1245.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Davinorm-H Tablet
	Composition	Each film coated tablet contains: Irbesartan …… 300 mg Hydrochlorothiazide …… 25mg
	Diary No. Date of R& I & fee	Dy.No 15829 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Avalide by Sanofi-Aventis
	Me-too status	CO-APROVEI by M/s Sanofi
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: Approved.	
1246.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Sodoval Tablet 500 mg
	Composition	Each enteric coated tablet contains: Divalproex Sodium eq. to Valproic Acid …… 500 mg
	Diary No. Date of R& I & fee	Dy.No 15872 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Anti-convulsant
	Type of Form	Form 5
	Finished Product Specification	USP Specification

	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved
	Me-too status	Epival by M/s Abbott
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	• The formulations available in reference regulatory authority are, delayed release tablets. • Firm needs to submit details of ingredients for coating procedure along with list of equipment in manufacturing process to clarify whether formulation is designed for immediate release in intestine or controlled / extended release in intestine.
	Decision: **Registration Board deferred the case for submission of reply of following shortcomings:** • **The formulations available in reference regulatory authority are, delayed release tablets.** • **Firm needs to submit details of ingredients for coating procedure along with list of equipment in manufacturing process to clarify whether formulation is designed for immediate release in intestine or controlled / extended release in intestine.**	
1247.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Cozaar Tablet 100/25
	Composition	Each film coated tablet contains: Losartan Potassium …… 100 mg Hydrochlorothiazide ……..... 25mg
	Diary No. Date of R& I & fee	Dy.No 15872 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Anti-hypersensitive
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Hyzaar
	Me-too status	Xavor Forte by M/s Ferozsons
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	Brand name needs to be changed
	Decision: Approved with change of brand name.	
1248.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Davirib Capsule 200mg
	Composition	Each capsule contains: Ribavirin …… 200 mg
	Diary No. Date of R& I & fee	Dy.No 16449 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Anti-viral
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Rebetol by Merck
	Me-too status	Ribazole by M/s Getz
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: Approved	

1249.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Isotretenoin Capsule 20 mg
	Composition	Each capsule contains: Isotretenoin …… 20 mg
	Diary No. Date of R& I & fee	Dy.No 15943 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Anti-Acne
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved Accutance 20 mg soft gel capsule
	Me-too status	Acnewin by M/s wnsfield
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	• The formulations available in reference regulatory authority is in soft gel capsules while firm doesn't possess soft gel capsule manufacturing facility.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
1250.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Cardicor Tablet 10/6.25
	Composition	Each film coated tablet contains: Bisoprolol fumarate …… 10 mg Hydrochlorothiazide …… 6.25 mg
	Diary No. Date of R& I & fee	Dy.No 15827 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved
	Me-too status	Actim-H by M/s Sami
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: Approved	
1251.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Terlox Tablet 2 mg
	Composition	Each film coated tablet contains: Tolterodine Tartrate …… 2 mg
	Diary No. Date of R& I & fee	Dy.No 15855 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Urinary antispasmodic
	Type of Form	Form 5
	Finished Product Specification	Manufacture Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved Detrusitol® by Upjohn, UK.
	Me-too status	Detrusitol® by M/s Pfizer Laboratories
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024

	Remarks of the Evaluator.	
	Decision: **Approved with Innovator's specifications.** • **Registration letter will be issued after submission of updated GMP certificate / inspection report conducted within a period of last 3 years.** • **Firm shall submit 7,500/- fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1252.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Lovastin Tablet 20 mg
	Composition	Each tablet contains: Lovastatin …… 20 mg
	Diary No. Date of R& I & fee	Dy.No 15853 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Cholesterol lowering agent
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Mevacor® by Mylan.
	Me-too status	Lovastatin 20mg Tablets by M/s Zafa
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: Approved	
1253.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Finsta Tablet 5 mg
	Composition	Each film coated tablet contains: Finasteride …… 5 mg
	Diary No. Date of R& I & fee	Dy.No 15935 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Testosterone 5-alpha reductase inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Proscar® by Merck Sharp & Dohme.
	Me-too status	Proscar® by OBS.
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: Approved	
1254.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Finsta Tablet 1 mg
	Composition	Each film coated tablet contains: Finasteride …… 1 mg
	Diary No. Date of R& I & fee	Dy.No 16452 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Testosterone 5-alpha reductase inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved Propecia® by Organon, UK.

	Me-too status	Genesis 1 mg tablet by M/s Ferozsons
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: Approved	
1255.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Davinorm-H Tablet 150/12.5
	Composition	Each film coated tablet contains: Irbesartan …… 150 mg Hydrochlorothiazide …… 12.5mg
	Diary No. Date of R& I & fee	Dy.No 15830 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Avalide® by Sanofi-Aventis
	Me-too status	CO-APROVEL by M/s Sanofi
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: Approved	
1256.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Davitel Tablet 80/12.5
	Composition	Each tablet contains: Telmisartan …… 80 mg Hydrochlorothiazide …… 12.5mg
	Diary No. Date of R& I & fee	Dy.No 15826 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	EMAE approved MicardisPlus® by Boehringer Ingelheim Pharma GmbH & Co. Germany
	Me-too status	CoTasmi by M/s Getz
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: Approved	
1257.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Davilox Tablet 7.5mg
	Composition	Each tablet contains: Meloxicam …… 7.5mg
	Diary No. Date of R& I & fee	Dy.No 15875 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	NSAIDs
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Mobic® by Boehringer Ingelheim Pharmaceuticals, USA
	Me-too status	Xobic by M/s Hilton
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024

	Remarks of the Evaluator.	
	Decision: Approved	
1258.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Co-Tenidone Tablet 100/25
	Composition	Each tablet contains: Atenolol …… 100 mg Chlorthalidone …. 25mg
	Diary No. Date of R& I & fee	Dy.No 15811 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Tenoteric100® by AstraZeneca
	Me-too status	Blokium DIU by M/s Highnoon
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: Approved	
1259.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Clomain Tablet 50mg
	Composition	Each tablet contains: Clomiphene Citrate …… 50 mg
	Diary No. Date of R& I & fee	Dy.No 15951 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Urinary Antispasmodics
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Clomid® by Sanofi Aventis
	Me-too status	Femeg by M/s Global
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: Approved	
1260.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Davinorm-H Tablet 300/12.5
	Composition	Each film coated tablet contains: Irbesartan …… 300 mg Hydrochlorothiazide …… 12.5mg
	Diary No. Date of R& I & fee	Dy.No 15829 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Avalide by Sanofi-Aventis
	Me-too status	CO-APROVEL by M/s Sanofi
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	

	Decision: Approved	
1261.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Simcord Tablet 20 mg
	Composition	Each film coated tablet contains: Simvastatin……20 mg
	Diary No. Date of R& I & fee	Dy.No 16453 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Cholesterol Lowering agent
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Zocor® by MERCK SHARP & DOHME
	Me-too status	Zocor® by M/s OBS
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: Approved	
1262.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Gastrix Tablet 100 mg
	Composition	Each film coated tablet contains: Rebamipide……100 mg
	Diary No. Date of R& I & fee	Dy.No 15809 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Quinolinone derivative
	Type of Form	Form 5
	Finished Product Specification	JP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	PMDA Japan approved Mucosta® by Otsuka Japan
	Me-too status	Mucosta® by M/s Otsuka
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: Approved	
1263.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Trandate Tablet 100mg
	Composition	Each film coated tablet contains: Labetalol HCl ……100 mg
	Diary No. Date of R& I & fee	Dy.No 15835 dated 05-03-2019 Rs. 20,000/-
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Trandate® by Prometheus Laboratories
	Me-too status	Labetalol by M/s Zafa
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: Approved	
1264.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.

	Brand Name +Dosage Form + Strength	Lefomid Tablet 20 mg
	Composition	Each film coated tablet contains: Lefunomide ……20 mg
	Diary No. Date of R& I & fee	Dy.No 15933 dated 05-03-2019 Rs. 20,000/-
	Pharmacological Group	DMARD (disease-modifying anti-rheumatic drug)
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Arava® by Sanofi Aventis
	Me-too status	Ariva by M/s Bosch
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: Approved	
1265.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Isotretenoin Capsule 10 mg
	Composition	Each capsule contains: Isotretenoin …… 10 mg
	Diary No. Date of R& I & fee	Dy.No 1592 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Anti-Acne
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved Accutance 20 mg soft gel capsule
	Me-too status	Acnewin by M/s wnsfield
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	The formulations available in reference regulatory authority is in soft gel capsules while firm doesn't possess soft gel capsule manufacturing facility.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • **The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.**	
1266.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Davilox Tablet 15mg
	Composition	Each tablet contains: Meloxicam …… 15mg
	Diary No. Date of R& I & fee	Dy.No 15876 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	NSAIDs
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Mobic® by Boehringer Ingelheim Pharmaceuticals, USA
	Me-too status	Xobic by M/s Hilton
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: Approved	

1267.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Glucon Tablet 500/400
	Composition	Each tablet contains: Glucosamine Sulphate …… 500 mg Chondtroitin Sulphate …… 400 mg
	Diary No. Date of R& I & fee	Dy.No 15876 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Anti-inflammatory & anti-rheumatoid agent
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	**Regulatory status not confirmed**
	Me-too status	Cartigen plus by Getz
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision.	
1268.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Co-Tenidone Tablet 50/12.5
	Composition	Each tablet contains: Atenolol …… 50 mg Chlortalidone …. 12.5mg
	Diary No. Date of R& I & fee	Dy.No 15837 dated 05-03-2019 Rs. 20,000/-
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved Tenoret® by Atnahs Pharma UK
	Me-too status	Blokium DIU by M/s Highnoon
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: Approved	
1269.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	DavixateTablet 200 mg
	Composition	Each film coated tablet contains: Flavoxate HCl …… 200 mg
	Diary No. Date of R& I & fee	Dy.No 15936 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Antimuscarinic
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved Urispas® by Recordati Pharmaceuticals UK
	Me-too status	Genurex by M/s Cirin
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: Approved	

1270.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Innovace Tablet 10/25
	Composition	Each tablet contains: Enalapril Maleate …… 10 mg Hydrochlorothiazide …… 25 mg
	Diary No. Date of R& I & fee	Dy.No 15889 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Vaseretic® by Valeant Pharmaceuticals
	Me-too status	CoRentiec by M/s OBS
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: Approved	
1271.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Sastravi Tablet 25/100/200
	Composition	Each film coated tablet contains: Carbidopa (as monohydrate) …… 25 mg Levodopa …… 100 mg Entacapone …… 200 mg
	Diary No. Date of R& I & fee	Dy.No 15867 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Anti-Parkinson agent
	Type of Form	Form 5
	Finished Product Specification	Manufcature Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Stalevo® by Novartis
	Me-too status	ObsonERV by M/s OBS
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: Approved	
1272.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Davixonin Tablet 60mg
	Composition	Each tablet contains: Loxoprofen Sodium dihydrate 68.1 mg equivalent to Loxoprofen Sodium (as anhydrate) ……..60 mg
	Diary No. Date of R& I & fee	Dy.No 15888 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	NSAIDs
	Type of Form	Form 5
	Finished Product Specification	JP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	PMDA Japan approved Loxonin® by Daiichi Sankyo
	Me-too status	Loxfen 60 mg Tablet by M/s Medisure
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: Approved	

1273.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Davigest Tablet 10mg
	Composition	Each film coated tablet contains: Dydrogesterone …… 10 mg
	Diary No. Date of R& I & fee	Dy.No 15937 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Progesterone
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	HPRA Ireland approved Duphaston® by Abbott
	Me-too status	Duphaston Tablet 10 mg by M/s Highnoon
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: Approved	
1274.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Maloride Sachet
	Composition	Each Sachet contains: Macrogol 3350 …… 13.125 g Sodium Chloride ……. 0.3507 g Sodium Bicarbonate ….0.1785g Potassium Chloride ……0.0466 g
	Diary No. Date of R& I & fee	Dy.No 15937 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Osmotically active laxative
	Type of Form	Form 5
	Finished Product Specification	Manufacture Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	HPRA Ireland approved Macrolief® by Rowex Ltd.
	Me-too status	Movopeg Sachet by M/s wnsfield
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: **Approved with Innovator's Specifications.** • **Registration Board further decided that registration letter will be issued after submission of applicable fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1275.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Mebrine-Husk Sachet
	Composition	Each Sachet contains: Ispaghula Husk BP …… 3.5 g Mebeverine HCl BP …….. 135 mg
	Diary No. Date of R& I & fee	Dy.No 15938 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Antispasmodics/Laxatives
	Type of Form	Form 5
	Finished Product Specification	Manufacture Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved Fybogel Mebeverine® by Reckitt
	Me-too status	Colopas Fibro by M/s NabiQasim

	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: **Approved with ……. Specifications.** **Registration Board further decided that registration letter will be issued after submission of applicable fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1276.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Davistat Capsule 120mg
	Composition	Each Capsule contains: Orlistat …… 120 mg
	Diary No. Date of R& I & fee	Dy.No 16454 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Peripherally acting anti-obesity agent
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved Xenical® by Neon Healthcare UK
	Me-too status	Colopas Fibro by M/s NabiQasim
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	• **Source of pellets not provided .**
	Decision: Approved. **Firm shall submit the source of pellets in which stability studies of the pellets have been conducted at real time conditions i.e., 30°C ± 2°C/65% RH ± 5% RH alongwith quantification of degradation products throughout the stability studies / assigned shelf life along with COA, accelerated stability study data, GMP certificate of pellets manufacturer and differential fee (in case of imported pellets) before issuance of registration letter.**	
1277.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Davischoll Cream
	Composition	Each tube contains: Terbinafine (as HCl) …… 10mg/g (1% w/w)
	Diary No. Date of R& I & fee	Dy.No 15802 dated 05-03-2019 Rs. 20,000/-
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished Product Specification	JP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved Lamisil AT® by GSK
	Me-too status	Lamisil Cream by M/s Sandoz
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: Approved.	
1278.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Kanidex-NN Cream
	Composition	Each tube contains: Clobetasol (as Propionate) …… 0.5mg/g (0.05% w/w) Neomycin ……. 5mg/g (0.5% w/w) Nystatin ……. 100000 IU/g
	Diary No. Date of R& I & fee	Dy.No 15946 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Antifungal
	Type of Form	Form 5

	Finished Product Specification	Manufacture Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA approved Dermovate NN Cream ® by ChemiDex
	Me-too status	**Me too not available**
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: **Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, or else application on Form 5D along with balance fee and stability study data of three batches of drug product as per the checklist provided in 293rd meeting of Registration Board**.	
1279.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Davicling Gel
	Composition	Each gram of gel contains: Clindamycin phosphate eq to clindamycin…10mg (1% w/w) Hydrous benzoyl peroxide eq to anhydrous benzoyl peroxide …50mg (5 % w/w)
	Diary No. Date of R& I & fee	Dy.No 15947 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Anti-Acne Preparations For Topical Use
	Type of Form	Form 5
	Finished Product Specification	Manufacture Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Duac ® by stiefel
	Me-too status	Benclin Gel of M/s Sante (Pvt),
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: **Approved with Innovator's Specifications.** • **Registration Board further decided that registration letter will be issued after submission of applicable fee for revision of specifications as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021.**	
1280.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Dermolin Cream
	Composition	Each gram of gel contains: Clobetasol (as propionate) …0.5 mg (0.05% w/w)
	Diary No. Date of R& I & fee	Dy.No 15842 dated 05-03-2019 Rs. 20,000/-
	Pharmacological Group	Corticosteroids
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Temovate ® by GlaxoWelcome
	Me-too status	Dermovate Cream of M/s GSK
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	
	Decision: Approved.	
1281.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Deviscab Lotion

	Composition	Each ml contains: Permethrin …….. 50 mg
	Diary No. Date of R& I & fee	Dy.No 15944 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Anti-scabies
	Type of Form	Form 5
	Finished Product Specification	Manufacture Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved Temovate ® by GlaxoWelcome
	Me-too status	Perm of M/s Amarant
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	**Firm has cream / ointment / gel section. Lotion / external preparation section is requirement.**
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Topical Lotion section" from CLB. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision	
1282.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Ciclomine Shampoo
	Composition	Each bottle contains: Ciclopirox olamine 1.5% v/v
	Diary No. Date of R& I & fee	Dy.No 15801 dated 04-03-2019 Rs. 20,000/-
	Pharmacological Group	Anti-fungal
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Health Canada approved Stieprox ® by GSK
	Me-too status	Stieprox ® by Stiefel GSK
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	**Firm has cream / ointment / gel section.** **External preparation section is requirement.**
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Topical Lotion section" from CLB. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision	
1283.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Ragine Topical Solution
	Composition	Each ml contains: Minoxidil ……. 50 mg (5% w/v)
	Diary No. Date of R& I & fee	Dy.No 15807 dated 05-03-2019 Rs. 20,000/-
	Pharmacological Group	Hair growth stimulant (vasodilator)
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved formulation
	Me-too status	Minoxin by brookes
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	**Firm has cream / ointment / gel section.** **External preparation section is requirement.**
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Topical Lotion section" from CLB. The Board further decided that the applicant shall submit the	

	response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision	
1284.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceutical Laboratories ***(DML # 000432)*** 121, Industrial Triangle Area, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Ragine Topical Solution
	Composition	Each ml contains: Minoxidil ……. 20 mg (2% w/v)
	Diary No. Date of R& I & fee	Dy.No 15807 dated 05-03-2019 Rs. 20,000/-
	Pharmacological Group	Hair growth stimulant (vasodilator)
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved formulation
	Me-too status	Minoxin by brookes
	GMP status	Latest GMP inspection submitted and valid till 01-02-2024
	Remarks of the Evaluator.	**Firm has cream / ointment / gel section.** **External preparation section is requirement.**
	Decision: Deferred for submission of evidence of approval of required manufacturing facility of "Topical Lotion section" from CLB. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision	

Registration-I Section

Case No.01. Recommendation of Provincial Quality Control Board, Punjab Regarding Cancellation of Muscadol Tablet (R.No.067173)

Registration Brad in its 324th meeting held on 24th-26th January, 2023 considered the recommendation of PQCB, Punjab regarding cancellation of "Muscadol Tablet (Reg. No.067173)" manufactured by M/s Lisko Pakistan (Pvt) Ltd., Karachi as per following detail:

Proceedings of M-324:

Provincial Quality Control Board in its 251st meeting held on 20th October, 2022 considered the following case under section 11 of the Drugs Act, 1976 on grounds that Drug Testing Laboratory showed inability for the test/ analysis of the following sample:

S/N	DTL Letter No. & Date	Product Name & Batch No.	DTL	Manufacturer	Area DI	Memo No. & Date	Reason of FNA rom DTL
1	DPN/17350 /DTL Dated 18-03-2022	Muscadol Film Coated Tablet (Paracetamol: 450mg Orphenadrine Citrate USP: 35mg) Batch No. T-052	Lahore	Lisko	Sir Ganga Raam Hospital	0000117776 dated 03-02-2022	Due to provision of wrong method of analysis from manufacturer

In this context, it has been communicated that PQCB after deliberation and discussion decided to recommend the Drug Regulatory Authority of Pakistan (DRAP) for cancellation of registration of drug in best of public interest.

Decision of M-324:

Registration Board decided to issue show cause notice to M/s Lisko Pakistan (Pvt) Ltd., L-10/D, Block 21, Federal B Industrial Area, Karachi (DML No.000110) under Section 7 (11)(c) of the Drug Act, 1976 that why the registration of their drug product 'Muscadol Tablet (Reg.No.067173)' may not be cancelled for violation of the conditions subject to which the drug product was registered. The Board also decided to provide an opportunity of personal hearing to the management of the firm under section 42 of the Drugs Act, 1976.

In line with the above-mentioned decision, show cause notice was issued to the firm vide letter dated 26-04-2023. In this regard, response received from M/s Lisko (vide letter dated 02-05-2023), has been summarized as under:

- *"M/s Lisko Pakistan is supplying medicines to government institutes / hospitals & market of Pakistan since 1980s and whenever any testing method, COA, reference standard or any other requirements have been asked by DTLs or DRAP, we have always made sure to timely submit requirements.*
- *We supplied Muscadol tablet 450mg/35mg to Sir Ganga Ram hospital and subsequently, DTL Lahore asked us to submit analytical method via letter no# 17003 (received on 11-2-2022) to test samples of supplied batch# T-052. We submitted our reply with method of analysis and other required documents on 15-2-2022.*
- *We agree that there was **typographical mistake in heading of submitted method** in which wrong strength of Muscadol forte (650mg/50mg) tablet was mentioned instead of Muscadol plain tablet (Paracetamol 450mg and /Orphenadrine citrate 35mg). We would like to clarify that it was human error while typing heading of method of analysis. All other submitted information like product description, method of analysis and calculation were correct of Muscadol tablet 450mg/35mg.*
- *It should not be treated as inability of firm to test / analysis of the product as we have tested said product numerous time through given method as Muscadol tablet is frequently being manufactured by us.*
- *It is also to be noted that we have already shared contact No. of our Quality Control manager to concerned persons of PQCB and DTLs of Punjab in case of any query and for better communication and timely submission of requirements to avoid any delays but in this case, no one from DTL Lahore contacted us to re-submit method with correct heading and if anyone from DTL Lahore would have contacted us for re-submission, we would have immediately submitted it without any delays.*
- *We request you not to take any action against our product (Muscadol tablet 450mg/35mg) as **we apologize on our typographical mistake which was an unintentional human error and we assure you that we will be more careful in future** that we do not repeat such mistake.*
- *Our product Muscadol tablet is running product of market and we also supply same product to government institutions of Pakistan to fulfil demand of such essential medicine. If you wish us to explain our case before the registration board, kindly communicate us date and time of meeting."*

Decision: **Keeping in view the response submitted by M/s Lisko Pakistan (Pvt) Ltd., Karachi (DML No.000110) to the show cause notice issued on 26.04.2023, Registration Board decided that the firm shall be issued an advisory to remain cautious in future and avoid submission of any unverifiable information.**

Case No.02. Request of M/s Abbott Laboratories (Pakistan) Limited, Karachi for Discontinuation of Manufacturing of Oral Drug Products

M/s Abbott Laboratories (Pakistan) Limited, Opposite Radio Pakistan Transmission Centre, Hyderabad Road, Landhi Karachi (DML No. 000001) vide their letter dated 24-01-2023 requested for discontinuation of manufacturing of following registered oral drug products due to commercial non-viability. Detail is as under:

Sr.No.	Reg.No.	Product Name	Reason for Discontinuation
1.	008160	Theograd Tablet 350mg (Theophylline)	Various alternative therapeutic molecules for bronchodilation like Doxofylline used in asthma, chronic bronchitis and emphysema are already available in the market with better efficacy
2.	000042	Cecon Oral Drops (Vitamin C) 10ml	Various alternative therapeutic molecules in the segment of this dietary vitamins supplement are available for infants and children in the market.
3.	007279	Cofcol Tablet	Various alternative therapeutic molecules in the segment of this Cold, flu and cough relieve preparations are available in the market.
4.	025526	Neophage Tablet (Metformin HCl) 500mg	Various alternative brands that are use with diet to lower high blood sugar levels in patients with type 2 diabetes are available in the market
5.	025527	Neophage Tablet (Metformin HCl) 850mg	

The firm also stated that there is no possibility of any shortage or lack of availability for these established molecules to the patients and public at large. Furthermore, the firm will also look into the possibilities to file hardship in DRAP for the said products soon.

Vide letter dated 02-03-2023, the firm was directed to comply with the following conditions of registration under Rule 30 of Drugs (L, R & A) Rules, 1976 and to ensure regular and adequate supply of above-mentioned products to avoid shortage in the market.

i. **Every drug shall be produced in sufficient quantity so as to ensure its regular and adequate supply in the market.**
ii. **The manufacturing of any drug shall not without the prior approval of the Registration Board, be discontinued for a period which may result in its shortage.**

The firm (vide letter dated 07-03-2023) has responded as under:

- Through our application dated 24th January 2023, we had applied for the approval from Registration Board, to discontinue the drugs.
- The second clause stated in your letter is incompletely stated. The complete clause of (L, R & A) Rule 30(5) states: *"The manufacture of any drug shall not without prior approval of the Registration Board, be discontinued for a period which may result in its shortage.* ***Provided that in the circumstances beyond the control of manufacturer of a drug which may lead to reduction in the production of that drug, the circumstances may be intimated to the Registration Board****."*
- We have already highlighted the reasons in our letter that are beyond our control and forcing us for the discontinuation of above-mentioned drugs. The reasons are reiterated again for consideration of our application:
  i. All products are having negative margin and hence commercially non-viable to continue production.
  ii. Better and new advanced formulations are now registered and available in the market, due to which patronage by the physicians has reduced to greater extent, resulting in commercially non-viability of the products.
  iii. The matter of hardship case of Cofcol Tablets is pending for many years and has been under discussion in many DRB meetings and recently discussed in 323rd DRB meeting held on December 6-8, 2022, as ***"Case No. 13. Concerns of Health Task Force, M/o National Health Services Regulations & Coordination, Page #. 2381 2386"***. Since relief in hardship application has not yet been granted which has resulted to discontinue the production due to commercially non-viability of the product.

The firm has again requested to consider their application on urgent basis and grant approval at earliest as there is no possibility of marketing these products.

With respect to the case considered by the Board in its 323rd meeting (as referred above by the applicant), it is informed that the Board decided to ***refer the product to Pakistan Chest Society for evaluation of therapeutic value with respect to the quality, safety and efficacy of cough and cold preparations.***

Decision: **Registration Board deliberated that in line with the conditions of registration described under Rule 30(4) and 30(5) of L.R.A Rules, 1976, availability of a registered drug product is responsibility of registration holder. Furthermore, requests for de-registration/ discontinuation/ withdrawal of registered therapeutic goods on grounds of commercial non-viability due to negative profit margin raise serious concern regarding fate of other registrations granted to these manufacturers/ registration holders.**

Accordingly, keeping in view that such cases raise concerns of availability due to pricing issues, Registration Board decided to refer the case to DRAP's Authority for seeking guidance regarding disposal thereof.

Case No.3. **Request for Change in Registration Status of Products from M/s Getz Pharma Pvt. Ltd Plot No. 29-30, Sector 27, Korangi Industrial Area Karachi to M/s. Getz Pharma Pvt. Ltd Plot No. 01, Sector 25, Korangi Industrial Area Karachi.**

M/s. Getz Pharma Pvt. Ltd Plot No. 01, Sector 25, Korangi Industrial Area Karachi (DML No.000933) has requested for change in registration status of below mentioned products from M/s. Getz Pharma Pvt. Ltd Plot No. 29-30, Sector 27, Korangi Industrial Area Karachi (DML No.000284) to their name.

Detail is as under:

Administrative Documents Submitted in the light of SOP approved by the Registration Board in its 283rd meeting
Copy of registration letter and last renewal status.
Copy of DML of M/s. Getz Pharma Pvt. Ltd Plot No. 01, Sector 25, Korangi Industrial Area Karachi (Manufacturer) issued on 25-05-2021(DML No.000933)
Copy of approved sections by Central Licensing Board of M/s. Getz Pharma Pvt. Ltd Plot No. 01, Sector 25, Korangi Industrial Area Karachi confirming "Tablet (general)" section.
Copy of GMP certificate of M/s. Getz Pharma Pvt. Ltd Plot No. 01, Sector 25, Korangi Industrial Area Karachi based on evaluation conducted on 17-11-2021.
NOC dated 29-05-2023 from M/s. Getz Pharma Pvt. Ltd Plot No. 29-30, Sector 27, Korangi Industrial Area Karachi for transfer of products in the name of M/s. Getz Pharma Pvt. Ltd Plot No. 01, Sector 25, Korangi Industrial Area Karachi.
Request dated 29-05-2023 from M/s. Getz Pharma Pvt. Ltd Plot No. 29-30, Sector 27, Korangi Industrial Area Karachi for withdrawal/ cancellation of registration.
Application with Form-5F and required fee as per relevant SRO.
Relevant undertakings & commitments.
Firm has also submitted comparative batch manufacturing record, method transfer / method verification studies of drug substance to new site.

Detail of submitted documents/ remarks of evaluators have been mentioned as under:

Evaluator: Mst. Urooj Fatima (DD-QMS)

I	II	III	IV
S.No.	**Reg. No.**	**Existing Product Name & Composition**	**Registration Trail**

1.	103093	Diampa-M Tablet 5mg + 850mg Each film coated tablet contains: Empagliflozin……5mg Metformin Hydrochloride…..850mg (As per Innovator's Specifications)	Initial Reg. Date: **21-05-2020** Renewal not due yet.
	Name, address of Applicant / Marketing Authorization Holder		M/s. Getz Pharma Pvt. Ltd Plot No. 01, Sector 25, Korangi Industrial Area Karachi **DML # 000933**
	Name, address of Manufacturing site.		M/s. Getz Pharma Pvt. Ltd Plot No. 01, Sector 25, Korangi Industrial Area Karachi **DML # 000933**
	Status of the applicant		☒**Manufacturer** ☐ Importer ☐Is involved in none of the above (contract giver)
	GMP status of the firm		Copy of GMP inspection report of M/s. Getz Pharma Pvt. Ltd Plot No. 01, Sector 25, Korangi Industrial Area Karachi conducted on 17-11-2021 with recommendations for grant of GMP certificate to the firm.
	Evidence of approval of manufacturing facility		Applicant has provided copy of approved sections by Central Licensing Board confirming "Tablet (general)" section.
	Status of application		☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product		☐Domestic sale ☐ Export sale ☒Domestic and Export sales
	Dy. No. and date of submission		Dy.No.35008 (R&I) dated 02-12-2022
	Details of fee submitted		**For transfer of registration:** PKR. 30,000/- DS# 30658327631 dated 03-11-2022
	The proposed proprietary name / brand name		Diampa-M Tablet 5mg + 850mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		Diampa-M Tablet 5mg + 850mg Each film coated tablet contains: Empagliflozin……5mg Metformin Hydrochloride…..850mg
	Pharmaceutical form of applied drug		Cream coloured, oblong shaped, biconvex film coated tablet, plain on both sides.
	Pharmacotherapeutic Group of (API)		Combination of oral blood glucose lowering drugs (Anti-diabetic)
	Reference to Finished product specifications		Manufacturers Specifications
	Proposed Pack size		7's, 10's, 14's, 20's, 28's
	Proposed unit price		Rs.322.06/-, Rs.460.32/-, Rs.645.74/-, Rs.922.26/-, Rs.1265.47/-

	The status in reference regulatory authorities	Jardiamet 5mg/850mg, Boehringer Ingelheim (TGA Australia)
	For generic drugs (me-too status)	Diampa-M of M/s Getz Pharma.
	Name and address of API manufacturer.	**Empagliflozin:** M/s Jiangsu Yongan Pharmaceutical Co., Ltd. No. 18, 237 provincial highway, Jiangsu Huai'an Economic Development Zone, Jiangsu, China. DML Issued by: Jiangsu Drug Administration Valid till 06-12-2025 **Metformin HCl:** M/s Shouguang Fukang Pharmaceutical Co., Ltd., North-East of Dong waihuan Road Dongcheng Industrial Area, Shouguang City, Shandong Province GMP certificate Issued by: Shandong Food and Drug Administration valid till 12-03-2024.
	1.5.11-Proposed Label	Specimen of proposed label (secondary + primary) provided which are in accordance with the Drug (Labelling & Packing) Rules, 1986.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information of **Empagliflozin**, related structure, solubilities, and other general properties, manufacturing site, character elucidation, impurities characterizations, specifications based on In-house specifications, analytical procedures and its validation, batch analysis, reference standard, container closure and stability studies summaries of Empagliflozin. Firm has summarized information of **Metformin Hydrochloride**, related structure, solubilities, and other general properties, manufacturing site, character elucidation, impurities characterizations, specifications based on USP, analytical procedures and its validation, batch analysis, reference standard, container closure and stability studies summaries of Metformin Hydrochloride. Similarly, information summaries for drug product (Diampa-M) including its description, composition, pharmaceutical development, justification for selection of manufacturing process and in-process controls, analytical procedure and its verification, batch analysis and specification, reference standard, container closure system and stability studies has been provided.
	Module-III Drug Substance:	Firm has submitted data for drug substances (Empagliflozin and Metformin HCl) related to nomenclature, structure, general properties, solubilities, character elucidation, physical form, manufacturer, a brief on manufacturing process, polymorphism, structure elucidation, impurities, specifications, analytical method, its validation, analytical method verification performed by DP manufacturer, certificate of analysis, impurity profiling of all listed impurities of Empagliflozin and Metformin HCl, specifications (in-house for Empagliflozin and USP for Metformin HCl), analytical procedures, batch analysis, reference standard and its CoA, container closure system, specification and stability studies with study protocol.
	Stability Studies of Drug Substance (Conditions & duration of Stability	**Empagliflozin**: Firm has submitted stability study data of 3 batches of drug substance (Empagliflozin) at both

<table>
<tr><td></td><td>studies)</td><td>accelerated as well as real time conditions. The accelerated stability data was conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months and the long-term stability data was conducted at 30ºC ± 2ºC / 65% ± 5% RH for 24 months. DS was packed in polyethylene bag. The DS remained within specified limits as tested on defined intervals.

Metformin Hydrochloride: Firm has submitted stability study data of 3 batches of drug substance (Metformin HCl) at both accelerated as well as real time conditions. The accelerated stability data was conducted at 40ºC ± 2ºC / 75% ± 5% RH for 6 months and the long-term stability data was conducted at 30ºC ± 2ºC / 75% ± 5% RH for 60 months. DS was packed in double layered LDPE bags and packaged again in paperboard drums. The DS remained within specified limits as tested on defined intervals.</td></tr>
<tr><td></td><td>Module-III Drug Product:</td><td>Firm has submitted data of drug product including its composition, manufacturing process and process control, manufacturing process validation protocol, excipients testing methods, pharmaceutical equivalence, specifications, analytical procedures and its validation, dissolution method verification, batch analysis, justification of specifications, specification procedure for organic impurities, reference standard or materials, container closure system and stability. The Specifications and control tests comply to innovators' specifications.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical equivalence was performed against Jardiamet tablet of Boehringer Ingelheim, Newzealand, which shows comparable results within specified limits.
The comparative dissolution profile was performed for Diampa-M 5+850mg Tablet against the Jardiamet tablet of Boehringer Ingelheim, Newzealand. Comparison was performed using 12 samples at pH 1.2, pH 4.5 and pH 6.8 for 60 mins.

Calculation of value for <u>Empagliflozin</u> is as under:
<table>
<tr><th>Media</th><th>Time interval</th><th>Jardiamet Tab (%)</th><th>Diampa-M Tab (%)</th></tr>
<tr><td rowspan="8">Acidic buffer (pH 1.2)</td><td>5 min</td><td>48.59</td><td>50.71</td></tr>
<tr><td>10 min</td><td>83.59</td><td>87.83</td></tr>
<tr><td>15 min</td><td>96.79</td><td>98.86</td></tr>
<tr><td>20 min</td><td>99.88</td><td>99.42</td></tr>
<tr><td>30 min</td><td>99.92</td><td>99.83</td></tr>
<tr><td>45 min</td><td>100.05</td><td>99.58</td></tr>
<tr><td>60 min</td><td>100.16</td><td>99.87</td></tr>
<tr><td colspan="3"></td></tr>
<tr><td rowspan="8">Acetate buffer (pH 4.5)</td><td>5 min</td><td>42.67</td><td>61.38</td></tr>
<tr><td>10 min</td><td>80.36</td><td>92.81</td></tr>
<tr><td>15 min</td><td>97.89</td><td>98.60</td></tr>
<tr><td>20 min</td><td>99.58</td><td>98.71</td></tr>
<tr><td>30 min</td><td>99.78</td><td>98.99</td></tr>
<tr><td>45 min</td><td>100.25</td><td>99.25</td></tr>
<tr><td>60 min</td><td>100.85</td><td>99.47</td></tr>
</table>
</td></tr>
</table>

Phosphate Buffer (pH 6.8)	5 min	46.77	52.80
	10 min	79.58	88.36
	15 min	96.78	97.76
	20 min	97.12	97.98
	30 min	98.99	98.16
	45 min	100.36	98.78
	60 min	100.85	99.57

f1 and f2 value has not been calculated because both reference and test sample achieved 85% dissolution within 15 minutes, hence, comparative profile is considered similar.

Calculation of value for **Metformin HCl** is as under:

Media	Time interval	Jardiamet Tab (%)	Diampa-M Tab (%)
Acidic buffer (pH 1.2)	5 min	61.89	52.34
	10 min	91.21	88.16
	15 min	92.85	91.51
	20 min	99.20	95.69
	30 min	99.71	96.76
	45 min	99.83	98.41
	60 min	100.36	99.79
Acetate buffer (pH 4.5)	5 min	62.15	45.26
	10 min	92.36	76.34
	15 min	99.14	95.14
	20 min	99.76	95.97
	30 min	100.10	99.78
	45 min	100.36	101.28
	60 min	100.89	103.44
Phosphate Buffer (pH 6.8)	5 min	59.65	43.31
	10 min	89.74	73.23
	15 min	99.47	93.30
	20 min	100.15	95.08
	30 min	100.35	97.94
	45 min	100.58	99.05
	60 min	100.74	100.15

f1 and f2 value has not been calculated because both reference and test sample achieved 85% dissolution within 15 minutes, hence, comparative profile is considered similar.

Firm has also submitted comparative dissolution results of product manufactured at current manufacturing site and newly proposed manufacturing sites. The dissolution results of Empagliflozin and Metformin shows that comparative profile is similar.

Analytical method validation/verification of product	Firm has claimed In-house specifications for which report of validation of analytical method for the drug product has been provided**.** Assay method and dissolution method validation

		protocol and study reports were also provided.

STABILITY STUDY DATA			
Manufacturer of API	**Empagliflozin:** M/s Jiangsu Yongan Pharmaceutical Co., Ltd. No. 18, 237 provincial highway, Jiangsu Huai'an Economic Development Zone, Jiangsu, China. **Metformin HCl:** M/s Shouguang Fukang Pharmaceutical Co., Ltd., North-East of Dong waihuan Road Dongcheng Industrial Area, Shouguang City, Shandong Province		
API Lot No.	**Empagliflozin:** Vendor Batch No: 20211019 Getz Batch No: 0000197643 **Metformin HCl:** Vendor Batch No: A-32612201096 Getz Batch No: 0000203971		
Description of Pack (Container closure system)	Alu/Alu blister of 7's, 10's, 14's, 20's and 28's in secondary carton		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, (Months) (Continued for 24 months)		
Batch No.	055ES01	055ES02	
Batch Size	10,000 Tablets	10,000 Tablets	
Manufacturing Date	28-06-2022	28-06-2022	
Date of Initiation	04-07-2022	04-07-2022	
No. of Batches	02		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Last panel inspection was conducted for Emclide (Empagliflozin + Linagliptin) 10+5 mg tablets on 02-12-2021. The said panel inspection report was discussed in 316th meeting of Registartion Board held on 15th - 18th March, 2022 and the Board decided to approve the product.
2.	Approval of API/DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copies of DML for: **Empagliflozin:** M/s Jiangsu Yongan Pharmaceutical Co., Ltd. No. 18, 237 provincial highway, Jiangsu Huai'an Economic Development Zone, Jiangsu, China. DML Issued by: Jiangsu Drug Administration Valid till 06-12-2025. A GMP certificate dated 25-05-2020 was also provided which certifies that manufacturing is carried out according to current Chinese GMP requirements. **Metformin HCl:** M/s Shouguang Fukang Pharmaceutical Co., Ltd., North-East of Dong waihuan

		Road Dongcheng Industrial Area, Shouguang City, Shandong Province GMP certificate Issued by: Shandong Food and Drug Administration valid till 12-03-2024 certifying that manufacturer is complying to current Chinese GMP requirements.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of commercial invoice from Jiangxi Cavir Apollo Pharma Co., Ltd., China for import of Empagliflozin manufactured by M/s Jiangsu Yongan Pharmaceutical Co., ltd. China (invoice dated 26-11-2021, cleared 01-12-2021 from DRAP, Karachi). **Metformin HCl:** Firm has submitted copy of commercial invoices from M/s JCTECH Pharma Ltd., China for the import of Metformin HCl manufactured by M/s Shouguang Fukang Pharmaceutical Co., Ltd., (invoice dated 14-02-2022, cleared 22-03-2022 from DRAP, Karachi).
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail of stability batches.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Remarks OF Evaluator:

The drug substances for Diampa-M 5+850mg Tablet (Empagliflozin & Metformin HCl) are manufactured by:
Empagliflozin: M/s Jiangsu Yongan Pharmaceutical Co., Ltd. No. 18, 237 provincial highway, Jiangsu Huai'an Economic Development Zone, Jiangsu, China.
Metformin HCl: M/s Shouguang Fukang Pharmaceutical Co., Ltd., North-East of Dong waihuan Road Dongcheng Industrial Area, Shouguang City, Shandong Province.
The impurity profiling of DS is also carried out for listed impurities. Manufacturing and controls, comparability protocols, structural characterization, and stability protocol has been submitted. Specification for Empagliflozin and Metformin HCl are in-house and USP, respectively. Finished Pharmaceutical Product (FPP) manufacturer has also performed analysis of Drug Substance (DS) according to aforementioned specifications.

The drug product is film coated tablet of 5+850mg manufactured by M/s. Getz Pharma Pvt. Ltd Plot No. 01, Sector 25, Korangi Industrial Area Karachi (DML# 000933) (Formulation) (Cream coloured, oblong shaped, biconvex film coated tablet, plain on both sides). The method of manufacturing is wet granulation and film coating with adequate process controls at critical points. Submitted regulatory specifications are as per innovator's and submitted stability data shows no degradation product at specified time points.

M/s. Getz Pharma Pvt. Ltd Plot No. 01, Sector 25, Korangi Industrial Area Karachi (DML# 000933) is a GMP complaint unit as per GMP inspection conducted on 17-11-2021 with recommendations for grant of GMP certificate to the firm.

Diampa-M 5+850mg Tablet's pharmaceutical equivalence has been established against the **Jardiamet tablet of Boehringer Ingelheim, Newzealand**, which shows comparable results within specified limits. Comparative dissolution profile was conducted against the **Jardiamet tablet of Boehringer Ingelheim, Newzealand**. The clinical particulars and pharmacological properties of the Diampa-M, based on the reliance principle, are as per the reference regulatory authority's product. This product is indicated for the treatment of adults with type-II diabetes mellitus as an adjunct to diet and exercise.

Conclusion:

The applicant shall maintain consistency in clinical particulars and pharmacological properties with the current version of the reference medicinal product as approved by reference regulatory authority and this information shall be updated regularly when the new information becomes available for reference medical product in accordance with the post registration variation procedures.
The firm shall also ensure black boxed information "Life-threatening lactic acidosis can occur due to accumulation of metformin. Risk factors include renal impairment, old age and the use of high doses of metformin above 2000 mg per day" in the beginning of the leaflet.

Application is complete as per SOP/ guidelines. Accordingly, the case is recommended for consideration of Registration Board.

Evaluator: Mr. Salateen Waseem Philips (DD-PR)

I	II	III	IV
S.No.	**Reg. No.**	**Existing Product Name & Composition**	**Registration Trail**
1.	029434	Fexet Tablet 60mg Each tablet contains: Fexofenadine……60mg	**Initial Registration:** 14-12-2002 **Last Renewal Submission Date**: 11-11-2022 with Fee of Rs.15000/- Remarks of RRR Section: Renewal application submitted within time.
	Name of the Applicant /Market Authorization Holder		M/s Getz Pharma (Pvt) Ltd **(DML # 000933)** Plot # 01, Sector 25, Korangi Industrial Area, Karachi
	Name, address of Manufacturing site.		M/s Getz Pharma (Pvt) Ltd **(DML # 000933)** Plot # 01, Sector 25, Korangi Industrial Area, Karachi
	Status of the applicant		☒ **Manufacturer** ☐ Importer ☐Is involved in none of the above (contract giver)
	Status of application		☐ New Drug Product (NDP) ☒ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product		☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Dy. No. and date of submission		Dy. No. 10620 (dated: 26-03-2023)
	Details of fee submitted		PKR 30,000/-: dated: 03-11-2022 (Invoice # 607780278188)
	The proposed proprietary name / brand name		**Tablet FEXET 60 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		Each film coated tablet contains: Fexofenadine HCl BP……. 60 mg
	Pharmaceutical form of applied drug		Film coated Tablet
	Pharmacotherapeutic Group of (API)		Other antihistamines for systemic use
	Reference to Finished product specifications		BP Specification
	Proposed Pack size		20's & 30's
	Proposed unit price		MRPs: 320.85/- (20s) & 481.27/- (30s)
	The status in reference regulatory authorities		*USFDA approved* **ALLERGA®** a trademark of Sanofi
	For generic drugs (me-too status)		**Telfast tablet 60mg** by M/s Sanofi.

	GMP status of the Finished product manufacturer	Routine GMP inspection conducted on 12-01-2023 and cGMP compliance level rated as **"Good"**
	Name and address of API manufacturer.	Source of API is same for drug product manufacturer at **existing facility as well as proposed facility** IND-SWIFT LABORATORIES LIMITED Village Bhagwanpur, Barwala Road, Derabassi, District – S.A.S. Nagar (Mohali), Punjab, INDIA **GMP valid till 05-12-2024**
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**Stability study conditions**: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**DML # 000284 (Formulation)** *existing facility* The firm has submitted results of pharmaceutical equivalence for all the quality tests for their product as per specification and comparative study against the **comparator product i.e. Telfast Tablets 60mg by M/s Sanofi** by performing quality tests (appearance, identification, average weight, Disintegration Dissolution, Assay). **DML # 000933 (Formulation)** *New Facility* The firm has submitted results of pharmaceutical equivalence for all the quality tests for their product as per specification and comparative study against the **comparator product i.e. Fexet Tablets 60mg by M/s Getz DML # 000284** by performing quality tests (appearance, identification, average weight, Disintegration Dissolution, Assay).
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including

		system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.		
STABILITY STUDY DATA *(at existing facility)* Plot # 29-30, Sector 27, Korangi Industrial Area, Karachi **DML # 000284 (Formulation)**				
Manufacturer of API		**Fexofenadine HCl BP** IND-SWIFT LABORATORIES LIMITED Village Bhagwanpur, Barwala Road, Derabassi, District – S.A.S. Nagar (Mohali), Punjab, INDIA		
API LOT #		00000121864 , 0000121865		
Description of Pack (Container closure system)		60mg, white, oblong shaped, film coated tablet, engraved "GETZ' on one side and plain on other side, packed in ALU-ALU blister, further packed in carton along with the package insert.		
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 0,3,6 months (Data submitted for 06 months)		
Frequency		Real Time: 0, 3, 6, 9, 12, 18, 24 & 36 (Months)		
Batch No.		**166F04**	**191F04**	**205F04**
Batch Size		1600000 tablets	1600000 tablets	1600000 Tablets
Manufacturing Date		12/2016	08/2018	08/2019
Date of Initiation		16/01/2017	26/11/2018	25/09/2019
No. of Batches		03		
STABILITY STUDY DATA *(at new facility)* Plot # 01, Sector 25, Korangi Industrial Area, Karachi **DML # 000933 (Formulation)**				
Manufacturer of API		**Fexofenadine HCl BP** IND-SWIFT LABORATORIES LIMITED Village Bhagwanpur, Barwala Road, Derabassi, District – S.A.S. Nagar (Mohali), Punjab, INDIA		
API LOT #		7270222027		
Description of Pack (Container closure system)		60mg, white, oblong shaped, film coated tablet, engraved "GETZ' on one side and plain on other side, packed in ALU-ALU blister, further packed in carton along with the package insert.		
Stability Storage Condition		Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Accelerated: 0,3,6 months Real time: 0,3,6 months (Data submitted for 06 months)		
Frequency		Accelerated: 0,3,6 months Real Time: 0, 3, 6, 9, 12, 18, 24 & 36 (Months)		
Batch No.		**065ES01**	**065ES02**	
Batch Size		10,000 tablets	10,000 tablets	
Manufacturing Date		07/2022	07/2022	
Date of Initiation		26/07/2022	26/07/2022	
No. of Batches		02		
Administrative Portion				
49.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable		

50.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	provided	
51.	Documents for the procurement of API with approval from DRAP (in case of import).	**Existing unit**	Invoice # 9100013442 dated 11/07/2016
		New Unit	E-939512113247 dated 23-04-2022
52.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.	
53.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted	
54.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.	

Remarks of the Evaluator:

Fexet® is already a registered brand of M/s Getz Pharma (Pvt.) Ltd, since 14-12-2002 with **DRAP's Registration No. 029434** at their manufacturing facility with **DML # 000284 (Formulation)** for the manufacturing site located at Plot # 29 – 30, Sector 27, Korangi Industrial Area.

M/s Getz Pharma (Pvt) Ltd has recently established another manufacturing facility with **DML # 000933 (Formulation)** for the manufacturing site located at Plot # 01, Sector 25, Korangi Industrial Area, Karachi.

Firm has now applied for **Replacement** of the manufacturing site of their registered brand **Fexet®**	
From	**To**
DML # 000284 (Formulation) Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi	**DML # 000933 (Formulation)** Plot # 01, Sector 25, Korangi Industrial Area, Karachi.

Comparison of Batch analysis reports

Test	Proposed Specification	New Site		Previous Site		
		065ES01	065ES02	266F04	267F04	268F04
Appearance	White oblong shaped, film coated tablet, engraved 'GETZ' on one side and plain on other side.	Complies	Complies	Complies	Complies	Complies
Disintegration Time	NMT 30.0 minutes	2 minutes	2 minutes	5 min	4 min	4 min
Identification of Fexofendaine HCl by HPLC	The retention time of the major peak of sample solution corresponds to that of standard solution, as obtained in the assay.	Complies	Complies	Complies	Complies	Complies
Assay	(95.00 – 105.00) %	99.70%	100.20%	96.71%	99.10%	100.97%
Dissolution of Fexofenadine HCl	NLT 75.00% (Q) of the labelled amount	98.42%	97.50%	100.70%	104.51%	103.86%

Remarks of Evaluator	**Application is complete as per SOP/ guidelines. Accordingly, the case is recommended for consideration of Registration Board.**

I	II	III	IV
S.No.	**Reg. No.**	**Existing Product Name & Composition**	**Registration Trail**

3.	036059	Advant Tablet 8mg Each tablet contains: Candesartan Cilexetil……8mg	Initial Registration: 31-12-2004 Last Renewal Submission Date: 08-11-2019 with Fee of Rs.10000/- Remarks of RRR Section: Renewal application submitted within time.
	Name of the Applicant /Market Authorization Holder		M/s Getz Pharma (Pvt) Ltd **(DML # 000933)** Plot # 01, Sector 25, Korangi Industrial Area, Karachi
	Name, address of Manufacturing site.		M/s Getz Pharma (Pvt) Ltd **(DML # 000933)** Plot # 01, Sector 25, Korangi Industrial Area, Karachi
	Status of the applicant		☒ **Manufacturer** ☐ Importer ☐Is involved in none of the above (contract giver)
	Status of application		☐ New Drug Product (NDP) ☒ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product		☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Dy. No. and date of submission		Dy. No. 11392 (dated: 08-05-2023)
	Details of fee submitted		PKR 30,000/-: dated: 16-05-2022 (Invoice # 662208580)
	The proposed proprietary name / brand name		**Tablet ADVANT 8 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		Each tablet contains: Candesartan Cilexetil……. 8 mg
	Pharmaceutical form of applied drug		Tablet
	Pharmacotherapeutic Group of (API)		*Angiotensin II receptor blockers (ARBs)*
	Reference to Finished product specifications		USP Specification
	Proposed Pack size		As per SRO
	Proposed unit price		As per SRO
	The status in reference regulatory authorities		*USFDA approved* **ATACAND®** a trademark of AstraZeneca
	For generic drugs (me-too status)		**Treatan tablet 8 mg** by M/s PharmEvo.
	GMP status of the Finished product manufacturer		Routine GMP inspection conducted on 12-01-2023 and cGMP compliance level rated as **"Good"**
	Name and address of API manufacturer.		**Candesartan Celixetil BP** M/s Jiangxi Synergy Pharmacutical Co. Ltd Jiangxi Fengxin Industrial Park, Fengxin, 330700, Jiangxi Provnce, China **GMP valid till 26/11/2025**
	Module-II (Quality Overall Summary)		The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug

		substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**Stability study conditions**: Real time: 30°C ± 2°C / 65% ± 5%RH for 48 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	The firm has submitted results of pharmaceutical equivalence for all the quality tests for their product as per specification and comparative study against the **comparator product i.e. Blopress 8 mg Tablets** by **M/s Hilton** by performing quality tests (appearance, identification, average weight, Dissolution, Assay).
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA		
Manufacturer of API	**Candesartan Celixetil BP** M/s Jiangxi Synergy Pharmacutical Co. Ltd Jiangxi Fengxin Industrial Park, Fengxin, 330700, Jiangxi Provnce, China	
API LOT #	00000189105	
Description of Pack (Container closure system)	Alu-Alu Blisters packed in a printed unit carton along with the package insert.	
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Period	Real time: 06 months Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 & 36 (Months)	
Batch No.	**041ES01**	**041ES02**
Batch Size	10,000 tablets	10,000 tablets
Manufacturing Date	01/2022	01/2022
Date of Initiation	27/04/2022	27/04/2022

No. of Batches	02

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice # 21ATGZ034-1 dated 05-03-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Advant® is already a registered brand of M/s Getz Pharma (Pvt.) Ltd, since 20th October 2004 with **DRAP's Registration No. 034070** at their manufacturing facility with **DML # 000284 (Formulation)** for the manufacturing site located at Plot # 29 – 30, Sector 27, Korangi Industrial Area.

M/s Getz Pharma (Pvt) Ltd has recently established another manufacturing facility with **DML # 000933 (Formulation)** for the manufacturing site located at Plot # 01, Sector 25, Korangi Industrial Area, Karachi.

Firm has now applied for **Replacement** the manufacturing site of their registered brand **ADVANT®**	
From	**To**
DML # 000284 (Formulation) Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi	**DML # 000933 (Formulation)** Plot # 01, Sector 25, Korangi Industrial Area, Karachi.

Firm has submitted stability data of ADVANT® for both manufacturing sites as under: -

Plot # 01, Sector 25, Korangi Industrial Area, Karachi **DML # 000933 (Formulation)**			
Stability data 6th months *(at new site)* .	**Batch No.**	**041ES01**	**041ES02**
	Batch Size	10,000 tablets	10,000 tablets
	Manufacturing Date	01/2022	01/2022
	Date of Initiation	27/04/2022	27/04/2022

Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi **DML # 000284 (Formulation)**				
Stability data 36th Months *(at previous site)*	**Batch No.**	**197T01**	**221T01**	**237T01**
	Batch Size	500,000 Tablets	500,000 Tablets	2000,000 Tablets
	Manufacturing Date	04/2017	04/2018	11/2018
	Date of Initiation	17/05/2017	14/05/2018	01/01/2019

Comparison of batch analysis reports of batches manufactured in previous and new facility.

		New Site	Previous Site

Test	Proposed Specification	B. 041ES01	B. 041ES02	197T01	221T01	237T01
Appearance	Cream colored, square shaped tablet, bisect line on one side and plain on other side.	Complies	Complies	Complies	Complies	Complies
Disintegration Time	NMT 15.0 minutes	8.0 minutes	7.0 minutes	11.0 min	8.0 min	8.0 min
Average weight	134.00 mg ± 7.5%	135.2 mg	134.8 mg	134.22mg	133.96mg	130.83mg
Identification of Candesartan Cilexetil	The retention time of the major peak in the chromatogram of the assay preparation corresponds to that of the standard preparation as obtained in the Assay.	Complies	Complies	Complies	Complies	Complies
Assay of Candesartan Cliexetil	Release Limit: (95.00 – 105.00) % Shelf: 90.0 – 110.0 %	99.70%	100.20%	97.15%	96.19%	96.11%
Dissolution of Candesartan Cilexetil	NLT 75.00% (Q) of the labelled amount dissolved in 45 minutes	94.86%	92.16%	98.13%	101.10%	99.34%
Uniformity of dosage unit of Candesartan Cilexetil by content uniformity	%L1 is less than or equal to 15.0	7.4%	6.1%	3.9%	4.3%	4.1%

Firm has submitted comparative dissolution profile and pharmaceutical equivalence of **ADVANT®** as under: -

Pharmaceutical Equivalence and Comparative Dissolution Profile	
(At New Manufacturing Facility) DML # 000911	***(At Previous Manufacturing Facility)*** DML # 000284
Comparator product is the batch of same brand **Advant® 8 mg** manufactured in existing manufacturing facility with **DML # 000284 (Formulation).**	Comparator product is **Blopress® 8 mg** innovator brand.

Remarks of Evaluator	**Application is complete as per SOP/ guidelines. Accordingly, the case is recommended for consideration of Registration Board.**

I	II	III	IV
S.No.	**Reg. No.**	**Existing Product Name & Composition**	**Registration Trail**
4.	034070	Advant Tablet 16mg Each tablet contains: Candesartan Cilexetil……16mg	**Initial Registration:** 20-10-2004 **Last Renewal Granted w.e.f. 20-10-2019 to 19-10-2024.**

	Name of the Applicant /Market Authorization Holder	M/s Getz Pharma (Pvt) Ltd **(DML # 000933)** Plot # 01, Sector 25, Korangi Industrial Area, Karachi
	Name, address of Manufacturing site.	M/s Getz Pharma (Pvt) Ltd **(DML # 000933)** Plot # 01, Sector 25, Korangi Industrial Area, Karachi
	Status of the applicant	☒ **Manufacturer** ☐ Importer ☐Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Dy. No. and date of submission	Dy. No. 11393 (dated: 08-05-2023)
	Details of fee submitted	PKR 30,000/-: dated: 16-05-2022 (Invoice # 35815502941)
	The proposed proprietary name / brand name	**Tablet ADVANT 16mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Candesartan Cilexetil……. 16 mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	*Angiotensin II receptor blockers (ARBs)*
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	*USFDA approved* **ATACAND®** a trademark of AstraZeneca
	For generic drugs (me-too status)	**Treatan tablet 16mg** by M/s PharmEvo.
	GMP status of the Finished product manufacturer	Routine GMP inspection conducted on 12-01-2023 and cGMP compliance level rated as **"Good"**
	Name and address of API manufacturer.	**Candesartan Celixetil BP** M/s Jiangxi Synergy Pharmacutical Co. Ltd Jiangxi Fengxin Industrial Park, Fengxin, 330700, Jiangxi Provnce, China **GMP valid till 26/11/2025**
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical

		procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**Stability study conditions**: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 48 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	The firm has submitted results of pharmaceutical equivalence for all the quality tests for their product as per specification and comparative study against the **comparator product i.e. Blopress 16mg Tablets** by **M/s AstraZeneca** by performing quality tests (appearance, identification, average weight, Dissolution, Assay).
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA		
Manufacturer of API	**Candesartan Celixetil BP** M/s Jiangxi Synergy Pharmacutical Co. Ltd Jiangxi Fengxin Industrial Park, Fengxin, 330700, Jiangxi Provnce, China	
API LOT #	00000189105	
Description of Pack (Container closure system)	Alu-Alu Blisters packed in a printed unit carton along with the package insert.	
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH	
Time Period	Real time: 06 months Accelerated: 06 months	
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24 & 36 (Months)	
Batch No.	**042ES01**	**042ES02**
Batch Size	10,000 tablets	10,000 tablets
Manufacturing Date	01/2022	01/2022
Date of Initiation	25/01/2022	25/01/2022
No. of Batches	02	

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Invoice # 21ATGZ034-1 dated 05-03-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Advant® is already a registered brand of M/s Getz Pharma (Pvt.) Ltd, since 20th October 2004 with **DRAP's Registration No. 034070** at their manufacturing facility with **DML # 000284 (Formulation)** for the manufacturing site located at Plot # 29 – 30, Sector 27, Korangi Industrial Area.

M/s Getz Pharma (Pvt) Ltd has recently established another manufacturing facility with **DML # 000933 (Formulation)** for the manufacturing site located at Plot # 01, Sector 25, Korangi Industrial Area, Karachi.

Firm has now applied for changing the manufacturing site of their registered brand **ADVANT®**	
From	**To**
DML # 000284 (Formulation) Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi	**DML # 000933 (Formulation)** Plot # 01, Sector 25, Korangi Industrial Area, Karachi.

Firm has submitted stability data of ADVANT® for both manufacturing sites as under: -

Plot # 01, Sector 25, Korangi Industrial Area, Karachi **DML # 000933 (Formulation)**			
Stability data 0,3,6th months *(at new site)* .	**Batch No.**	**042ES01**	**042ES02**
	Batch Size	10,000 tablets	10,000 tablets
	Manufacturing Date	01/2022	01/2022
	Date of Initiation	25/01/2022	25/01/2022

Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi **DML # 000284 (Formulation)**				
Stability data 36th months *(at previous site)*	**Batch No.**	**190T02**	**221T02**	**238T02**
	Batch Size	300,000 Tablets	300,000 Tablets	300,000 Tablets
	Manufacturing Date	03/2017	03/2018	11/2018
	Date of Initiation	17/05/2017	14/05/2018	01/01/2019

Comparison of Batch analysis reports

Test	Proposed Specification	New Site		Previous Site		
		B. 042ES01	B. 042ES02	190T02	221T02	238T02
Appearance	Cream colored, square shaped tablet, bisect line on one	Complies	Complies	Complies	Complies	Complies

	side and plain on other side.					
Disintegration Time	NMT 15.0 minutes	10 minutes	6.0 minutes	8.0 min	6.0 min	7.0 min
Identification of Candesartan Cilexetil	The retention time of the major peak in the chromatogram of the assay preparation corresponds to that of the standard preparation as obtained in the Assay.	Complies	Complies	Complies	Complies	Complies
Assay of Candesartan Cliexetil	Release Limit: (95.00 – 105.00) % Shelf: 90.0 – 110.0 %	99.70%	100.20%	96.71%	99.10%	100.97%
Dissolution of Candesartan Cilexetil	NLT 75.00% (Q) of the labelled amount dissolved in 45 minutes	94.86%	92.16%	98.08%	99.46%	101.64%
Uniformity of dosage unit of Candesartan Cilexetil by content uniformity	%L1 is less than or equal to 15.0	7.4%	6.1%	3.9%	4.3%	4.1%

Firm has submitted comparative dissolution profile and pharmaceutical equivalence of **ADVANT®** as under: -

Pharmaceutical Equivalence and Comparative Dissolution Profile	
(At New Manufacturing Facility) DML # 000911	***(At Previous Manufacturing Facility)*** DML # 000284
Comparator product is the batch of same brand **Advant® 16 mg** manufactured in existing manufacturing facility with **DML # 000284 (Formulation).**	Comparator product is **Blopress® 16 mg** innovator brand.

Remarks of Evaluator	**Application is complete as per SOP/ guidelines. Accordingly, the case is recommended for consideration of Registration Board.**

Decision: Registration Board decided as under:

i. Cancelled registration of following products from the name of M/s Getz Pharma Pvt. Ltd. Plot No. 29-30, Sector 27, Korangi Industrial Area Karachi (DML No.000284):

S. No.	Reg. No.	Product Name & Composition
1.	**103093**	**Diampa-M Tablet 5mg + 850mg** **Each film coated tablet contains:** **Empagliflozin……..……..…5mg** **Metformin Hydrochloride……..…..850mg**
2.	**029434**	**Fexet Tablet 60mg** **Each tablet contains:** **Fexofenadine…….……60mg**
3.	**036059**	**Advant Tablet 8mg** **Each tablet contains:** **Candesartan Cilexetil……8mg**

4.	**034070**	**Advant Tablet 16mg** **Each tablet contains:** **Candesartan Cilexetil……16mg**

ii. Approved registration of following products in the name of M/s Getz Pharma Pvt. Ltd. Plot No. 01, Sector 25, Korangi Industrial Area Karachi (DML No.000933).

a) Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.

b) Manufacturer will perform process validation of first three batches of both products as per the commitment submitted in the registration application.

c) For product at S.No. 1 of below table, the applicant shall submit fee of Rs. 7500/- (in the light of notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021) for pre-registration variation/ change in finished product specifications from "Manufacturer's Specifications" to "As per Innovator's Specifications".

S. No.	Product Name & Composition
1.	**Diampa-M Tablet 5mg + 850mg** **Each film coated tablet contains:** **Empagliflozin……..……5mg** **Metformin Hydrochloride…….…....850mg** **(As per Innovator's Specifications)**
2.	**Fexet Tablet 60 mg** **Each film coated tablet contains:** **Fexofenadine Hydrochloride…….. 60mg** **(BP Specifications)**
3.	**Advant Tablet 8mg** **Each tablet contains:** **Candesartan Cilexetil…….8mg** **(USP Specifications)**
4.	**Advant Tablet 16mg** **Each tablet contains:** **Candesartan Cilexetil……..……16mg** **(USP Specifications)**

iii. Reference will be sent to Costing and Pricing Division for confirmation of maximum retail price (MRP).

Case No.4. Request for Change in Registration Status of Products from M/s Getz Pharma Pvt. Ltd Plot No. 29-30, Sector 27, Korangi Industrial Area Karachi to M/s. Getz Pharma Pvt. Ltd Plot No. 01, Sector 25, Korangi Industrial Area Karachi.

M/s. Getz Pharma Pvt. Ltd Plot No. 01, Sector 25, Korangi Industrial Area Karachi (DML No.000933) has requested for change in registration status of below mentioned products from M/s. Getz Pharma Pvt. Ltd Plot No. 29-30, Sector 27, Korangi Industrial Area Karachi (DML No.000284) to their name.

Detail is as under:

Administrative Documents Submitted in the light of SOP approved by the Registration Board in its 283rd meeting
Copy of registration letter and last renewal status.
Copy of DML of M/s. Getz Pharma Pvt. Ltd Plot No. 01, Sector 25, Korangi Industrial Area Karachi (Manufacturer) issued on 25-05-2021(DML No.000933)

Copy of approved sections by Central Licensing Board of M/s. Getz Pharma Pvt. Ltd Plot No. 01, Sector 25, Korangi Industrial Area Karachi confirming "Tablet (general)" section.
Copy of GMP certificate of M/s. Getz Pharma Pvt. Ltd Plot No. 01, Sector 25, Korangi Industrial Area Karachi based on evaluation conducted on 17-11-2021.
NOC dated 29-05-2023 from M/s. Getz Pharma Pvt. Ltd Plot No. 29-30, Sector 27, Korangi Industrial Area Karachi for transfer of products in the name of M/s. Getz Pharma Pvt. Ltd Plot No. 01, Sector 25, Korangi Industrial Area Karachi.
Request dated 29-05-2023 from M/s. Getz Pharma Pvt. Ltd Plot No. 29-30, Sector 27, Korangi Industrial Area Karachi for withdrawal/ cancellation of registration.
Application with Form-5F and required fee as per relevant SRO.
Relevant undertakings & commitments.
Firm has also submitted comparative batch manufacturing record, method transfer / method verification studies of drug substance to new site.

Detail of submitted documents/ remarks of evaluators have been mentioned as under:

Evaluator: Mr. Salateen Waseem Philips (DD-PR)

I	II	III	IV
S.No.	**Reg. No.**	**Existing Product Name & Composition**	**Registration Trail**
1.	029435	Fexet Tablets 120mg Each tablet contains:- Fexofenadine HCl……120mg	Initial Reg. Date: 14-12-2002 Last Renewal Submission Date: 11-11-2022 with Fee of Rs.15000/- Remarks of RRR Section: Renewal application received within time.
	Name, address of Applicant / Marketing Authorization Holder.		M/s Getz Pharma (Pvt.) Ltd. Plot No. 01, Sector 25, Korangi Industrial Area, Karachi Pakistan
	Name, address of Manufacturing site.		M/s Getz Pharma (Pvt.) Ltd. Plot No. 01, Sector 25, Korangi Industrial Area, Karachi Pakistan
	Status of the applicant		☒ **Manufacturer** ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP Status of the firm		Firm has been granted new License (DML 000933) by way of formulation dated 25-05-2021.
	Evidence of approval of manufacturing facility		Firm has been granted new License (DML 000933) by way of formulation dated 25-05-2021, with approved Tablet, Capsules & Dry Powder Suspension sections.
	Status of application		☐ New Drug Product (NDP) ☒ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product		☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Dy. No. and date of submission		Dy. No.: 32166 and 08-11-2022 & Dy. No.: 10329 dated 18-04-2023
	Details of fee submitted		PKR 30,000/-: 02-11-2022 (Invoice # 590989106)
	The proposed proprietary name / brand name		**Fexet Tablets 120mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		Each film-coated tablet contains: Fexofenadine HCl BP ……. 120mg
	Pharmaceutical form of applied drug		Film coated tablet
	Pharmacotherapeutic Group of (API)		Other antihistamines for systemic use

	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	2x10 (20's) & 3x10 (30's)
	Proposed unit price	Rs.446.42/- (20's) & Rs. 669.63/- (30's)
	The status in reference regulatory authorities	"Telfast Tablets 120mg" Approved by MHRA manufactured by Sanofi Winthrop Industrie, France
	For generic drugs (me-too status)	FEXET TABLETS 120mg (Reg. No.: 029435) manufactured by M/s Getz Pharma (Pvt.) Limited Plot No. 29 -30, Sector 27, Korangi Industrial Area, Karachi
	Name and address of API manufacturer.	IND-SWIFT LABORATORIES LIMITED Village Bhagwanpur, Barwala Road, Derabassi, District – S.A.S. Nagar (Mohali), Punjab, INDIA. **GMP valid till 05-12-2024.**
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability studies.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Getz Pharma (Pvt) Limited Plot no. 29 – 30, sector 27 Korangi Industrial Area, Karachi** Pharmaceutical Equivalence Studies & Comparative Dissolution Profile studies of Fexet Tablets 120mg against the reference product Telfast Tablets 180mg and Fexet Tablets 180mg, in three dissolution mediums has been submitted with acceptable level of f2 results. **Getz Pharma (Pvt) Limited** **Plot No. 01, Sector 25 Korangi Industrial Area, Karachi** Firm has also submitted the Comparative Dissolution Profile studies of Fexet Tablets 120mg against the reference product Telfast Tablets 120mg, in Routine Release Medium with acceptable level of f2 results.
	Analytical method validation / verification of product	Firm has submitted verification studies of the drug substance & drug product.

<table>
<tr><td></td><td>Stability studies</td><td colspan="3">Firm has submitted stability studies data of three batches at both accelerated and long term conditions from existing site and stability studies data of two batches at initial time interval (both accelerated and long term conditions) from new site.</td></tr>
<tr><td colspan="5">STABILITY STUDY DATA (Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi)</td></tr>
<tr><td colspan="2">Manufacturer of APIs</td><td colspan="3">IND-SWIFT LABORATORIES LIMITED
Located at Village Bhagwanpur, Barwala Road, Derabassi, District – S.A.S. Nagar (Mohali), Punjab, INDIA.</td></tr>
<tr><td colspan="2">API Lot No.</td><td colspan="3">F150040015, F150040016, F150040029, F150040030</td></tr>
<tr><td colspan="2">Description of Pack
(Container closure system)</td><td colspan="3">Alu-Alu blister</td></tr>
<tr><td colspan="2">Stability Storage Condition</td><td colspan="3">Real time: 30°C ± 2°C / 75% ± 5%RH
Accelerated: 40°C ± 2°C / 75% ± 5%RH</td></tr>
<tr><td colspan="2">Time Period</td><td colspan="3">Real time: 6 months
Accelerated: 36 months</td></tr>
<tr><td colspan="2">Frequency</td><td colspan="3">Accelerated: 0, 3, 6 (Months)
Real Time: 0, 3, 6, 9, 12, 18, 24, 36 (Months)</td></tr>
<tr><td colspan="2">Batch No.</td><td>120F05</td><td>121F05</td><td>122F05</td></tr>
<tr><td colspan="2">Batch Size</td><td>800,000 Tablets</td><td>800,000 Tablets</td><td>800,000 Tablets</td></tr>
<tr><td colspan="2">Manufacturing Date</td><td>26.06.2014</td><td>29.08.2014</td><td>02.09.2014</td></tr>
<tr><td colspan="2">Date of initiation</td><td>18.09.2014</td><td>31.10.2014</td><td>01.10.2014</td></tr>
<tr><td colspan="2">No. of Batches</td><td colspan="3">03</td></tr>
<tr><td colspan="5">DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA</td></tr>
<tr><td>1.</td><td>Reference of previous approval of applications with stability study data of the firm (if any)</td><td colspan="3">Firm has referred to onsite inspection report of their product Estine (Ebastine) tablets 10mg & 20mg which was conducted on 06th May, 2019 and was presented in 289th meeting of Registration Board held on 14th -16th May, 2019. According to the report following points were confirmed.
• The firm has 21 CFR compliant HPLC software
• The firm has audit trail reports available.
• The firm possesses stability chambers with digital data loggers.</td></tr>
<tr><td>2.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.</td><td colspan="3">Firm has submitted copy of GMP certificate (Certificate No. Drugs (10)Pb.2019/5348) issued by Food and Drugs Administration Punjab, India valid till November 29, 2022.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td colspan="3">Firm has submitted copy of commercial invoice attested by AD I&E DRAP, Karachi.
<table>
<tr><th>Batch No.</th><th>Invoice No.</th><th>Date of approval by DRAP</th></tr>
<tr><td>F150040015</td><td rowspan="2">9100009776</td><td rowspan="2">07-05-2014</td></tr>
<tr><td>F150040016</td></tr>
<tr><td>F150040029</td><td rowspan="2">9100009947</td><td rowspan="2">10-06-2014</td></tr>
<tr><td>F150040030</td></tr>
</table></td></tr>
<tr><td>4.</td><td>Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.</td><td colspan="3">Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.</td></tr>
<tr><td>5.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td colspan="3">Firm has submitted compliance certificate of HPLC software and audit trail reports on product testing.</td></tr>
<tr><td>6.</td><td>Record of Digital data logger for temperature & humidity monitoring of stability chambers</td><td colspan="3">Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)</td></tr>
</table>

	(real time and accelerated)			
STABILITY STUDY DATA (Plot No. 01, Sector 25 Korangi Industrial Area, Karachi)				
Manufacturer of APIs		IND-SWIFT LABORATORIES LIMITED Located at Village Bhagwanpur, Barwala Road, Derabassi, District – S.A.S. Nagar (Mohali), Punjab, INDIA.		
API Lot No.		7270221008		
Description of Pack (Container closure system)		Alu-Alu blister		
Stability Storage Condition		Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period		Real time: 0, 3 months Accelerated: 0, 3 months		
Frequency		Accelerated: 0, 3, 6 months Real Time: Initial, 3, 6, 9, 12, 18, 24, 36 months		
Batch No.		001ES01	001ES02	-
Batch Size		10,000 Tablets	10,000 Tablets	-
Manufacturing Date		25.05.2021	25.05.2021	-
Date of initiation		02.06.2021	02.06.2021	-
No. of Batches		02		
DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA				
Observations		**Reply**		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Getz Pharma (Pvt.) Limited situated at Plot No. 01, Sector 25 Korangi Industrial Area, Karachi is a new License facility hence no such inspection has been conducted.		
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (Certificate No. Drugs (10)Pb.2019/5348) issued by Food and Drugs Administration Punjab, India valid till November 29, 2022.		
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice attested by AD I&E DRAP, Karachi.		
		Batch No.	**Invoice No.**	**Date of approval by DRAP**
		7270221008	9100131157	02-03-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.		
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted compliance certificate of HPLC software and audit trail reports on product testing.		
6.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)		

Case History:

In 312th meeting of Drug Registration Board conducted on 14-16th September, 2021, the case of replacement of manufacturing site was discussed. Firm submitted stability data of **Fexet®** of 03 months only, for their newly established manufacturing facility. Meanwhile, firm decided to withdraw application to complete stability data of minimum 06 months. Accordingly, the Drug Registration Board decided as under: -

Decision of 312th meeting of DRB
Acceded to firm's request regarding withdrawal of their submitted applications for change in registration status of following products. Accordingly, below-mentioned applications for registration at M/s Getz Pharma (Pvt)

Ltd, Plot No.01, Sector 25, Korangi Industrial Area, Karachi (DML No.000933) stand disposed of and firm will continue manufacturing at M/s Getz Pharma (Pvt) Ltd, 29-30, Sector 27, Korangi Industrial Area, Karachi (DML No. 000284).

S. No.	Reg. No.	Product Name
1.	029435	Fexet Tablets 120mg Each tablet contains: - Fexofenadine HCl …… 120mg
2.	029436	Fexet Tablets 180mg Each tablet contains: - Fexofenadine HCl …… 180mg

Now firm has submitted stability data for the studies conducted on interval of 06th month for samples of the batches manufactured & placed in accelerated and real time conditions in proposed manufacturing facility, along with requisite fee of Rs. 30,000/- for replacement / change of manufacturing site.

STABILITY STUDY DATA *(06th month)* **(Plot No. 01, Sector 25 Korangi Industrial Area, Karachi)** **DML # 000933**			
Manufacturer of APIs	IND-SWIFT LABORATORIES LIMITED Located at Village – Bhagwanpur, Barwala Road, Derabassi , District – S.A.S. Nagar (Mohali), Punjab, INDIA.		
API Lot No.	7270221008		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 0, 3, 6 months Accelerated: 0, 3, 6 months		
Frequency	Accelerated: 0, 3, 6 months Real Time: Initial, 3, 6, 9, 12, 18, 24, 36 months		
Batch No.	**001ES01**	**001ES02**	**-**
Batch Size	10,000 Tablets	10,000 Tablets	-
Manufacturing Date	25.05.2021	25.05.2021	-
Date of initiation	02.06.2021	02.06.2021	-
No. of Batches	02		
Remarks of Evaluator	**Application is complete as per SOP/ guidelines. Accordingly, the case is recommended for consideration of Registration Board.**		

I	II	III	IV
S.No.	**Reg. No.**	**Existing Product Name & Composition**	**Registration Trail**
2.	029436	Fexet Tablets 180mg Each tablet contains:- Fexofenadine HCl……180mg	Initial Reg. Date: 14-12-2002 Last Renewal Submission Date: 11-11-2022 with Fee of Rs.15000/- Remarks of RRR Section: Renewal application received within time.
	Name, address of Applicant / Marketing Authorization Holder.		M/s Getz Pharma (Pvt.) Ltd. Plot No. 01, Sector 25, Korangi Industrial Area, Karachi Pakistan
	Name, address of Manufacturing site.		M/s Getz Pharma (Pvt.) Ltd. Plot No. 01, Sector 25, Korangi Industrial Area, Karachi Pakistan
	Status of the applicant		☒ **Manufacturer** ☐ Importer

		☐ Is involved in none of the above (contract giver)
	GMP Status of the firm	Firm has been granted new License (DML 000933) by way of formulation dated 25-05-2021.
	Evidence of approval of manufacturing facility	Firm has been granted new License (DML 000933) by way of formulation dated 25-05-2021, with approved Tablet, Capsules & Dry Powder Suspension sections.
	Status of application	☐ New Drug Product (NDP) **☒ Generic Drug Product (GDP)**
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale **☒ Domestic and Export sales**
	Dy. No. and date of submission	Dy. No.: 32166 and 08-11-2022 & Dy. No. 10328 dated 18-04-2023
	Details of fee submitted	PKR 30,000 dated 02-11-2022 (Invoice # 2952121963)
	The proposed proprietary name / brand name	**Fexet Tablets 180mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film-coated tablet contains: Fexofenadine HCl BP ……. 180mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Other antihistamines for systemic use
	Reference to Finished product specifications	BP Specifications
	Proposed Pack size	2x10 (20's) & 3x10 (30's)
	Proposed unit price	Rs. 607.41 & Rs. 911.12
	The status in reference regulatory authorities	"Telfast Tablets 180mg" Approved by MHRA manufactured by Sanofi Winthrop Industrie, France
	For generic drugs (me-too status)	FEXET TABLETS 180mg (Reg. No.: 029436) manufactured by M/s Getz Pharma (Pvt.) Limited Plot No. 29 -30, Sector 27, Korangi Industrial Area, Karachi
	Name and address of API manufacturer.	IND-SWIFT LABORATORIES LIMITED Located at Village Bhagwanpur, Barwala Road, Derabassi – 140507, District – S.A.S. Nagar (Mohali), Punjab, INDIA **GMP valid till 05-12-2024**
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed data for drug substance related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65 ± 5% RH for 60 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development,

		manufacture, manufacturing process and process control, process validation, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability studies.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	**Getz Pharma (Pvt) Limited Plot no. 29 – 30, sector 27 Korangi Industrial Area, Karachi** Pharmaceutical Equivalence Studies & Comparative Dissolution Profile studies of Fexet Tablets 180mg against the reference product Telfast Tablets 180, in three dissolution mediums has been submitted with acceptable level of f2 results. **Getz Pharma (Pvt) Limited Plot No. 01, Sector 25 Korangi Industrial Area, Karachi** Firm has also submitted the Comparative Dissolution Profile studies of Fexet Tablets 180mg against the reference product Telfast Tablets 180mg, in Routine Release Medium with acceptable level of f2 results.
	Analytical method validation/ verification of product	Firm has submitted verification studies of the drug substance & drug product.
	Stability studies	Firm has submitted stability studies data of three batches at both accelerated and long term conditions from existing site and stability studies data of two batches at initial time interval (both accelerated and long term conditions) from new site.

STABILITY STUDY DATA (Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi)			
Manufacturer of APIs	IND-SWIFT LABORATORIES LIMITED Village – Bhagwanpur, Barwala Road, Derabassi, District – S.A.S. Nagar (Mohali), Punjab, INDIA.		
API Lot No.	F150040014, F150040015, F150040030, F007040202, F007900033		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 48 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24, 36, 48 (Months)		
Batch No.	099F06	100F06	101F06
Batch Size	275,000 Tablets	275,000 Tablets	275,000 Tablets
Manufacturing Date	17.06.2014	23.09.2014	07.11.2014
Date of initiation	21.10.2014	06.12.2014	15.12.2014
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Firm has referred to onsite inspection report of their product Estine (Ebastine) tablets 10mg & 20mg which was conducted on 06th May, 2019 and was presented in 289th meeting of Registration Board held on 14th -16th May, 2019. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers.

2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (Certificate No. Drugs (10)Pb.2019/5348) issued by Food and Drugs Administration Punjab, India valid till November 29, 2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of commercial invoice attested by AD I&E DRAP, Karachi.

Batch No.	Invoice No.	Date of approval by DRAP
F150040014	9100009776	06-05-2014
F150040015	9100009776	06-05-2014
F150040030	9100009947	10-06-2014
F007040202	9100010377	04-09-2014
F007900033	9100010572	16-10-2014

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted compliance certificate of HPLC software and audit trail reports on product testing.
6.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

STABILITY STUDY DATA (Plot No. 01, Sector 25 Korangi Industrial Area, Karachi)

Manufacturer of APIs	IND-SWIFT LABORATORIES LIMITED Located at Village – Bhagwanpur, Barwala Road, Derabassi , District – S.A.S. Nagar (Mohali), Punjab, INDIA.		
API Lot No.	7270221008		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 0, 3 months Accelerated: 0, 3 months		
Frequency	Accelerated: 0, 3, 6 months Real Time: Initial, 3, 6, 9, 12, 18, 24, 36 months		
Batch No.	010ES01	010ES02	-
Batch Size	10,000 Tablets	10,000 Tablets	-
Manufacturing Date	25.05.2021	26.05.2021	-
Date of initiation	02.06.2021	02.06.2021	-
No. of Batches	02		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	Getz Pharma (Pvt.) Limited situated at Plot No. 01, Sector 25 Korangi Industrial Area, Karachi is a new License facility hence no such inspection has been conducted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (Certificate No. Drugs (10)Pb.2019/5348) issued by Food and Drugs Administration Punjab, India valid till November 29, 2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of invoice attested by AD I&E DRAP, Karachi.

Batch No.	Invoice No.	Date of approval by DRAP
7270221008	9100131157	02-03-2021

4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted compliance certificate of HPLC software and audit trail reports on product testing.
6.	Record of Digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature & humidity monitoring of stability chambers (real time and accelerated)

Miscellaneous Data:

The firm has submitted the following documents as per WHO TRS 981,2013 (47th report, Annex 3) and SOP for approval of post-registration variations approved in 283rd DRB meeting:

- Stability Data of 3 batches till shelf life manufactured at their existing facility located at Plot No. 29 – 30, Sector 27, Korangi Industrial Area.
- Stability Data of 2 stability batches (at initial time point) from new facility located at Plot No. 01, Sector 25, Korangi Industrial Area as per Guidance Document for Submission of Application on Form 5-F (CTD) for registration of pharmaceutical drug products for human use issued in October, 2020.
- Pharmaceutical Equivalence studies of the product with the innovator from existing manufacturing facility & also submitted Comparative Dissolution Profile against innovator from new manufacturing facility.
- Comparative batch analysis data on two batches from the new facility and comparative data on the last three batches from the existing facility.
- Executed Production document of stability batch.
- Process Validation Protocol from new site.
- Undertakings in accordance with SOP for approval of post-registration variations by DRAP.
- Analytical Method Verification studies of API & Finished product.
- Valid GMP certificate of the API manufacturer.

Remarks of Evaluator:

Shortcomings communicated	Reply by firm	Evaluation by PEC
Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / Active Pharmaceutical Ingredient manufacture.	Relevant batch analysis of Drug Substance performed by Drug Product manufacturer submitted.	Submitted.
Drug excipient compatibility studies shall be submitted since, "Lactose" has been used in addition to reference product excipients.	Firm has submitted that that Lactose has been used in formulation to increase the bulk density of powder blend. Moreover, Lactose is inert that has no added advantage on product performance. All added excipients in the formulation including Lactose are compatible with active ingredient based on the stability studies both at real time and accelerated conditions tested on stability indicating parameters and stability indicating method such as assay and related substances as per analytical testing method published in BP monograph. Hence, it is concluded that addition of Lactose in formulation has no impact on product performance and quality.	Justification for Drug-excipient compatibility studies submitted.

	Till date 298 batches of Fexet Tablets 120mg & 206 batches of Fexet Tablets 180mg have been manufactured. Moreover, annually one batch of Fexet Tablets 120mg and Fexet Tablets 180mg is put on stability at real time conditions as per WHO requirement. The results are satisfactory and no degradation and out of specification / out of trend result is reported. Therefore, performing drug excipient compatibility study will be of no significance.	
System suitability solution analysis in the Assay test is not as per BP monograph.	Firm has submitted that the test of system suitability (%RSD, tailing factor/peak symmetry and theoretical plates) is performed prior to conducting test of assay during routine batch analysis. Moreover, with regards to resolution between Fexofenadine HCl and Impurity A, the said parameter is evaluated during assay method verification and result is in compliance with BP monograph of Fexofenadine Tablets i.e. ≥ 10. Repeat testing of said parameter is not required during routine batch analysis as the chromatographic conditions including the column dimension (4.5 x 250mm, L11, 5µm), mobile phase composition, retention time window (10.0 – 13.0 minutes) are fixed and verified. Further, the brand of column used in routine testing of assay method is same as that used in verification studies. Hence, evaluating system suitability parameters such as %RSD, tailing factor/peak symmetry and theoretical plates suffice the requirements of establishing system suitability during routine batch analysis.	Justification submitted.

Case History:

In 312th meeting of Drug Registration Board conducted on 14-16th September, 2021, the case of replacement of manufacturing site was discussed. Firm submitted stability data of **Fexet®** of 03 months only, for their newly established manufacturing facility. Meanwhile, firm decided to withdraw application to complete stability data of minimum 06 months. Accordingly, the Drug Registration Board decided as under: -

Decision of 312th meeting of DRB

Acceded to firm's request regarding withdrawal of their submitted applications for change in registration status of following products. Accordingly, below-mentioned applications for registration at M/s Getz Pharma (Pvt) Ltd, Plot No.01, Sector 25, Korangi Industrial Area, Karachi (DML No.000933) stand disposed of and firm will continue manufacturing at M/s Getz Pharma (Pvt) Ltd, 29-30, Sector 27, Korangi Industrial Area, Karachi (DML No. 000284).

S. No.	Reg. No.	Product Name
1.	029435	Fexet Tablets 120mg Each tablet contains: - Fexofenadine HCl …… 120mg
2.	029436	Fexet Tablets 180mg Each tablet contains: - Fexofenadine HCl …… 180mg

Now firm has submitted stability data for the studies conducted on interval of 06th month for samples of the batches manufactured & placed in accelerated and real time conditions in proposed manufacturing facility, along with requisite fee of Rs. 30,000/- for replacement / change of manufacturing site.

STABILITY STUDY DATA *(06th month)* **(Plot No. 01, Sector 25 Korangi Industrial Area, Karachi)** **DML # 000933**			
Manufacturer of APIs	IND-SWIFT LABORATORIES LIMITED Located at Village – Bhagwanpur, Barwala Road, Derabassi , District – S.A.S. Nagar (Mohali), Punjab, INDIA.		
API Lot No.	7270221008		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real time: 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 0, 3, 6 months Accelerated: 0, 3, 6 months		
Frequency	Accelerated: 0, 3, 6 months Real Time: Initial, 3, 6, 9, 12, 18, 24, 36 months		
Batch No.	**010ES01**	**010ES02**	**-**
Batch Size	10,000 Tablets	10,000 Tablets	-
Manufacturing Date	25.05.2021	26.05.2021	-
Date of initiation	02.06.2021	02.06.2021	-
No. of Batches	02		
Remarks of Evaluator	**Application is complete as per SOP/ guidelines. Accordingly, the case is recommended for consideration of Registration Board.**		

I	**II**	**III**	**IV**
S.No.	**Reg. No.**	**Existing Product Name & Composition**	**Registration Trail**
1.	057803	Tenofo-B 300mg Tablet Each film coated tablet contains:- Tenofovir Disoproxil Fumarate……..300mg eq. to Tenofovir Disoproxil……245mg	14/07/2009 Last Renewal Submission Date: 31-05-2019 with Fee of Rs.10000/- Remarks of RRR Section: Renewal application received within time.
	Name of the Applicant /Market Authorization Holder		M/s Getz Pharma (Pvt) Ltd **(DML # 000933)** Plot # 01, Sector 25, Korangi Industrial Area, Karachi
	Name, address of Manufacturing site.		M/s Getz Pharma (Pvt) Ltd **(DML # 000933)** Plot # 01, Sector 25, Korangi Industrial Area, Karachi
	Status of the applicant		☒ **Manufacturer** ☐ Importer ☐Is involved in none of the above (contract giver)
	Status of application		☐ New Drug Product (NDP) ☒ **Generic Drug Product (GDP)**
	Intended use of pharmaceutical product		☐ Domestic sale ☐ Export sale ☒ **Domestic and Export sales**
	Dy. No. and date of submission		Dy.No.32166 (dated 08-11-2022) Dy. No. 12720 (dated: 23-05-2023)

	Details of fee submitted	PKR 30,000/-: dated: 02-11-2022 (Invoice # 949812660731)
	The proposed proprietary name / brand name	**Tablet Tenofo-B 300 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Tenofovir Disoproxil Fumarate 300 mg equivalent to Tenofovir Disoproxil ……. 245mg
	Pharmaceutical form of applied drug	Film coated Tablet
	Pharmacotherapeutic Group of (API)	Nucleoside Reverse Transcriptase Inhibitors(NRTIS)
	Reference to Finished product specifications	Intl. Ph. Specification
	Proposed Pack size	30's
	Proposed unit price	MRPs: 5397.03/-
	The status in reference regulatory authorities	*USFDA approved* **Viread®** a trademark of Gilead
	For generic drugs (me-too status)	**Tenovir tablet 300mg** by M/s CCL.
	GMP status of the Finished product manufacturer	Routine GMP inspection conducted on 12-01-2023 and cGMP compliance level rated as **"Good"**
	Name and address of API manufacturer.	Source of API is same for drug product manufacturer at **existing facility as well as proposed facility** M/s ACEBRIGHT (INDIA) PHARMA PVT. LTD No. 116/117, KIADB Industrial Area, Jigani, Bengaluru, India. **GMP valid till 14-07-2025**
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	**Stability study conditions**: Real time: 30˚C ± 2˚C / 65% ± 5%RH for 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 06 months
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	**DML # 000284 (Formulation)** *existing facility* The firm has submitted results of pharmaceutical equivalence for all the quality tests for their product as per specification and comparative study against the **comparator product i.e. Tenvir Tablets 300mg by M/s**

		AJ Mirza by performing quality tests (appearance, identification, average weight, Disintegration Dissolution, Assay). **DML # 000933 (Formulation)** *New Facility* The firm has submitted results of pharmaceutical equivalence for all the quality tests for their product as per specification and comparative study against the **comparator product i.e. Tablet Tenofo-B 300 mg by M/s Getz DML # 000284** by performing quality tests (appearance, identification, average weight, Disintegration Dissolution, Assay).
	Analytical method validation/verification of product	Firm has submitted report of validation of analytical method for the drug product including system suitability, specificity, accuracy, repeatability, intermediate precision, linearity, range & robustness.

STABILITY STUDY DATA *(at existing facility)*
Plot # 29-30, Sector 27, Korangi Industrial Area, Karachi **DML # 000284 (Formulation)**

Manufacturer of API	M/s ACEBRIGHT (INDIA) PHARMA PVT. LTD No. 116/117, KIADB Industrial Area, Jigani, Bengaluru, India.		
API LOT #	0000085800		
Description of Pack (Container closure system)	300mg, Light pink colored, round biconvex shaped film coated plain on both sides packed in HDPE bottle, further packed in secondary carton along with insert.		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Accelerated: 0,3,6 months Real time: 0,3,6 months (Data submitted for 06 months)		
Frequency	Accelerated: 0,3,6 months Real Time: 0, 3, 6, 9, 12, 18, 24,36 (Months)		
Batch No.	**130F44**	**131F44**	**132F44**
Batch Size	100,000 tablets	100,000 tablets	100,000 Tablets
Manufacturing Date	08/2014	09/2014	09/2014
Date of Initiation	23/09/2014	26/09/2014	26/09/2014
No. of Batches	03		

STABILITY STUDY DATA *(at new facility)*
Plot # 01, Sector 25, Korangi Industrial Area, Karachi **DML # 000933 (Formulation)**

Manufacturer of API	M/s ACEBRIGHT (INDIA) PHARMA PVT. LTD No. 116/117, KIADB Industrial Area, Jigani, Bengaluru, India.
API LOT #	TDFB21018
Description of Pack (Container closure system)	300mg, Light pink colored, round biconvex shaped film coated plain on both sides packed in HDPE bottle, further packed in secondary carton along with insert.
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
Time Period	Accelerated: 0,3,6 months Real time: 0,3,6 months (Data submitted for 06 months)
Frequency	Accelerated: 0,3,6 months Real Time: 0, 3, 6, 9, 12, 18, 24 & 36 (Months)

Batch No.		**003ES01**	**003ES02**
Batch Size		10,000 tablets	10,000 tablets
Manufacturing Date		06/2021	06/2021
Date of Initiation		16/06/2021	16/06/2021
No. of Batches		02	
Administrative Portion			
1.	Reference of previous approval of applications with stability study data of the firm (if any)	Not applicable	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	provided	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Existing unit**	Invoice # 024/2014-2015 dated 26/06/2014
		New Unit	Invoice # 203-2020-2021 dated 02-03-2021
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.	
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted	
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.	

Remarks of the Evaluator:

Tenofo-B 300 mg is already a registered brand of M/s Getz Pharma (Pvt.) Ltd, since 14-07-2009 with **DRAP's Registration No. 057803** at their manufacturing facility with **DML # 000284 (Formulation)** for the manufacturing site located at Plot # 29 – 30, Sector 27, Korangi Industrial Area.

M/s Getz Pharma (Pvt) Ltd has recently established another manufacturing facility with **DML # 000933 (Formulation)** for the manufacturing site located at Plot # 01, Sector 25, Korangi Industrial Area, Karachi.

Firm has now applied for **Change** of the manufacturing site of their registered brand **Tenofo-B**	
From	**To**
DML # 000284 (Formulation) Plot # 29 – 30, Sector 27, Korangi Industrial Area, Karachi	**DML # 000933 (Formulation)** Plot # 01, Sector 25, Korangi Industrial Area, Karachi.

Comparison of Batch analysis reports

Test	Proposed Specification	New Site		Previous Site	
		003SE01	003SE02	130F44	131F44
Appearance	Light pink colored, round, biconvex shaped film coated plain on both sides.	Complies	Complies	Complies	Complies
Average weight	575.50mg ± 5.0%	576.89mg	578.41 mg	574.0mg	582.7mg
Uniformity of dosage by weight variation	Acceptance value should be less than or equal to L1% (L1 is 15.0)	2.8	4.5	4.4	8.5
Disintegration Time	NMT 30.0 minutes	2 minutes	3 minutes	3 min	3 min
Identification	The retention time of the major peak of sample solution corresponds to that of standard solution, as obtained in the assay.	Complies	Complies	Complies	Complies
Assay	(90.00 – 110.00) %	100.14%	100.69%	97.964%	98.178%
Dissolution	NLT 75.00% (Q) of the labelled amount in 45 minutes.	99.13%	99.52%	101.415%	100.718%

Remarks of Evaluator	**Application is complete as per SOP/ guidelines. Accordingly, the case is recommended for consideration of Registration Board.**

Decision: Registration Board decided as under:

i. **Cancelled registration of following products from the name of M/s Getz Pharma Pvt. Ltd. Plot No. 29-30, Sector 27, Korangi Industrial Area Karachi (DML No.000284):**

S. No.	Reg. No.	Product Name & Composition
1.	029435	Fexet Tablets 120mg Each tablet contains:- Fexofenadine HCl……..…120mg
2.	029436	Fexet Tablets 180mg Each tablet contains:- Fexofenadine HCl……..…180mg
3.	057803	Tenofo-B 300mg Tablet Each film coated tablet contains:- Tenofovir Disoproxil Fumarate…….300mg eq. to Tenofovir Disoproxil……245mg

ii. **Approved registration of following products in the name of M/s Getz Pharma Pvt. Ltd. Plot No. 01, Sector 25, Korangi Industrial Area Karachi (DML No.000933).**

a) **Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months as per the commitment submitted in the registration application.**
b) **Manufacturer will perform process validation of first three batches of both products as per the commitment submitted in the registration application.**
c) **For product at S.No. 1 of below table, the applicant shall submit fee of Rs. 7500/- (in the light of notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021) for pre-registration variation/ change in finished product specifications from "Manufacturer's Specifications" to "As per Innovator's Specifications".**

S. No.	Product Name & Composition
1.	**Fexet Tablets 120mg** **Each film-coated tablet contains:** **Fexofenadine Hydrochloride ……..…. 120mg** **(BP Specifications)**
2.	**Fexet Tablets 180mg** **Each film-coated tablet contains:** **Fexofenadine Hydrochloride ……..….. 180mg** **(BP Specifications)**
3.	**Tablet Tenofo-B 300 mg** **Each film coated tablet contains:** **Tenofovir Disoproxil Fumarate 300mg** **Eq. to Tenofovir Disoproxil ……. 245mg** **(IP Specifications)**

iii. Reference will be sent to Costing and Pricing Division for confirmation of maximum retail price (MRP).

Case No.5. Decision of DRAP' Authority Regarding Extension in Validity of Registrations of Potassium Iodide Tablet Issued on Priority Basis

Background & Previous Decision:

Drug Regulatory Authority of Pakistan in its 88th meeting held on 7th August, 2020 discussed the application of Pakistan Atomic energy Commission (PAEC) for the registration of Potassium Iodide tablets. In order to facilitate & expedite the process of registration of Potassium Iodide tablets; the Authority exercising its power under Rule 26 of Drugs (LRA) Rules amended vide SRO 713 (1)/2018 dated 8th June, 2018 allowed to submit registration applications on Form 5/ Form 5-A/ Form 5-D instead of Form 5-F, for registration of Potassium Iodide tablets in light of approvals granted by the reference regulatory authorities and with the following additional conditions;

i. The applicants can submit their applications till 30-09-2020 and these applications will be considered out of queue.
ii. Registration Board shall consider grant of registration and submission of data of product development and 6 months accelerated and 6 months real time stability studies data before sale of product along with other data as may be required

Accordingly, Registration Board approved a number of applications for registration of "Potassium Iodide Tablets 65mg & 130mg" subject to following additional condition:

"The Board further decided that registration shall be valid for one (01) year only and the registration holder shall perform product development including stability studies for 6 months as per intervals and data requirements decided by Registration Board in its 293rd meeting and shall submit within one year time for consideration by Registration Board for further extension of validity period of registration."

In line with the above-mentioned decision, a number of registrations of Potassium Iodide Tablets 65mg and 130mg have been issued. Furthermore, validity period of some of these registrations has either been elapsed or near to expiry. However, requisite data including product development and stability studies for 6 months has not been submitted by any registration holder.

Previously Authority in its 117th meeting (held on 24th August, 2021) decided to extend the validity period of all registrations issued in context with COVID-19 pandemic to 5 years from the date of registration with the condition to ensure submission of data of product development including stability studies for 6 months as per intervals and data requirements decided by the Registration board in its 293rd meeting before marketing of the products. Accordingly, a case was forwarded to DRAP's Authority for extension in validity of these registrations.

DRAP's Authority in its 152nd meeting (held on 25-11-2022) decided as under:

"The Authority decided to approve the recommendation of the Registration Board to extend the validity period of potassium iodide's registration up to 05 years from the date of registration with the condition to ensure submission of data of product development including stability studies for 6 months as per intervals and data requirements decided by Registration Board in its 293rd meeting before marketing of the products."

Keeping in view the above-mentioned decision of DRAP's Authority, pending registration letters of Potassium Iodide Tablets have also been processed with above-mentioned condition.

Accordingly, the case is submitted for information and endorsement by the Registration Board.

Decision: **Registration Board deliberated that the registrations of "Potassium Iodide Tablets 65mg & 130mg" were issued subject to performance and submission of product development including stability studies (for 6 months) within one-year. However, till to date, relevant registration holders have not submitted the requisite information.**

Foregoing in view, Registration Board decided that relevant registration holders shall be directed to submit compliance of the above-mentioned condition subject thereto the registrations were issued for 01 year. The Board further directed PE&R Division to evaluate data/ studies submitted in this regard and subsequently place evaluation reports for consideration and final decision by the Registration Board.

Case No.06. Request of M/s Asian Continental (Pvt) Ltd., Karachi for Issuance of Registration Letter with Correct Composition

Registration Board in its 296th meeting held on 08th-10th Sep, 2020 approved registration of following product in favour of M/s Asian Continental (Pvt) Ltd. D/32 SITE Super Highway Karachi (DML No. 000643):

Name and address of manufacturer / Applicant	Asian Continental, D-32, Site II, Super Highway, Karachi
Brand Name +Dosage Form + Strength	Calocin-D Tablet (830 mg +400 IU)
Diary No. Date of R& I & fee	Dy. No.187, R&I Dated 17-11-14, Rs: 20,000/-
Composition	Each film coated tablet contains: Ossein mineral complex…830 mg Hydroxyapatite compound 830 mg (eq. to calcium 177.6 mg, phosphorous 82.2 mg, residual mineral salts 24.9 mg, collagen 224 mg, other proteins 66.4 mg, trace elements F, Mg, Fe, Ni.Cu) Vitamin D……..400 IU
Pharmacological Group	Calcium ,Vitamin D Supplement
Type of Form	From 5
Finished Product Specification	As per innovator Specifications.
Pack size & Demanded Price	30's, Alu- Alu Blister, As per SRO.
Approval status of product in Reference Regulatory Authorities.	Ossopan MD by Xymogen ,USA
Me-too status	Ossobon D by Platinum Pharmaceuticals (R. No. 044003)

GMP status	GMP inspection report dated 03-06-2020 with the following conclusion: Based on the above observations their current GMP compliance level is rated as Good.
Remarks of the Evaluator.	I. Presence of Atomic Absorption Spectrophotometer confirmed by FID inspection report. II. Referred product in reference regulatory authority could not be confirmed.
Previous Decision	Registration board in its 270th meeting decided as under: Deferred for confirmation of approval status in reference regulatory authorities.
Evaluation by PEC (AD PEC-XII)	• Firm provide the evidence of Me-Too Product Ossobon D Tablet by M/s. Platinum Pharmaceuticals (Reg.no. 044003). • Firm provide the evidence of GMP inspection report dated 11th Nov, 2015, wherein the area FID stated that the firm has recently installed Atomic Absorption Spectrophotometer.
Decision: Approved with Innovator's specifications.	

While processing for issuance of registration letter, it was identified that applied composition is different that of the generic product. Detail is as under:

Product Name and Applied Composition	**Product Name and Composition of Generic Product/ Brand Leader**
I	II
Calocin-D Tablet (830 mg +400 IU) Each film coated tablet contains: Vitamin D……..400 IU Ossein Mineral Complex…830 mg **Hydroxyapatite compound 830 mg** (eq. to calcium 177.6 mg, Phosphorous 82.2 mg, Residual mineral salts 24.9 mg, Collagen 224 mg, other proteins 66.4 mg, trace elements **F, Mg, Fe, Ni.Cu**)	Ossobon-D (Platinum)/ Osnate-D Tablet (AGP) Each film coated tablet contains: Vitamin D……..400 IU Ossein Mineral Complex…830mg Corresponding to Calcium……177.6mg Phosphorous…….. 82.2mg Residual Mineral Salts……. 24.9mg Collagen…….. 224mg Other Proteins……..66.4mg Trace Elements **F, Mg, Fe, Zn, Cu, Ni** ***Corresponding to approx.** **Hydroxyapatite……440mg**

In this context, the firm has now submitted correct composition (as mentioned in column II of above table) along-with following documents:

i. Revised form-5.
ii. Fee of Rs.30000/-(DS#3810798304).
iii. Copy of Last GMP Inspection Report (dated 27-09-2022) stating "Good" compliance.

Decision: Registration Board noted that the above-mentioned formulation falls in grey area between pharmaceuticals and H&OTC products, therefore, the case shall be referred for seeking opinion of committee on grey molecules.

Case No.07. Request of M/s Medimarker Laboratories (Pvt) Ltd. Hyderabad for Cancellation of Registrations.

M/s Medimarker Laboratories (Pvt) Ltd. Plot No. A-104 S.I.T.E Hyderabad (DML No. 000615) has requested for cancellation of registration of their following products which were registered by way of contract manufacturing at M/s Uni-Tech Pharmaceuticals, Karachi.

S. No.	Reg. No.	Product Name & Composition	Reason for Cancellation

1.	047034	Markxim Dry Powder 500mg Injection Each vial contains: Cefotaxime (as Sodium)…….500mg	• Non-submission of renewal/ extension in contract manufacturing permission. • The firm has been granted fresh approvals for registration of same formulations (for self-manufacturing) vide 322nd meeting of Registration Board.
2.	047037	Rifodime Dry Powder Injection 500mg Each vial contains: Ceftazidime……..……500mg	
3.	047031	Cefmark Dry Powder Injection 500mg Each vial contains: Ceftriaxone (as Sodium)……500mg	

Decision: **Registration Board acceded to the request of M/s Medimarker Laboratories (Pvt) Ltd. Plot No. A-104 S.I.T.E Hyderabad (DML No. 000615) and cancelled the registrations of above-mentioned products due to non- submission of renewal/ extension in contract manufacturing permission.**

Case No.08. Request of M/s Mission Pharmaceuticals Karachi for Cancellation of Approvals Granted by Registration Board.

Registration Board in its 324th meeting, held on 24th-26th January, 2023, approved following products in favour of M/s Mission Pharmaceuticals Plot No. A-94, S.I.T.E Super Highway Karachi (DML No. 000809) has requested for cancellation of registration of their following products:

Table-I

S. No.	Product Name & Composition	Decision of M-324
1.	Cepaxin Tablet 250mg Each Film Coated Tablet Contains: Ciprofloxacin As Hcl…250mg	Approved.
2.	Cepaxin 500mg tablet Each Film Coated Tablet Contains: Ciprofloxacin Hcl Eq To Ciprofloxacin …500mg	Approved.
3.	Diafac K 50mg Tablet Each Film Coated Tablet Contains: Diclofenac Potassium…50mg	Decision not mentioned in minutes.
4.	Merzole Capsule 40mg Each Capsule Contains: Esomeprazole Enteric Coated Pellets…40mg	Approved as per following label claim: Each Capsule Contains: Esomeprazole as Magnesium Trihydrate (enteric coated pellets)…40mg The firm shall submit fee of Rs.30,000/- for correction/pre-approval change in product label claim as per notification No.F.7-11/2012-B&A/DRAP dated 07-05-2021, before issuance of registration letter.

However, the firm has now requested to cancel the above-mentioned approvals stating that they have already been issued registrations of same formulations. Detail is given below:

Table-II

S. No	Reg. No.	Name of Drug(s) & Composition

1.	096357	Cipracept Tablet 250mg Each film coated tablet contains: Ciprofloxacin as Hydrochloride……..250mg (USP Specifications)
2.	096358	Cipracept Tablet 500mg Each film-coated tablet contains: Ciprofloxacin as Hydrochloride ……..500mg (USP Specifications)
3.	096359	Vorenac-K Tablet 50mg Each film coated tablet contains: Diclofenac Potassium……...50mg (USP Specifications)
4.	098804	Prasium Capsule 40mg Each capsule contains: Esomeprazole Magnesium Trihydrate Enteric Coated Pellets eq. to Esmomeprazole……..40mg (USP Specifications)

Decision: **Registration Board acceded to the request of M/s Mission Pharmaceuticals Plot No. A-94, S.I.T.E Super Highway Karachi (DML No. 000809) and declared the decisions of 324th meeting regarding approval of products mentioned in Table-I above as redundant/ disposed of.**

Case No.09. Cancellation of Approval Granted to M/s Lisko Pakistan (Pvt) Ltd., Karachi for Registration of Maxime DS Suspension 100mg/5ml

Registration Board in its 324th meeting, held on 24th-26th January, 2023, approved following products in favour of M/s Lisko Pakistan (Pvt) Ltd., L-10/D, Block 21, Federal B Industrial Area, Karachi (DML No.000110):

Table-I

S. No.	Product Name & Composition	Decision of M-324
1.	Maxime DS 100mg/5ml Each ml contains: Cefixime as Trihydrate……..100mg	Approved.

While processing for issuance of registration letter, it was identified that the firm has already been issued registration of same formulation in same strength and dosage form. Detail is as under:

Table-II

S. No	Reg. No.	Name of Drug(s) & Composition
1.	050427	Liskoxime Dry Suspension 100mg/5ml Each ml contains: Cefixime as Trihydrate……..100mg

Decision: **Registration Board declared the decision of 324th meeting regarding approval of product mentioned in Table-I above as redundant/ disposed of.**

Case No.10. Request for Change in Registration Status of Mosegor 0.5mg Tablet from M/s Novartis Pharma Pakistan Limited, 15 West wharf, Karachi to M/s Novartis Pharma (Pakistan) Limited, C-21, S.I.T.E. Area, Karachi.

M/s. Novartis Pharma (Pakistan) Limited C-21, S.I.T.E. Area, Karachi (DML No.000003) has requested to change the registration status of Mosegor 0.5mg Tablet from M/s Novartis Pharma Pakistan Limited, 15- West Wharf, Dockyard Road, Karachi (DML#000193) to M/s Novartis Pharma Pakistan Limited (Formerly M/s Bayer Pakistan (Pvt.) Ltd,), C-21, S.I.T.E, Area, Karachi (DML#000003). They have also requested for change in manufacturing site from M/s GSK CHC, Petaro Road, Jamshoro (DML No. 000010) (i.e., contract manufacturer) to M/s Novartis Pharma Pakistan Limited, C-21, S.I.T.E, Area, Karachi (i.e., self-manufacturing).

The detail of the case is as follows:

Administrative Documents Submitted in the light of SOP approved by the Registration Board in its 283rd meeting
i. Copy of GMP certificate on the basis of inspection conducted on 08-09-2021.
ii. Copy of DML of M/s Novartis Pharma Pakistan Limited (DML # 000003) renewed w.e.f. 18-09-2020.
iii. Copy of Tablet (General) section approval letter dated 28-12-2021 issued by Licensing Division in the name of M/s Novartis Pharma Pakistan Ltd, C-21, S.I.T.E Area Karachi (DML# 000003)
i. NOC from M/s. Novartis Pharma Pakistan Limited, Karachi for transfer of Mosegor 0.5mg Tablet in the name of M/s. Novartis Pharma Pakistan Limited, C-21, S.I.T.E, Area, Karachi, issued on 03-01-2023
ii. Relevant undertakings & commitments.

Detail of submitted documents and remarks of evaluators have been mentioned as under:

Evaluator: Mr. Asadullah (DD-QMS)

I	II	III	IV
S/N	**Reg. No.**	**Existing Product Name & Composition**	**Registration Trail**
1.	006641	Mosegor Sugar Coated Tablets Each sugar coated tablet contains: - Pizotifen (as hydrogen maleate)……. 0.5mg (Manufacturer's Specification)	Reg. Date: **22-01-2020** Renewal Granted w.e.f. **22-06-2022 to 21-06-2027** vide letter dated 28-10-2022.
	Name, address of Applicant / Marketing Authorization Holder		**M/s. Novartis Pharma (Pakistan) Limited (**Formerly M/s Bayer Pakistan (Pvt.) Ltd)**, C-21, S.I.T.E. Area, 75700, Karachi, Pakistan**
	Name, and address of Manufacturing site.		M/s. Novartis Pharma (Pakistan) Limited (Formerly M/s Bayer Pakistan (Pvt.) Ltd), C-21, S.I.T.E. Area, 75700, Karachi, Pakistan **(DML 000003)**
	Status of the applicant		☒Manufacturer ☐ Importer ☐Is involved in none of the above (contract giver)
	GMP status of the firm		**For transfer of registration:** GMP certificate of M/s. Novartis Pharma (Pakistan) Limited (Formerly M/s Bayer Pakistan (Pvt.) Ltd), C-21, S.I.T.E. Area, 75700, Karachi issued on 31-12-2021 based on an inspection conducted on 08.09.2021.
	Evidence of approval of manufacturing facility		The applicant has provided a copy of the GMP certificate 31-12-2021 mentioning the Tablet (General) section among the formulation sections.
	Status of application		☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product		☒Domestic sale

		☐ Export sale ☐Domestic and Export sales
	Dy. No. and date of submission	Dy.No.1089 (R&I) dated 12-01-2023
	Details of fee submitted	**For transfer of registration:** PKR 30,000/- DS# 996179471 deposited on 06-12-2022
	The proposed proprietary name / brand name	Mosegor 0.5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sugar-coated tablet contains: Pizotifen (as hydrogen malate) 0.5mg
	Pharmaceutical form of applied drug	Off-white tablet & circular biconvex sugar coated tablet.
	Pharmacotherapeutic Group of (API)	Anti-migraine
	Reference to Finished product specifications	Manufacturers' Specifications
	Proposed Pack size	30's
	Proposed unit price	Already registered product
	The status in reference regulatory authorities	Sandomigrin 0.5 mg Table, Ethyx Pharmaceuticals France, (Danish Medical Agency D.SP.NR 3049)
	For generic drugs (me-too status)	--
	Name and address of API manufacturer.	Novartis Pharma AG Lichtstrasse 35, 4056 Basel, Switzerland
	1.5.11-Proposed Label	Same as already registered
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. DS monograph exist in BP while DP monograph is not available in any pharmacopeia. Firm has summarized information of DS for its physical properties, solubility, polymorphism facts and other general properties. The DS manufacturer Novartis Pharma Switzerland is GMP certified and responsible for all steps of manufacturing, packing and testing, however certain in-process steps were being performed at three other sites in the Switzerland. Manufacturing process and process controls were briefly stated. Characterization elucidation studies was conducted using UV an NMR and spectroscopic techniques. Degradation and process related impurities was listed and analyzed and acceptable limits were defined. DS manufacturers followed BP specification and accordingly analytical methods were verified. DS lot procured was analyzed by DP manufacturer. Working standards, container closure and stability studies summaries of 04 batches were provided for long term study parameter at 25°C ± 2°C / 60% ± 5% RH. Similarly, information summaries for drug product

		related to its description, composition, choice of excipients, formulation development, manufacturing process, pharmaceutical equivalence and comparative dissolution profile against reference product were provided. Development of manufacturing process, and in-process controls were provided. DP specifications were developed based on in-house / manufacturer's specification. Excipients control as per pharmacopeia reference were provided. Analytical procedure and its validation were performed. Batch analysis of 03 stability batches were provided. Working standard its CoA, container closure system and stability studies summaries have been provided.
	Module-III Drug Substance:	Firm has submitted data for drug substance related to nomenclature, structure, general properties, solubilities, synthesis process, manufacturer and manufacturing process, character elucidation using spectroscopy, and NMR, physical form, polymorphism, structure elucidation using UV, FTIR, NMR, etc. intermediates and potential Impurities were identified and acceptable limits were assigned. Testing methods for impurities was provided. DS specifications were based on the BP monograph. 2% overages were added to compensate inherent processing loss. Analytical method and its verification were performed. DP manufacturer also performed analytical method verification of DS. Manufacturing process and in-process control and process validation studies were provided. Certificate of analysis of DS lot, batch analysis, reference standard and its CoA were provided. Container closure system, specification and test methods for packing materials, and stability studies sheet were provided.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at long term conditions**. The stability studies were conducted at 25ºC ± 2ºC / 60% ± 5% RH for 36 months.** DS was packed in a double polyethylene bags which were sealed in plastic closure band and place di metal drum wit temper resistant seal. The DS remained stable and within specified limits as tested on defined intervals. The firm has also provided temperature data logs for transposition of DS (batch C0035). Firm has also provided transport studies of Drug Substance (Pizotifen) conducted at 30ºC ± 2ºC / 65% ± 5% RH and 50ºC. Although it was established that DS is not sensitive to humidity and remains stable at 50ºC, but these studies were conducted in 1994. Furthermore, firm has also provided real time studies of DP for 06 months and informed that these studies will be continued for shelf life. However, forced degradation studies are not made part of

<table>
<tr><td></td><td></td><td>these real time studies.</td></tr>
<tr><td></td><td>Module-III Drug Product:</td><td>Firm has submitted data of drug product including its qualitative and quantitative composition, formulation development, manufacturing process development and in-process control, manufacturing process validation protocol and report, excipients testing methods based on pharmacopeia references with analysis reports, pharmaceutical equivalence and comparative dissolution profile, specifications and analytical procedures developed on the basis of in-house method and its validation studies, dissolution method validation, batch analysis, justification of specifications, reference standard, container closure system and stability studies.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Pharmaceutical equivalence was performed against the Mosegor product manufactured by GSK, which shows comparable results within specified limits.
The comparative dissolution profile was performed of the stability batch (BAC303) against the Mosegor 0.5mg Tablet (Batch HK7R) manufactured by GSK, Karachi. Comparison was performed using 12 samples at pH 1.2, pH 4.5 and pH 6.8 for 30 min. CDP method was also validated by DP manufacturer. Calculation of value is as under:
<table>
<tr><th>Sr</th><th>Mediums</th><th>Time interval</th><th>Sample</th><th>Reference</th></tr>
<tr><td rowspan="4">i.</td><td rowspan="4">Acidic buffer (pH 1.2)</td><td>10 min</td><td>36.6 %</td><td>36.6 %</td></tr>
<tr><td>20 min</td><td>63.2 %</td><td>63.7 %</td></tr>
<tr><td>30 min</td><td>78.5 %</td><td>78.3 %</td></tr>
<tr><td colspan="3">f1 = 0.168
f2= 99.758</td></tr>
<tr><td rowspan="4">ii</td><td rowspan="4">Acetate buffer (pH 4.5)</td><td>10 min</td><td>59.8 %</td><td>60.9 %</td></tr>
<tr><td>20 min</td><td>95.7 %</td><td>91.5 %</td></tr>
<tr><td>30 min</td><td>101.8 %</td><td>102.2 %</td></tr>
<tr><td colspan="3">f1=1.453
f2=83.858</td></tr>
<tr><td rowspan="4">iii</td><td rowspan="4">Phosphate Buffer (pH 6.8)</td><td>10 min</td><td>19.9 %</td><td>17.7 %</td></tr>
<tr><td>20 min</td><td>70.5 %</td><td>71.5 %</td></tr>
<tr><td>30 min</td><td>99.8%</td><td>100.0 %</td></tr>
<tr><td colspan="3">f1=0.523
f2=97.577</td></tr>
<tr><td rowspan="4">iv</td><td rowspan="4">0.1N HCl</td><td>10 min</td><td>43.1 %</td><td>43.1 %</td></tr>
<tr><td>20 min</td><td>69.6 %</td><td>70.2 %</td></tr>
<tr><td>30 min</td><td>90.3 %</td><td>91.0 %</td></tr>
<tr><td colspan="3">f1=0.459
f2=97.577</td></tr>
</table>
</td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>Firm has claimed in-house manufacturer' specifications for which report of validation of analytical method for the drug product has been provided. Dissolution method validation studies were also provided.</td></tr>
<tr><td colspan="3">STABILITY STUDY DATA</td></tr>
</table>

Manufacturer of API	Novartis Pharma AG Lichtstrasse 35, 4056 Basel, Switzerland		
API Lot No.	COO35		
Description of Pack (Container closure system)	Alu-PVC blister packed along with patient information leaflet in a unit folding carton box, Pack Size : 20 tablets (2 x 10's).		
Stability Storage Condition	Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, (Months)		
Batch No.	BAC303	BAC304	BAC310
Batch Size	2,000,000 Tablets	2,000,000 Tablets	2,000,000 Tablets
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	05-2022	05-2022	05-2022
No. of Batches	03		

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

1.	Reference of previous approval of applications with stability study data of the firm (if any)	-
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm has submitted copy of GMP certificate No. GMP-CH-1002419 dated 06-08-2021 issued by Swissmedic, Swiss Agency for Therapeutic Goods, Switzerland valid till 16/03/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	API was purchased from Novartis Pharma AG, Switzerland, invoice # 2001723021 dated 19-01-2022, cleared on 27-01-2022 from DRAP, Karachi.
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted complete record of testing of all batches along with chromatograms, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has submitted audit trail of stability batches.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation Remarks and Response:-

Following queries were asked from the applicant during evaluation round:-

S. No.	Query	Response
1.	DS Stability was conducted at 25C /60RH. Registration Board decision in this regard with respect to force degradation studies and transport log maintenance.	Kindly be informed that since stability of DS is conducted at 25C /60RH, therefore as per the CTD Guidelines PE&R/GL/AF/004 dated 01-10-2020, we are providing you data logger of DS in Annex 1. In addition to this, being the finished product manufacturer, we have also provided you real time stability studies of the product along-with accelerated studies for 6 months. The real time stability studies are ongoing and will be continued till shelf life. Additionally, we are providing you stability studies for DS at zone IV-A as well which is included in DMF of Pizotifen Malate in 3.2.S.7 of module 3. We are attaching stability data as well for your kind consideration.
2.	Why firms is carrying an analytical method for Mosegor tablets from Sandoz, is it the same as developed by Sandoz decades ago and no amendments were made by Novartis or GSK site?	The analytical method shared in CTD dossier is current and validated and method validation is part of CTD.
3.	Why dissolution testing were excluded at 3, 6 month intervals in long term studies?	As per ICH Q1F Stability guidelines, "It is not expected that every test listed be performed at each point." attached in Annex 2. Given the provided guidelines, we have set the following periods for performing the dissolution studies at 0, 12 & 24 months and we will perform the tests as per protocol matrix till shelf life. Furthermore, we have already submitted dissolution studies for 0, 3, 6 months on accelerated conditions 40/75 and results are satisfactory as well.
4.	Justification for process loss is covered with 2% overages?	Mosegor 0.5mg Tablet contains a very small quantity of Pizotifen Hydrogen Malate (API) at 0.5mg per tablet (equivalent to 0.9% of individual tablet core weight). API is introduced at the granulation stage from initial step and undergoes sieving, dry mixing, wet mixing, fluidization, dry granulation and finally blending. These manufacturing steps inherit minor process losses during activity by design. Therefore, to compensate the inherit processing loss within entire manufacturing process, a minor 2% of API quantity (equivalent to 30 grams in total Core batch size of 110Kg) is added, subsequently validated and ensures that the final product contains the API quantity as per label claim for intended dosage and purpose.
5.	Why unfilled BMR was signed and submitted in the dossier?	As per the CTD guidance document PE&R/GL/AF/004 dated 01-10-2020 for submission of application form 5-F (CTD) in

		section 3.2.R it is stated that "for application of locally manufactured drug product, provide blank master production document / batch manufacturing record to be used during the commercial manufacturing of the applied product." Therefore, as per the requirement, we have provided unfilled BMR, signature is the evidence that the BMR template is controlled & approved.

Conclusion:

As per the decision of 290th meeting of Registration Board, the firm was required to submit followings information:-

- ✓ *In case where the real time stability data of drug substance is conducted at 25°C ± 2°C/60% RH ± 5% RH, the firm shall submit the record of data logger for the storage conditions throughout the transportation.*
- ✓ *Moroever, in case of use of ingredients whose stability testing has not been done as per Zone IVA, then the manufacturer of finished pharmaceutical product, shall submit real term stability studies data of the product for atleast 1 year along with degradation studies in the finished pharmaceutical product.*
- However, the firm has submitted stability study data of 3 batches of drug substance conducted at long term conditions **of 25ºC ± 2ºC / 60% ± 5% RH for 36 months.**
- The firm has also provided temperature data logs for transposition of DS (batch C0035). Firm has also provided transport studies of Drug Substance (Pizotifen) conducted at 30ºC ± 2ºC / 65% ± 5% RH and 50ºC. Although it was established that DS is not sensitive to humidity and remains stable at 50ºC, but these studies were conducted in 1994.
- Furthermore, firm has also provided real time studies of DP for 06 months and informed that these studies will be continued for shelf life. However, forced degradation studies are not made part of these real time studies.
- Pharmaceutical equivalence and comparative dissolution profile study have not been performed against the innovator's product. In this context, the firm has stated that Mosegor tablet is innovator product of Novartis Pakistan approved at GSK Jamshoro site for the manufacturing. Since we are transferring the product from GSK manufacturing Site, we have compared the dissolution profile with the Mosegor Tablet manufactured at GSK manufacturing site.

Decision: **Registration Board deferred the case for submission of following documents/ information by the applicant:**

i. Long term stability studies data of the finished pharmaceutical product for at least 1 year including degradation studies performed by M/s. Novartis Pharma (Pakistan) Limited, C-21, S.I.T.E., Karachi.

OR

Updated stability studies data of 3 batches of drug substance as per long term conditions of Zone-IV-A, performed by M/s Novartis Pharma AG Lichtstrasse 35, 4056 Basel, Switzerland.

ii. Request for withdrawal/ cancellation of registration of "Mosegar Tablet 0.5mg (Reg. No.006641) to be submitted by existing registration holder.

Case No.11. Request for Change in Registration Status of Panadol Extend Tablet (Reg. No.097070) from M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.TE. Karachi to M/s GSK Consumer Healthcare Pakistan Limited, Petaro Road Jamshoro Along-with End to End Local Manufacturing.

Registration Board in its 323rd meeting held on 06th-08th December16th-17th May, 2022 considered the request of M/s GSK Consumer Healthcare Pakistan Limited, Petaro Road Jamshoro for change in registration status of Panadol Extend Tablet (Reg. No.097070) from M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.TE. Karachi to their name as per following details:

Detail of Previous Proceedings:

M/s GSK Consumer Healthcare Pakistan Limited, Petaro Road Jamshoro initially applied for change in registration status from M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.TE. Karachi to their name along-with end to end local manufacturing (Dy.No.33338/R&I dated 21-12-2021). However, the firm vide their letter No.REF/DRAP/Reg-003/0322 received dated10-03-2022 (Dy.No.6669) revised their request by informing that there is no change in manufacturing site (abroad) and repacking site (local). The case was considered by the Registration Board in its 317th meeting (held on 16th-17th May, 2022) and decided as under:

Decision of M-317:

Registration Board deferred the case for submission of updated approval status of the applied formulation along-with safety and efficacy profile in reference regulatory authorities adopted by the Board in its 275th meeting. Moreover, the Board further advised to submit valid and legalized CoPP of the product as existing has been expired.

In line with the above-mentioned decision of Registration Board, following information has been collected regarding risk-benefit profile of Paracetamol MR Tablet and regulatory steps taken by different reference regulatory authorities in the best interest of patients.

[Reference: Application to amend the Poisons Standard - Modified Release Paracetamol (tga.gov.au) accessed dated 04-11-2022]:

Paracetamol Modified Release Tablet:

Paracetamol MR tablets are constructed in two layers, an IR layer (31%) and a SR layer (69%) that gradually releases paracetamol over a period of 8 hours at normal doses.

The highest recommended dose of paracetamol for adults is 1.3 g and the maximum daily dose is 4 g (i.e., 2 tablets 3 times a day with highest dose of 6 tablets a day). A toxic dose is 10g or 200mg/kg (whichever is greater). The majority of patients who overdose take less than 30 g.

Summary of Benefits of MR Paracetamol:

i. Three times daily dosing and reduction of tablet burden (compared with four times daily dosing of IR formulations);
ii. MR paracetamol may be preferred over IR paracetamol for long term use in patients with chronic pain conditions such as osteoarthritis.

Summary of Risks of MR paracetamol:

i. Unpredictable and undefined pharmacokinetic profile following an overdose with MR paracetamol.
ii. Severe consequences of overdose may be more likely to occur in patients who have ingested MR paracetamol;
    a. High potential for treating clinician to not be aware that a patient has ingested MR paracetamol
    b. Unpredictable pharmacokinetic profile making monitoring and treatment difficult
iii. Current best practice guidelines do not completely address MR toxicity.
iv. Chronic supratherapeutic overdose is also thought to be not uncommon. This is likely largely due to confusion about the difference in dose between MR and IR paracetamol with the maximum dose being 6 tablets per day for the MR formulation rather than 8 tablets per day for IR. This confusion may be contributed to by the products being available adjacent to one another OTC without counselling/education provided at the point of sale.
v. Paracetamol overdose can result in liver failure requiring liver transplant and may be fatal if not treated appropriately in a timely manner.

To overcome the risk associated with overdosing of Paracetamol MR Tablet, following different regulatory actions have been taken by EMA and TGA:

A. **European Medicines Agency (EMA)** on recommendations of Pharmacovigilance Risk Assessment Committee (PRAC) suspended the marketing of MR paracetamol formulations in September 2017 as the **advantages of a longer-acting product did not outweigh the complications of managing an overdose of the medicine**, since the treatment procedures for immediate-release products are not appropriate for modified-release paracetamol.

   In many cases, it may not be known whether an overdose of paracetamol involves immediate-release or modified release products, making it difficult to decide how the overdose should be managed.

   Furthermore, the **medicines will remain suspended unless the companies that hold the marketing authorizations can provide evidence of appropriate and practical EU-wide measures to help prevent overdose with these products and adequately reduce its risks.**

B. Therapeutic Goods Administration (TGA) Australia has up-scheduled MR paracetamol from ***Schedule 2 'Pharmacy Medicine'*** to ***Schedule 3 'Pharmacist Only'*** in order to ensure appropriate patient counselling on correct dosing and the risks associated with overdose, whether intentional or accidental.

- There are well established guidelines in Australia for the management of paracetamol overdose including with MR paracetamol.
- The treatment of paracetamol overdose is dependent on a number of factors and treatment given will vary accordingly. Key parameters include dose taken and time since exposure, if known.
- The mainstay of treatment is with acetylcysteine. Whether acetylcysteine is administered depends on certain clinical parameters, including the use of the paracetamol treatment nomogram which plots the blood paracetamol concentration against time.
- Other investigations include measurement of liver function to assess for liver toxicity.

Approval status of Paracetamol extended-release tablets in different regulatory authorities is as under:

S/N	Country	Authority	Product	Approval status
1.	Australia	TGA (Therapeutic Goods Administration) PANADOL OSTEO (reformulation) paracetamol 665 mg modified release tablet blister pack (260264) | Therapeutic Goods Administration (TGA)	PANADOL OSTEO paracetamol 665mg modified release tablet of M/s GlaxoSmithKline Consumer Healthcare Australia Pty Ltd	Active (Non-prescription medicine) **(Pharmacist Only Medicine)**
2.	Australia	TGA (Therapeutic Goods Administration) PANADOL BACK & NECK LONG LASTING paracetamol 665mg modified release tablets blister pack (78493) | Therapeutic Goods Administration (TGA)	PANADOL BACK & NECK LONG LASTING paracetamol 665mg modified release tablets of M/s GlaxoSmithKline Consumer Healthcare Australia Pty Ltd	Active (Non-prescription medicine) **(Pharmacist Only Medicine)**
3.	USA	US FDA Drugs@FDA: FDA-Approved Drugs	Acetaminophen 650mg extended release tablet	Active (Human OTC drug)
4.	Canada	Health Canada Search results summary (canada.ca)	ARTHRITIS PAIN EXTENDED RELIEF tablet 650mg (Paracetamol extended release tablet)	Approved.
5.	Finland	The Finnish Medicines Agency (Fimea) Drug search - Fimea	Panadol Extend 665mg modified release tablets of M/s GlaxoSmithKline Consumer Healthcare APS	Marketed.
6.	Denmark	Danish Medicine Agency Search - Summary of Product Characteristics (produktresume.dk)	Panodil, Modified Release Tablets 665mg of M/s GlaxoSmithKline Consumer Healthcare APS	Marketed.

List of Countries (Other than RRAs) where Paracetamol MR Tablet has been reported to be available	
i.	New Zealand **(Pharmacist Only Medicine)**
ii.	Singapore
iii.	Hong Kong
iv.	Malaysia
v.	UAE

vi.	Lebanon
vii.	Oman
viii.	Qatar
ix.	Bahrain
x.	Jordan
xi.	Kuwait
xii.	Egypt
xiii.	Saudi Arabia

Approval Status of Paracetamol MR tablets in Pakistan:

Application for registration of Panadol Extend Tablet (containing Paracetamol 665mg in modified release form) for finished import from Australia was received dated 22.06.2012 from M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi and initially considered by the Registration Board in its 243rd meeting held on 08th – 09th May, 2014. Later on, the firm revised the application from 'finished import' to 'bulk import and local repacking'. Registration Board in its 289th meeting held on 14th – 16th May, 2019 approved registration of aforementioned product such that the tablets will be imported in bulk from M/s GlaxoSmithKline Australia Pty Limited, Consumer Healthcare Division, 82 Hughes Avenue, Ermington NSW 2115, Australia and will be blistered and packed along-with final quality control release of the finished pharmaceutical product at M/s. GlaxoSmithKline Pakistan Limited, F-268 S.I.T.E, Karachi. The approval was granted on following grounds:

- Evidence of approval of applied formulation by the reference regulatory authority i.e., Therapeutic Goods Administration (TGA), Australia and confirmation of free sale status in Australia as determined from submitted legalized Certificate of Pharmaceutical Product (CoPP) for bulk labeled tablets.
- On-site Investigation by a panel comprising of Dr. Saif ur Rehman Khattak (Director, CDL, DRAP, Karachi), Dr. Najam us Saqib (Additional Director, DRAP, Karachi) and Mr. Kirshan Das (Assistant Director, DRAP, Karachi) for confirmation of Authenticity / Genuineness of stability data in final container closure system performed by M/s. GlaxoSmithKline Pakistan Limited, F-268 S.I.T.E, Karachi.

Reg. No.	**Product Name & Composition**	**Registration Trail**
097070	Panadol Extend Tablet Each modified release tablet contains: Paracetamol……665mg (USP Specifications) Bulk Import & Local Repacking	**Initial Reg. Date:** 08-07-2019 **Change of Source of Bulk Tablets dated 12- 03-2021:** From M/s GlaxoSmithKline Australia Pty Limited, Consumer Healthcare Division, 82 Hughes Avenue, Ermington NSW 2115, Australia to M/s Glaxo Welcome, S.A. Avda. Extremadura, 3, Pol. Ind. Allendeduero, Arvanda de Duero, 09400 Burgos, Spain **Change of Local Repacking Site dated 26- 10-2021**: From M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.TE. Karachi to M/s GSK Consumer Healthcare Pakistan Limited, Petaro Road Jamshoro
Information printed on label regarding management of Overdose:		In case of overdose, immediate medical management is required by visiting nearest Emergency Medical Center, even if symptoms of overdose do not appear.

Detail of Revised Application Considered in M-323-RB:

M/s GSK Consumer Healthcare Pakistan Limited, Petaro Road Jamshoro has now requested for change in registration status of Panadol Extend Tablet (Reg. No.097070) from M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.TE. Karachi to their name along-with **end to end local manufacturing**. The product is currently registered for bulk import (of tablets) from Glaxo Welcome Spain and local repacking along-with quality control release at M/s GSK Consumer Healthcare Pakistan Limited, Petaro Road Jamshoro.
Evaluation report will be placed before the Registration Board during the meeting.

Decision of M-323:

Registration Board deferred the case for following reasons:

i. *Evaluation of application submitted for change in registration status of Panadol Extend Tablet 665mg (Reg. No.097070) from M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.TE. Karachi to M/s GSK Consumer Healthcare Pakistan Limited, Petaro Road Jamshoro along-with end to end local manufacturing.*

ii. *The applicant shall submit detail of measures adopted by other countries (whether RRA or non-RRA) to mitigate the risk as reported by EMA.*

iii. *The applicant shall also submit detail of practicable measures which will be adopted after grant of marketing authorization to prevent the risk of toxicity associated with over-dose of above-mentioned product.*

i. Evaluation Report:

Administrative Documents Submitted in the light of SOP approved by the Registration Board in its 283rd meeting
i. Copy of GMP certificate on the basis of inspection conducted on 15-09-2020.
ii. Copy of DML (000010) of M/s GSK Consumer Healthcare Pakistan Limited, Petaro Road Jamshoro renewed w.e.f. 31-03-2020.
iii. Approval of "Tablet (General) Section" confirmed from Licensing Division's letter dated 27-01-2022.
iv. NOC (dated 13-01-2022) issued by M/s. GlaxoSmithKline Pakistan Limited in the light of De-Merger order of Sindh High Court.
v. Relevant undertakings & commitments.

Evaluator: Mr. Abdul Mughees Mudassir (AD to CEO)

	Name, address of Applicant / Marketing Authorization Holder	GlaxoSmithKline Consumer Healthcare, Sandoz Nagar, Petaro road, Jamshoro, Sindh, Pakistan.
	Name, address of Manufacturing site.	GlaxoSmithKline Consumer Healthcare, Sandoz Nagar, Petaro road, Jamshoro, Sindh, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐Domestic sale ☐ Export sale ☒ Domestic and Export sales
	Dy. No. and date of submission	Dy. No. 1636 dated 02/12/2022
	Details of fee submitted	Fee Slip Number: 231886180613, PKR 30,000/- dated 22/11/2021
	The proposed proprietary name / brand name	Panadol Extend Tablets
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each modified-release tablet contains: Paracetamol ….665mg
	Pharmaceutical form of applied drug	Oral (Tablet)
	Pharmacotherapeutic Group of (API)	Analgesic
	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	20's

	Proposed unit price	As per DRAP approved price
	The status in reference regulatory authorities	Panadol Osteo Paracetamol 665 mg modified release blister pack By GSK Consumer Healthcare, Australia
	For generic drugs (me-too status)	-
	GMP status of the Finished product manufacturer	-
	Name and address of API manufacturer.	Rhodia Operations SAS (Novacyl Pharmaceutical), 8 Guang Shi Xi Road, China 214185 Wuxi
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	Official monograph of Paracetamol is present in BP. The firm as submitted detail of nomenclature, structure, general properties, Solubilities, physical form, manufacturers, description of manufacturing process and controls, tests for impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability studies	Stability study conditions: Accelerated: 40°C ± 2°C, 75%RH ± 5% Long-term: 25°C ± 2°C, 60%RH ± 5% Batches: 20040226G01, 20040228G01 and 20040229G01
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure (including dissolution testing and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has claimed to be innovator
	Analytical method validation/verification of product	Method Verification studies have been submitted.
STABILITY STUDY DATA		
Manufacturer of API	Rhodia Operations SAS (Novacyl Pharmaceutical), 8 Guang Shi Xi Road, China 214185 Wuxi	

API Lot No.	Batch: DF3T : 0001265000 (Paracetamol) 0001262368 (DC-90) Batch: DFLT : 0001267970 (Paracetamol) 0001262368 (DC-90) Batch: DF3T : 0001265000 & 0001267970 (Paracetamol) 0001262368 (DC-90)		
Description of Pack (Container closure system)	Transparent PVC/PVDC 275-micron thickness/ Al foil Blister Pack		
Stability Storage Condition	Accelerated stability study: 40°C ± 2°C / 75 ± 5% RH Long-term stability study: 30°C ± 2°C / 65 ± 5% RH		
Time Period	Accelerated: Initial, 3 & 6 months Long-Term: Initial, 3 & 6 months		
Frequency	Accelerated: Initial, 3 & 6 months Long-Term: Initial, 3, 6, 9, 12, 18, 24 months		
Batch No.	DF3T	DF3L	DF3R
Batch Size	440.16 Kg	440.16 Kg	440.16 Kg
Manufacturing Date	01-2020	01-2020	01-2020
Date of Initiation	02-2022	02-2022	02-2022
No. of Batches	03		

Administrative Portion		
1.	Reference of previous approval of applications with stability study data of the firm (if any)	-
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	-
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted
4.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Panadol Extend Tablets are white to off-white, bi-layer, capsule-shaped, film-coated tablets with flat edges embossed with an 8 logo on the front face and plain on the back face.	
Remarks OF Evaluator:	**Firm's Response:**

• GMP certificate of DS manufacturer and Invoice clearance from ADC.	• The applicant has submitted certificate of suitability of API by EDQM i.e., valid till to date along-with copy of invoice attested by ADC on 12-11-2019.
• Forced degradation studies of DS are required as the long-term stability has been performed on 25°C ± 2°C, 60%RH ± 5%.	• Not submitted yet

ii. Measures Adopted by other Countries (whether RRA or non-RRA) to mitigate the risk as reported by EMA:

The applicant has shared following information under the heading of "Risk Mitigation Measure Adopted in Finland":

Risk Minimization Measure	Purpose	Information
Implementing additional warnings on the packaging material/leaflet	Proposal by GSK: Inform and increase focus on use of paracetamol, increase focus on handling overdose. FIMEAS response: *Please provide the updated PI for assessment.* GSK CH response: *Updated SPC sections 4.4 and 4.9 is attached to this response.*	GSK CH commits to submit the next global data sheet v 7 after closure of the current ongoing GDS updates. The updated text linked to OD in v7: "the lowest dose necessary to achieve efficacy- should be used for the shortest duration of treatment." The updated sections in the FI SPC were approved by Fimea.
Education of HCPS	Proposal by GSK: Encourage HCPs to educate patients of safe use and storage of the medicine. Encourage HCPs to prescribe 48 tablet blister packs for acute cases, 96 tablets blister packs for chronic cases and 100 tablet bottles only for hospital use and dose dispensing. FIMEAS response: *Encouraging HCPS to educate patients on safe use and storage of the medicine and to prescribe 48 blister packs for acute case is not consider necessary.* *The 100 tablet bottles should be restricted to hospital use only. Only the blister*	GSK CH commits to send out communication to HCPs upon relaunch if the suspension would be lifted. The final Finnish DHCP communication that was accepted by Fimea was sent out to HCPs in FEB 2019.

	packages should be available for dispensing to patients from pharmacies. The *Applicant is asked to comment on this proposal.* <u>GSK CH response:</u> *We confirm that 100 tablet bottles will be restricted to hospital use only and that only* *blister packages will be dispensed by pharmacies. We will make the necessary* *changes to implement this and in the meantime we will not produce or deliver any* *bottles.* <u>Proposal by GSK:</u> Increased focus on risk of overdose. <u>*FIMEAS response:*</u> *Informing emergency department and the PIC that MR paracetamol is back on the market is essential as well as a reminder of the updated treatment guideline. The current Finnish guideline states that the nomogram should only guide* *treatment in case of acute intoxications and is not reliable in case of intoxication with* *MR products. To minimise the risk of liver damage the Applicant should send out a* *DHCP communication to the Finnish emergency departments and the PIC* *emphasizing this update of the guideline as well as the need for repeated sampling* *of paracetamol.*	
Patient information campaigns	<u>Proposal by GSK:</u> Inform about risk of liver damage and importance of appropriate use of paracetamol. Inform and increase focus on the importance of storing medicines safely – both at home and on the move. Help parent to have "safe medicine" conversations with their children.	GSK CH commits to roll out: "Safe storage of medicine" campaign. Guide to guidegivers regarding medication management in elderly. Parent's guide. Patient folder. Information campaign targeting young people.
Child proof packaging	<u>Proposal by GSK:</u> Limit accessibility for children with child resistant packages.	GSK CH is committed to implementing child resistant packaging on all their products.

	FIMEAS response: *Will GSK implement child resistant blister packaging? And if so, the Applicant is asked* *to give an estimate of the timetable for this implementation.*	CRSF foil is implemented for all the registered pack types.

Furthermore, the applicant has also shared a review article on ***"Updated guidelines for the management of paracetamol poisoning in Australia and New Zealand"*** (https://pubmed.ncbi.nlm.nih.gov/31786822/)

iii. Measures to prevent the risk of overdosing after grant of marketing authorization:

PANADOL EXTEND TABLETS - OVERDOSING PREVENTION

Following are the practicable measures which will be adopted to prevent the overdosing risk of paracetamol through our product:

Globally we are mitigating the risk of overdose associated with all paracetamols' containing products including modified-release paracetamol through routine risk minimisation measures that includes product's labelling (GDS), the company's signal management activities and a targeted follow-up questionnaire (TFUQ) for medically confirmed spontaneous reports of liver or hepatobiliary adverse events in the context of paracetamol overdose. Also, our routine pharmacovigilance practices include:

- Established processes for the collection and as required, notification of any adverse events occurring anywhere in the world.
- Established processes for the regular and systematic review of ongoing safety data relating to its pharmaceutical products.

This employs a routine, pro-active process for identifying safety signals with four main components:

A. Ongoing awareness and review of important individual cases, including all reports with a fatal outcome.
B. Systematic, regular and proactive review of aggregate safety data. This includes trend analysis to detect increased frequency of reporting and, qualitative and quantitative methodologies to detect safety signals.
C. Systematic, regular review of the literature.
D. Starting 22 Feb 2018, regular review of data from EudraVigilance, the pharmacovigilance database of the EMA, for products included in EMA's list of medicines under additional monitoring as of 25 Oct 2017. Note that paracetamol is not included in EMA's list of medicines under additional monitoring.

Also, the TFUQ includes a comprehensive set of questions aimed at capturing specific and pertinent details regarding the potential paracetamol overdose such as: patient demographics, whether the patient was hospitalised, the quantity of paracetamol taken, the type of packaging, details about any other drugs ingested and quantities, whether treatment with N-acetylcysteine was given, details of any relevant laboratory results including serum paracetamol levels, N-acetyl-p-benzoquinoneimine and glutathione levels etc. Potential safety issues identified from non-clinical studies, clinical trials, individual case reviews, signal detection and data mining activities, Periodic Benefit Risk Evaluation Report/Periodic Safety Update Reports, from regulatory queries or other sources are carefully evaluated. Adverse drug reactions identified during these reviews are incorporated into the Core Safety Information for paracetamol and subsequently reflected in local country labelling.

On the basis of above locally we have following in place and in process:

1. Updated Patient information leaflet with paracetamol overdosing.
2. We have safety contact, and one may reach out to us through published e-mail and telephone numbers on our product's labelling and packaging.
3. We will establish website and upload right dosing and overdosing information for both healthcare professionals (HCPs) and patients.
4. Our on-ground expert team will reach out hospitals and provide related literature, educate on right dosing and overdosing.
5. In UK we have a website for patient awareness on different products www.letstreatitright.com we will develop one such for Pakistan and see the utility for HCPs and Patients.

In addition to above-mentioned information, the firm has also shared the following statistics regarding overdose instances reported globally with respect to paracetamol containing product:

Data Collected Globally Regarding Overdose Instances of Paracetamol Containing Products:

a. Since, Panadol Extend Tablet was launched, no complaints have been received with respect to formulation safety and no healthcare professional has raised any concern; in fact, this is currently the most in-demand product due to its efficacious nature and ease of administration.
b. Due to proper product labelling w.r.t. its indication, dosage and maximum daily intake quantity, no cases of overdosing or misuse of the product have been reported and nothing was communicated by authorities either.
c. From July 1, 2020, to December 31, 2022, a total of 46 overdose instances of Paracetamol products were reported globally as mentioned below in the country-wise table. Out of these, 20 were paracetamol combination products and junior, or children's, range products of paracetamol. Two of the remaining 26 cases are of Panadol Osteo, which is an SR formulation, while the rest are reported from the source countries as adult Paracetamol overdose cases.

Country	**Count of Case Number**
Australia	14
Sweden	6
Turkey	5
Spain	3
Denmark	2
Peru	2
United Kingdom	2
Canada	1
Russian Federation	1
Finland	1
China	1
South Africa	1
Colombia	1
Sri Lanka	1
New Zealand	1
France	1
Costa Rica	1
Hong Kong	1
India	1
Grand Total	**46**

d. Further dissecting the provided data with the available information of below 26 cases, global overdose instances were less than 26 during the last 30 months, as it includes some reported countries where Paracetamol SR formulation is not on the market. Out of these, 11 are reported as serious cases, and most were reported during the peak COVID period, where healthcare professionals' (HCP) accessibility was compromised.

Country	**Count of Case Number**
Australia	7
Sweden	3
Turkey	5
Spain	1
Denmark	1
United Kingdom	1
Finland	1
China	1
South Africa	1
Colombia	1
New Zealand	1
Costa Rica	1
Hong Kong	1

India	1
Grand Total	**26**

e. As a result, the proposal to educate HCPs and patients via different modes, highlighting the maximum daily intake, warnings and precautions of this formulation are helpful in ensuring its safe use in the local market.

Proceedings of M-326th Meeting:

i. Mr. Abdul Mateen, Deputy Director (Division of Pharmacy Services, DRAP) apprised the Board that the firm has merely reported number of overdose instances regardless of submitting complete case reports. Furthermore, keeping in view the practices adopted by different RRAs/ Non- RRAs, following proposals were also placed for consideration of Registration Board:

a. Possibility for change in prescription status of Panadol Extend Tablet in Pakistan from OTC to prescription only medicine; Or to be sold through pharmacies only across Pakistan *"Pharmacist only"*.
   - Or the firm should be asked about the legal status (OTC, prescription or pharmacist only) in all countries where the drug is registered/marketed.

b. Warning on outer carton/pack regarding the risk
   - Reference: Public assessment report of EMA (Page 24)

https://www.ema.europa.eu/en/documents/referral/paracetamol-article-31-referral-prac-assessment-report_en.pdf

c. Reduction in pack size of OTC product or the firm should be asked to submit detail of pack size in all the countries where the drug is registered/marketed both for prescription and OTC product.
   - 12 caplets in Malaysia and EMA public assessment report (https://www.panadol.com/en-my/adult-products/panadol-extend/
   - Australia has decided to reduce the OTC pack size to 16 from 20 (https://www.tga.gov.au/resources/publication/scheduling-decisions-interim/interim-decision-paracetamol-access-controls-poisons-standard-questions-and-answers)
   - 18 in Singapore (https://www.panadol.com/en-sg/products/adult/muscle-and-joint-pain-relief/panadol-extend.html)
   - 18 in Egypt (https://www.panadol.com/en-eg/products/adult-products/panadol-joint.html)

d. Educational tool for healthcare professionals and patients for reduction of risk of overdose toxicity.

ii. Dr. Ayesha Yaqoob, Govt. Analyst, DTL, Rawalpindi apprise that Board that DTL, Rawalpindi receive some samples from the market, which show different manufacturing sites / MA Holder. Accordingly, the case was taken up by the PQCB regarding availability of 3/three different types of packs of Panadol Extend Tablet in the market.

Decision of 326th meeting:

Registration Board deferred the case on following grounds:

i. The applicant shall submit following information/ documents for further deliberation by the Board:

a. Stability studies of active substance (API) as per conditions of Zone IV-A or/otherwise submission of requisite information/ documents as already decided by the Registration Board in its 290th meeting under "Requirement of The Storage Conditions for The API Stability and FPP Stability".

b. Reports of Pharmaceutical Equivalence and Comparative Dissolution Profile Study performed against the innovator's product.

c. Justification for adopting USP specifications with reference to following claim of innovator's product regarding release profile:

<table>
<tr><td>USP Dissolution Test 1</td><td>Claim of Innovator's Product (regarding release profile)</td></tr>
<tr><td><table><tr><td>Time</td><td>Amount Dissolved</td></tr><tr><td>15min</td><td>45%-65%</td></tr></table></td><td>MR paracetamol tablets are constructed in <u>two layers</u>, an IR layer that is absorbed rapidly (similar to standard paracetamol formulations)</td></tr>
</table>

1h	*60%-85%*	*and a sustained release layer which allows for the gradually release of paracetamol from tablet over a period of 8 hours.*
3h	*NLT 85%*	

ii. *Existing registration holder i.e., M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.TE. Karachi (DML No.000233) shall submit NOC (issued within 6 months) for grant of same brand name in favour of M/s GSK Consumer Healthcare Pakistan Limited, Petaro Road Jamshoro (DML No.000010) along-with a request for withdrawal/ cancellation of registration of Panadol Extend Tablet (R#097070).*

iii. *The firm shall submit the details of its pharmacovigilance system in line with guidelines issued by DRAP regarding the reporting of any ADR/ADE. The firm shall report any ADR/ADE accordingly.*

iv. *Educational tool to be adopted for healthcare professionals and patients to reduce the risk of toxicity associated with overdose*

v. *All the provincial health departments shall be requested to report any case/incidence regarding the Panadol Extend Tablet to the Quality Assurance Division DRAP.*

In line with the decision of 326th meeting of Registration Board, M/s GSK Consumer Healthcare Pakistan Limited, Petaro Road Jamshoro (DML No.000010) has submitted as under:

Table-I

S/N	Required Information/ Documents (As per Decision of M-326)	Response of the Firm	Remarks of Evaluator (Reg-I Section)
I	II	III	IV
1.	Stability studies of active substance (API) as per conditions of Zone IV-A or/otherwise submission of requisite information/ documents as already decided by the Registration Board in its 290th meeting under "Requirement of The Storage Conditions for The API Stability and FPP Stability".	Submitted	Complied.
2.	Reports of Pharmaceutical Equivalence and Comparative Dissolution Profile (CDP) Study performed against the innovator's product.	Submitted	i. In line with the notification No.14-1/2022-PEC dated 16-01-2023, it is required to submit image/ picture/ snapshot of the innovator pack against which pharmaceutical equivalence and CDP have been performed. Provided image/ picture/ snapshot should reveal the details of brand name, manufacturer, batch# and expiry date of the innovator's product. ii. Although, Pharmaceutical Equivalence Report has not been attached with current submission, however, the one shared via e-mail received dated 15-03-2023 has been reviewed wherein release profile/dissolution of the product has been analysed at **"15min, 30min, 60min and 120min"** time points which correspond to **'Table 1'** of the **'Test 1'** described in USP monograph. Similarly, CoA of the innovator's product (shared via email dated 16-03-2023) also depicts that analysis has been performed at aforementioned time-points. While, in current submission, it has been categorically stated that applied

<table>
<tr>
<td></td>
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<td></td>
<td>product conforms to 'Table 2' of 'Test 1' described in USP monograph. Accordingly, clarification is required.

Table 1
<table><tr><th>Time</th><th>Amount Dissolved</th></tr><tr><td>15 min</td><td>45%–65%</td></tr><tr><td>1 h</td><td>60%–85%</td></tr><tr><td>3 h</td><td>NLT 85%</td></tr></table>
Table 2
<table><tr><th>Time</th><th>Amount Dissolved</th></tr><tr><td>30 min</td><td>40%–60%</td></tr><tr><td>90 min</td><td>55%–85%</td></tr><tr><td>4 h</td><td>NLT 80%</td></tr></table></td>
</tr>
<tr>
<td>3.</td>
<td>Justification for adopting USP specifications with reference to following claim of innovator's product regarding release profile:

<table><tr><th>USP Dissolution Test 1</th><th>Claim of Innovator's Product (regarding release profile)</th></tr><tr><td><table><tr><th>Time</th><th>Amount Dissolved</th></tr><tr><td>15min</td><td>45%-65%</td></tr><tr><td>1h</td><td>60%-85%</td></tr><tr><td>3h</td><td>NLT 85%</td></tr></table></td><td>MR paracetamol tablets are constructed in two layers, an IR layer that is absorbed rapidly (similar to standard paracetamol formulations) and a sustained release layer which allows for the gradually release of paracetamol from tablet over a period of 8 hours.</td></tr></table></td>
<td>i.Panadol Extend was formulated in such a way that it follows coated tablets dissolution profile in USP monograph. Kindly refer table 2 of test 1 in USP monograph of Acetaminophen ER Tablet.
Furthermore, for innovator's product claim we are providing GSK/HLX Australia's MAH approval letter, which suggest that it is 8 hours relief over a period of 8 hours, we are reiterating MAH sentence below:
Product Specific Indications
Effective relief from persistent pain for upto 8 hours.

ii.The firm has also submitted that dissolution test is performed as net dissolution of both layers and separate release profile of both layers is not applicable due to following technical rational:
• USP general chapter <711> does not provide any guidance for carrying out dissolution test on individual layers of bi-layered tablets.
• The scientific knowledge also compels to understand that the dissolution of any dosage form is net dissolution of all layers.
• The test method received from innovator I.e., Glaxo Wellcome S.A. Aranda Spain is also check and it is verified that this is the total dissolution time for both layers.
• Reference pharmacopeial specifications for an overall claim of the product i.e., Extended release tablets and it meets the Test 1-Table 2 of USP monograph.</td>
<td>i. Product claim i.e., "Effective relief from persistent pain for upto 8 hours" still need to be justified in the light of description of the product available on Application to amend the Poisons Standard - Modified Release Paracetamol (tga.gov.au) i.e., "MR paracetamol tablets are constructed in two layers, an IR layer and a sustained release layer that gradually releases paracetamol over a period of 8 hours at normal doses."

ii.Furthermore, justification given for adopting finished product specifications (i.e., USP) and for analysing net dissolution of both layers is not sufficient as it will not be able to discriminate between the release profile of IR layer and SR layer.</td>
</tr>
<tr>
<td>4.</td>
<td>Existing registration holder i.e., M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.TE. Karachi (DML No.000233) shall submit NOC (issued within 6 months) for grant of same brand name in favour of M/s GSK Consumer Healthcare Pakistan Limited, Petaro Road Jamshoro (DML No.000010) along-with a request</td>
<td>NOC dated 24-05-2023 has been submitted by GlaxoSmithKline Pakistan Limited, Karachi.</td>
<td>Complied.</td>
</tr>
</table>

	for withdrawal/ cancellation of registration of Panadol Extend Tablet (R#097070).		
5.	The firm shall submit the detail of its pharmacovigilance system in line with guidelines issued by DRAP regarding the reporting of any ADR/ ADE. The firm shall report any ADR/ADE accordingly.	We are providing our Pharmacovigilance System Master File (SOP). It is in alignment with the guideline of good pharmacovigilance practice for registration holders.	Provided document describes pharmacovigilance system for MAHs of the members of the Haleon Group of Companies for Consumer Health (CH) products. However, region specific details (e.g., facilities, training, QPPV etc.,) in line with the guidelines issued by DRAP have not been attached.
6.	Educational tool to be adopted for healthcare professionals and patients to reduce the risk of toxicity associated with overdose.	Product global data sheet (GDS) attached in which complete guidance is available for healthcare professionals and patients to reduce the risk and toxicity associated with overdose.	Provided document is a confidential global data sheet (GDS) which is usually not accessible to health care providers and patients especially in case of OTC products. Even, if accessible, proper counselling of the patient to develop awareness regarding difference between IR and MR formulations of paracetamol is important as both are available over the counter.

Proceedings of 329th Meeting:

Registration Board was apprised that the firm (vide letter received dated 05-06-2023) has submitted response against the remarks mentioned vide column IV of Table-I

Table-II		
S. No.	**Remarks of Evaluator (Reg-I Section)**	**Firm's Response**

<table>
<tr>
<td>1</td>
<td>i. In line with the notification No. 14-1/2022-PEC dated 16-01-2023, it is required to submit image/ picture/ snapshot of the innovator pack against which pharmaceutical equivalence and CDP have been performed. Provided image/ picture/ snapshot should reveal the details of brand name, manufacturer, batch# and expiry date of the innovator's product.

ii. Although, Pharmaceutical Equivalence Report has not been attached with current submission, however, the one shared via e-mail received dated 15-03-2023 has been reviewed wherein release profile/dissolution of the product has been analysed at "15min, 30min, 60min and 120min" time points which correspond to 'Table l' of the 'Test 1' described in USP monograph. Similarly, COA of the innovator's product (shared via email dated 16-03-2023) also depicts that analysis has been performed at aforementioned time-points. While, in current submission, it has been categorically stated that applied product conforms to 'Table 2' of 'Test l' described in USP monograph. Accordingly, clarification is required.

Table 1
<table><tr><th>Time</th><th>Amount Dissolved</th></tr><tr><td>15 min</td><td>45%–65%</td></tr><tr><td>1 h</td><td>60%–85%</td></tr><tr><td>3 h</td><td>NLT 85%</td></tr></table>
Table 2
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<td>We are providing the image of the innovator pack against which pharmaceutical equivalence and CDP have been performed.

Dissolution profile of the product Panadol Extend Tablet fully complies with the acceptance criteria defined under Table-2/ Test I of USP monograph "Acetaminophen Extended-Release Tablets". The same has been demonstrated in comparative dissolution profile (CDP) test report.

Technical transfer and evaluation of this product was made from Glaxo Wellcome S.A. Aranda Spain where it was registered according to innovator's specifications. The dissolution method, time points and acceptance criteria were different from USP monograph as indicated in the COA from innovator. Accordingly, the initial pharmaceutical equivalency report was also indicating innovator's specifications for dissolution test.

After completion of technical transfer, in order to abide by the DRAP circular regarding compliance of Pharmacopeial specifications we had revised the specifications and testing method of dissolution test as per USP monograph and the product is fully compliant with Table-2/ Test 1 of USP monograph "Acetaminophen Extended-Release Tablets".</td>
</tr>
<tr>
<td>2</td>
<td>i. Product claim i.e., "Effective relief from persistent pain for upto 8 hours" still need to be justified in the light of description of the product available on Application to amend the Poisons Standard - Modified Release Paracetamol (tga.gov.au) i.e., "MR paracetamol tablets are constructed in two layers, an IR layer and a sustained release layer that gradually releases paracetamol over a period of 8 hours at normal doses."

ii. Furthermore, justification given for adopting finished product specifications (i.e., USP) and for analysing net dissolution of both layers is not sufficient as it will not be able to discriminate between the release profile of IR layer and SR layer.</td>
<td>For clarification we are providing ARTG link below, under which formulation is registered in TGA. Also please find the summary document of ARTG, supporting 8 hours relief claim as annexed.
PANADOL OSTEO (reformulation) paracetamol 665 mg modified release tablet blister pack (260264) | Therapeutic Goods Administration (TGA)

Regarding performance of dissolution test on individual IR & SR layers, we are performing dissolution test as described in the USP general chapter <711> DISSOLUTION which do not provide any method for performing dissolution test on individual layers. The test method received from innovator i.e. GSK Aranda Spain also states net dissolution for both layers. Furthermore, we could not find any other official method or guideline that could describe any such test.</td>
</tr>
<tr>
<td>3</td>
<td>Provided document describes pharmacovigilance system for MAI-Is of the members of the Haleon Group of Companies for Consumer Health (CFI) products. However, region specific details (e.g., facilities, training, QPPV etc.,) in line with the guidelines issued by DRAP have not been attached.</td>
<td>We have provided our regional master SOP for management of pharmacovigilance in this region (we fall under Europe Middle East region). This was further tailored and implemented locally with requirement deemed necessary as per local regulation. Kindly find attached the details of local safety officer (LSO) as per the issued DRAP guidelines.</td>
</tr>
</table>

4	Provided document is a confidential global data sheet (GDS) which is usually not accessible to health care providers and patients especially in case of OTC products. Even, if accessible, proper counselling of the patient to develop awareness regarding difference between IR and MR formulations of paracetamol is important as both are available over the counter.	We have already provided overdosing preventive practicable measures under the same heading addressed in the agenda at page no. 1262. Therefore, shared internal document (GDS) as master document for implementation. Our expert teams (Field Medical Representatives) will utilise same document for the education of HCPs.

Decision: **Registration Board deferred the case on following grounds:**

i. **DRAP's circular regarding compliance of "Pharmacopeial Specifications" is applicable to those formulations for which product specific monographs have been included in official pharmacopeiae.**
ii. **However, Panadol Extend Tablet 665mg is a modified release bi-layered tablet with defined content/ percentage of active substance in each layer (i.e., 31% in IR layer and 69% in SR layer).**
iii. **Therefore, the firm shall submit sound scientific justification for adopting "USP Monograph for Acetaminophen Extended Release Tablet", keeping in view that the adopted analytical method should be able to discriminate between release behaviour of IR and SR layers of the product.**
iv. **Furthermore, the firm shall also submit justification for adopting 'Table 2' of 'Test 1' (described in USP monograph) which is applicable for "Gelatin Coated Tablet" (as stated in USP), keeping in view that the submitted/ claimed formulation and manufacturing method of 'Panadol Extend Tablet' does not involve 'gelatin coating'.**
v. **Furthermore, keeping in view that "Panadol Extend Tablet (Reg. No. 097070)" has been registered since July, 2019 and despite of the fact that different reference regulatory authorities/ agencies (i.e., TGA, Finland) have adopted several measures to address the risk associated with overdosing/toxicity of the product, the firm has failed to develop a well-established system for addressing pharmacovigilance activities. Accordingly, Registration Board showed displeasure on absence of well-established pharmacovigilance system in such a renowned firm i.e., M/s GSK Consumer Healthcare Pakistan Limited, Petaro Road Jamshoro (DML No.000010).**

Registration-II Section

Case No.01: Issuance of Duplicate Registration Letter

M/s. P.D.H Laboratories (Pvt) Ltd. 9.5-Km Sheikhupura Road (Khaki) Lahore has submitted an application for Duplicate Registration Letter of following products as original registration letters were misplaced during shifting of their head office. Detail of products is as under:

Sr. No.	Registration Number	Brand Name and Composition
1.	**000794**	Aqua Pro Injection 5ml
2.	**000793**	Atropine Injection 1mg/ml
3.	**000784**	Benzyl Pencillin 5 Lac
4.	**000786**	Benzyl Pencillin 10 Lac

5.	**000792**	Chloroquine Phosphate Injection 5ml
6.	**000790**	La'Pen Injection 12 Lac
7.	**000791**	La'Pen Injection 6 Lac
8.	**000785**	Polybiotic Injection 1gm
9.	**000782**	Procaine Penicillin Forte 4 Lac
10.	**000783**	Streptomycin Injection 1gm

Firm has also submitted following documents:

i. Fee of Rs.7500/- each for issuance of duplicate registration letter, verified from website.
ii. Notarized copy of FIR.
iii. Copy of Newspaper in which advertisement reading loss of registration letters was published.
iv. Affidavit regarding contents of application for duplicate registration letter

As per computerized record (RDI) which is also confirmed from The Gazetter of Pakistan, Extra, October, 14, 1981 above mentioned products are registered with following details.

Sr. No.	Registration Number	Brand Name and Composition	Pack Size	MRP
1.	**000782**	Procaine Penicillin Forte Injection 4lac Each vial contains: Procaine Penicillin 4 lac	4 lac 20 lac	Rs.1.42/- Rs.4.08/-
2.	**000783**	Streptomycin Injection Each vial contains: Streptomycin Sulphate 1gm	1 vial	Rs.1.50/-
3.	**000784**	Benzyl Pencillin Injection 5lac Each vial contains: Benzyl Penicillin 5 lac	1 vial	Rs.1.42/-
4.	**000785**	Streptomycin Procaine Penicillin Forte Injection Each vial contains: Streptomycin Sulphate 1gm Procaine Penicillin 3,00,000 Units Benzyl Penicillin 1,00,000 Units	1 vial	Rs.2.67/-
5.	**000786**	Benzyl Pencillin Injection 10lac Each vial contains: Benzyl Penicillin 10 lac	1ml	Rs.2.20/-
6.	**000790**	Benzathine Penicillin Injection 12 lac Each vial contains: Benzathine Penicillin 12 lac	1 vial	Rs.4.50/-
7.	**000791**	Benzathine Penicillin Injection 6 lac Each vial contains: Benzathine Penicillin 6 lac	1 vial	Rs.2.45/-
8.	**000792**	Chloroquine Phosphate Injection Each ml contains: Chloroquine Phosphate 40mg	5ml x 100	Rs.82/-

9.	**000793**	Atropine Sulphate Injection Each ml contains: Atropine Sulphate 1mg	1ml x 100	Rs.25/-
10.	**000794**	Aqua Pro Injection Each ampoule contains: Aqua Pro Injection	100 x 5ml	Rs.30/-

Case was referred to RRR Section for confirmation of renewal status of these products and reply of RRR Section is reproduced as under:

> *"The renewal applications for the year 2021 and 2016 were submitted within time w.r.t date of registrations as provided by the firm in renewal application.*
>
> *The section is requested to verify the date of registration from their record as the copies of the registration letters are not submitted by the firm in aforesaid renewal applications*."

Decision of 323rd Meeting of RB.

> **Registration Board advised to seek guidance from Legal Affair Division.**

Case was referred to Legal Affair's Division for their opinion which is reproduced as under:

> ***"…that duplicate registration letter may be issued to the firm after duly verification of previous letter, MRP issued on that very letter, Gazette notification and non-cognizable police report. Moreover, the duplicate registration letter will have same contents as contained in original letter issued to the firm including MRP mentioned at original letter. Moreover, on duplicate registration letter, the word 'Duplicate' must be mentioned on the letter".***

Extract of requisite products from The Gazetter of Pakistan, Extra, October, 14, 1981 is attached as under:

000768. ALLERPHENE TABLET (P.D.H)
Chlorpheniramine Maleate 4 mg.
1000's : 14.10.

000769. SULPHADIMIDINE TABLET (P.D.H)
Sulphadimidine 0.5 gm.
1000's : 66.00 ; 5000's : 248.75.

000770. ZINCOCID EYE DROPS (P.D.H)
Each 100 ml contains :—
Boric acid 1.6 gm.
Zinc Sulphate 0.46 gm.
20ml : 2.95.

000771. BENZYL BENZOATE APPLICATION (P.D.H)
Each ml contains :—
Benzyl Benzoate 25% w/v
60 ml : 3.00 ; 1 lb : 14.70. 120ml5.00

000772. PANOCID EYE DROPS 10% (P.D.H)
Each 10 ml contains :—
Solution of Sulphacetamide Sodium 10%
10cc : 3.40.

000773. PANOCID EYE DROPS 20% (P.D.H)
Each 10 ml contains :—
Solution of Sulphacetamide Sodium 20%
10 cc : 4.00

000774. PANOCID EYE DROPS 30% (P.D.H)
Each 10 ml contains :—
Solution of Sulphacetamide sodium 30%
(Sulphacetemide Sodium 3gm)
10ml : 4.25.

000775. SULPHADIAZINE TABLET (P.D.H)
Sulphadiazine 0.5 mg.
1000's : 76.00

000776. TRISULPHA TABLET (P.D.H)
Each tablet contains :—
Sulphadiazine 167.0 mg.
Sulphadimidine 167.0 mg.
Sulphamerazine 167.0 mg.
1000 s : 50.00. 100 : 14.00

000777. AMMONIUM CHLORIDE COUGH SYRUP (P.D.H.)
Each ml contains :—
Ammonium Chloride 100 mg.
Sodium Citrate 60 mg.
Chlorpheniramine Maleate 2 mg.
Ephedrine Hydrochloride 7 mg.
Menthol crystal 1 mg.
120 ml : 5.00 ; 450 ml 14.50

000778. VITAMIN C TABLET 100 (P.D.H.)
Ascorbic Acid 100 mg.
100's : 3.50 ; 1000's : 29.75.

000779. VITAMIN C TABLET 500 mg. (P.D.H.)
Ascorbic Acid 500 mg.
40's : 6.25.

000780. SODIUM CHLORIDE INJECTION 0.9% (P.D.H.)
Each 100 ml contains :—
Sodium Chloride 0.9 mg.
100 × 10 ml : 60.00

000781. CYANOCOBALAMIN INJECTION (P.D.H.)
Cyanocobalamin 1000 mcg.
10 ml : 6.20.

000782. PROCAINE PENICILLIN FORTE INJECTION 4 LAC (P.D.H.)
Each vial contains :—
Procaine Penicillin 4 lac.
4 lac : 1.42 ; 20 lac : 4.08.

000783. STREPTOMYCIN INJECTION (P.D.H.)
Each vial contains :—
Streptomycin Sulphate 1 gm.
1 vial : 1.50.

000784. BENZYL PENCILLIN INJECTION 5 lac (P.D.H.)
Each vial contains :—
Benzyl Penicillin 5 lac
One vial : 1.42.

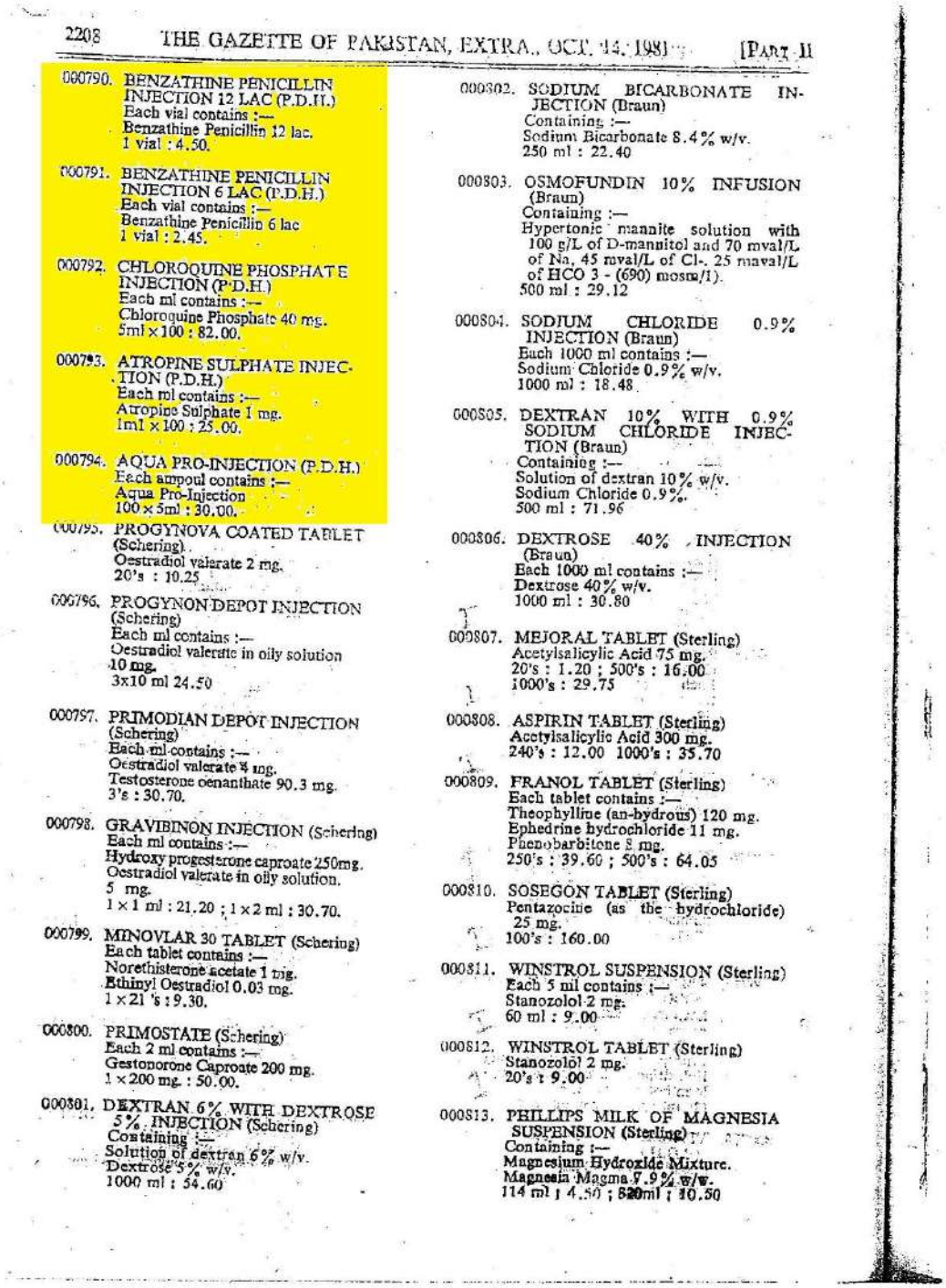
000785. STREPTOMYCIN PROCAINE PENICILLIN FORTE INJECTION (P.D.H.)
Each vial contains :—
Streptomycin Sulphate 1 gm.
Procaine Penicillin 3,00,000 Units.
Benzyl Penicillin 1,00,000 Units.
One vial : 2.67.

000786. BENZYL PENCILLIN INJECTION 10 LAC (P.D.H.)
Each vial contains :—
Benzyl Penicillin 10 lac.
1 ml : 2.20.

000787. NIKETHAMIDE INJECTION (P.D.H.)
Containing :—
Niketharnide 25%.
One vial : 1.40 ; 1 × 100 : 45.00

000788. DEXTROSE 25% INJECTION (P.D.H.)
Each 100 ml contains :—
Dextrose 25 gm.
25 × 25 ml : 50.00

000789. SULPHADIMIDINE SODIUM 33.33% (vety) (P.D.H.)
Each 100 ml contains :—
Sulphadimidine Sodium 33.33 gm.
100 ml : 12.00.



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000790. BENZATHINE PENICILLIN INJECTION 12 LAC (P.D.H.)
Each vial contains :—
Benzathine Penicillin 12 lac.
1 vial : 4.50.

000791. BENZATHINE PENICILLIN INJECTION 6 LAC (P.D.H.)
Each vial contains :—
Benzathine Penicillin 6 lac
1 vial : 2.45.

000792. CHLOROQUINE PHOSPHATE INJECTION (P.D.H.)
Each ml contains :—
Chloroquine Phosphate 40 mg.
5ml×100 : 82.00.

000793. ATROPINE SULPHATE INJECTION (P.D.H.)
Each ml contains :—
Atropine Sulphate 1 mg.
1ml × 100 : 25.00.

000794. AQUA PRO-INJECTION (P.D.H.)
Each ampoul contains :—
Aqua Pro-Injection
100 × 5ml : 30.00.

000795. PROGYNOVA COATED TABLET (Schering)
Oestradiol valerate 2 mg.
20's : 10.25

000796. PROGYNON DEPOT INJECTION (Schering)
Each ml contains :—
Oestradiol valerate in oily solution
10 mg.
3x10 ml 24.50

000797. PRIMODIAN DEPOT INJECTION (Schering)
Each ml contains :—
Oestradiol valerate 5 mg.
Testosterone oenanthate 90.3 mg.
3's : 30.70.

000798. GRAVIBINON INJECTION (Schering)
Each ml contains :—
Hydroxy progesterone caproate 250mg.
Oestradiol valerate in oily solution.
5 mg.
1 × 1 ml : 21.20 ; 1 × 2 ml : 30.70.

000799. MINOVLAR 30 TABLET (Schering)
Each tablet contains :—
Norethisterone acetate 1 mg.
Ethinyl Oestradiol 0.03 mg.
1 × 21 's : 9.30.

000800. PRIMOSTATE (Schering)
Each 2 ml contains :—
Gestonorone Caproate 200 mg.
1 × 200 mg. : 50.00.

000801. DEXTRAN 6% WITH DEXTROSE 5% INJECTION (Schering)
Containing :—
Solution of dextran 6% w/v.
Dextrose 5% w/v.
1000 ml : 54.60

000802. SODIUM BICARBONATE INJECTION (Braun)
Containing :—
Sodium Bicarbonate 8.4% w/v.
250 ml : 22.40

000803. OSMOFUNDIN 10% INFUSION (Braun)
Containing :—
Hypertonic mannite solution with 100 g/L of D-mannitol and 70 mval/L of Na, 45 mval/L of Cl-, 25 mval/L of HCO 3 - (690) mosm/l).
500 ml : 29.12

000804. SODIUM CHLORIDE 0.9% INJECTION (Braun)
Each 1000 ml contains :—
Sodium Chloride 0.9% w/v.
1000 ml : 18.48

000805. DEXTRAN 10% WITH 0.9% SODIUM CHLORIDE INJECTION (Braun)
Containing :—
Solution of dextran 10% w/v.
Sodium Chloride 0.9%.
500 ml : 71.96

000806. DEXTROSE 40% INJECTION (Braun)
Each 1000 ml contains :—
Dextrose 40% w/v.
1000 ml : 30.80

000807. MEJORAL TABLET (Sterling)
Acetylsalicylic Acid 75 mg.
20's : 1.20 ; 500's : 16.00
1000's : 29.75

000808. ASPIRIN TABLET (Sterling)
Acetylsalicylic Acid 300 mg.
240's : 12.00 1000's : 35.70

000809. FRANOL TABLET (Sterling)
Each tablet contains :—
Theophylline (an-hydrous) 120 mg.
Ephedrine hydrochloride 11 mg.
Phenobarbitone 8 mg.
250's : 39.60 ; 500's : 64.05

000810. SOSEGON TABLET (Sterling)
Pentazocine (as the hydrochloride) 25 mg.
100's : 160.00

000811. WINSTROL SUSPENSION (Sterling)
Each 5 ml contains :—
Stanozolol 2 mg.
60 ml : 9.00

000812. WINSTROL TABLET (Sterling)
Stanozolol 2 mg.
20's : 9.00

000813. PHILLIPS MILK OF MAGNESIA SUSPENSION (Sterling)
Containing :—
Magnesium Hydroxide Mixture.
Magnesia Magma 7.9% w/w.
114 ml : 4.50 ; 820ml : 10.50

Proceedings of 329th Meeting:

The Legal Affairs Division has been summoned to present themselves before the Board in order to provide clarification regarding their aforementioned opinion. Assistant Director of the Legal Affairs Division, appeared before the Registration Board to discuss the case in thorough detail. It is important to

note that the renewal applications for the years 2021 and 2016 were duly submitted within the specified timeframe, as indicated by the RRR Section of the PE&R Division of DRAP. Moreover, evidence of product registration can be found on pages 2207-2208 of the notification published in the Gazette of Pakistan on October 14, 1981. Hence, based on these factual considerations, the Board may issue the Duplicate Registration Certificate in compliance with the relevant laws

Decision: **Registration Board after through deliberation decided to issue duplicate registration letter to M/s. P.D.H Laboratories (Pvt) Ltd. 9.5-Km Sheikhupura Road (Khaki) Lahore as per details mentioned in The Gazette of Pakistan, Extra, October, 14, 1981.**

Case No 02: **Allocation of Quota for Control Substances Ephedrine HCl for the year 2017 to M/s. Sharex Laboratories, Sadiqabad.**

The case of M/s. Sharex Laboratories, Sadiqabad was considered in 275th and 286th meeting of Registration Board as per detailed below: -

2. Proceedings of 275th Meeting of Registration Board:

The instant case was presented based on the letter received from Assistant Director (CD) (Dated 21st Sep, 2017) wherein it has been stated that M/s Sharex Laboratories, sadiqabad applied for quota allocation of product Tracodil syrup (Reg. 003158). The case was presented before 43rd meeting of committee on allocation of controlled drug held on 26th July, 2017, the committee deferred the case for issuance of show cause by DRAP for manufacturing of Tracodil syrup (Reg. 003158) 60ml, 400ml pack without approval. It was requested to verify the status of product registration of Tracodil syrup (Reg. 003158) 400ml pack size.

The approved pack sizes of product Tracodil Syrup‖ (Reg. No. 003158) have been verified as per available record i.e 120ml, 450ml (National Formulary 1981) and 60ml (dated 27th October 1988).

3. Decision of 275th meeting of Registration Board:

Registration decided to call M/s Sharex Laboratories, Sadiqabad for personal hearing and for deliberating above mentioned matter before the Registration Board.

4. **Proceedings of 286th meeting of Registration Board:**

Mr. Muhammad Ishfaq, production pharmacist, appeared before Registration Board and apologized on behalf of the firm for applying quota of 400ml pack size of product Tracodil syrup (Reg.003158) without approval.

5. Decision of 286th meeting of Registration Board:

Registration Board in its 286th meeting decided to refer the case to Legal Affair division for legal opinion.

6. Accordingly, the case was refer to Legal Affairs, Division and in response, Legal Affairs, Division has provided following opinion:

i. That M/s. Sharex Laboratory applied for the quota allocation of product Tracodil Syrup (Reg.No.003158).

ii. That the Committee on Allocation of Controlled Drugs held on 26.07.2017 deferred the case for issuance of show cause by DRAP for manufacturing of "Tracodil Syrup" (Reg.No.003158) 60ml, 400ml pack without approval. It was requested to verify the status of product registration of "Tracodil Syrup" (Reg.No.003158) and 60ml (dated 27th October, 1988).

iii. That the approved pack size of the product "Tracodil Syrup" (Reg.No.003158) have been verified as per available record i.e 120ml, 450ml (National Formulary 1981) and 60ml (dated 27th October, 1988).

iv. That Mr. Muhammad Ishfaq production pharmacist, appeared in 286th meeting before Board and apologized on behalf of the firm for applying quota of 400ml pack size of product "Tracodil Syrup" (Reg.No.003158) without approval.

v. That the Registration Board in 286th meeting referred the case to Legal Affairs, Division for legal opinion.

vi. Drug Regulatory Authority of Pakistan Act, 2012 in Schedule-II A(1) (a) (vii) prohibits export, import or manufacture and sale or sell of any therapeutic goods which is not registered or is not in accordance with conditions of registration as disclosed in the registration dossier and that has undergone pharmaceutical evaluation. Furthermore, Schedule-II(A)(c) prohibits to sell any therapeutic goods except under, and in accordance with the conditions of a license issued under this Act. In addition, Schedule-II A(a)(f) prohibit to supply an incorrect, incomplete or misleading information when required to furnish any information under this Act or the rules.

vii. In this regard, DRAP Act, 2012 under section 27 read with schedule-III (6) provides penalty for violating the prohibitions mentioned above.

7. Decision of 289th meeting of Registration Board:

In light of the opinion of Legal Affair's Division on the matter, Registration Board deliberated the case and decided to issue show cause notice to M/s Sharex Laboratories, Sadiqabad for violation of condition of drug registration, as follows:

- Cancellation of registration.
- Suspension of registration.
- Prosecution in Drug Court

8. Accordingly, show cause notice was served to M/s. Sharex Laboratories, Sadiqabad.

9. Registration Board in its 295th meeting deliberated on the matter in details and decided to give an opportunity of personal hearing as per Drug Act, 1976 and Rules framed there under to M/s. Sharex Laboratories, Sadiqabad in forthcoming meeting of Registration Board.

10. In 296th meeting M/s. Sharex Laboratories, Sadiqabad was called for personal hearing. Mr. Muhammad Ishfaq, production pharmacist, appeared before Registration Board and apologized on behalf of the firm and stated that firm was unaware about the approval of pack sizes of Tracodil Syrup (Reg.No.003158) as on initial registration letter no pack size was written. He has further stated that firm will submit all the relevant documents / approvals granted by DRAP regarding said product.

11. Registration Board in 296th meeting deferred the case for further deliberation after submission of documents as stated by representative of the firm.

In compliance with 296th meeting of Registration Board firm has submitted following documents;

i. Initial registration letter of Ammonium Chloride Syrup Reg. No. 003158 dated 06-11-1977 in which Pack size & MRP are not mentioned.

ii. Change of brand name letter from Ammonium Chloride Syrup to Tracodil Cough Syrup dated 16-08-1979

iii. Price revision of locally manufactured / fixation of prices of additional packs letter dated 27-10-1988 in which Pack sizes along with MRPs are mentioned with following details;

Sr. No.	Reg. No.	Name of Drug	Packing	MRP
1.	003158	Tracodil Cough Syrup	120ml	8.00
			60ml	5.00
			450ml	18.50

12. **Decision of 308th Meeting of registration board:**

Registration Board after through deliberation decided as follows:

- Referred the case to Costing & Pricing Division for proceeding as per rules for overcharging of MRP.
- Manufacturing of product as per approval granted by relevant forums.

13. Accordingly, above decision of Registration Board was communicated to Costing & Pricing Division and reply of said Division is as under;

"In light of opinion of the Legal Division, the matter is of selling of an un-approved pack size which may fall under violation of the conditions of Registration. Moreover, no evidence of overpricing has been provided. Therefore, Division of PE&R may proceed in accordance with the opinion of the Legal Division."

14. Opinion of Legal Affair's Division is as under;

i. Drug Regulatory Authority of Pakistan Act, 2012 in Schedule-II A(1) (a) (vii) prohibits export, import or manufacture and sale or sell of any therapeutic goods which is not registered or is not in accordance with conditions of registration as disclosed in the registration dossier and that has undergone pharmaceutical evaluation. Furthermore, Schedule-II(A)(c) prohibits to sell any therapeutic goods except under, and in accordance with the conditions of a license issued under this Act. In addition, Schedule-II A(f) prohibit to supply an incorrect, incomplete or misleading information when required to furnish any information under this Act or the rules.

ii. In this regard, DRAP Act, 2012 under section 27 read with schedule-III (6) provides penalty for violating the prohibitions mentioned above.

Decision of 317th meeting of RB

Registration Board deliberated on the matter in details and decided to give an opportunity of personal hearing as per Drug Act, 1976 and Rules framed there under to M/s. Sharex Laboratories, Sadiqabad in forthcoming meeting of Registration Board.

As per above decision of the Board, case was referred to **Legal Affairs Division and opinion of said division** is as under:

"The apex courts have guided that Principles of natural justice must be read into each and every statute unless and until it is prohibited by the statute itself---Even if there is no provision as to issuance of notice of personal hearing to the affected party, in a statute, it cannot override the principles of natural justice and an opportunity of a hearing has to be provided to the affected party. Registration Board is statutory Board constituted under Section 7 of the drugs act, 1976. And if some new facts came before the Registration Board regarding the firm, then an opportunity of personal herring may be provided to the firm before final decision of the Board if it thinks fit to fulfill the principle of natural justice. It is pertinent to note that in case of any grievance the firm has alternate remedy of appeal under Section 9 of the drugs act, 1976 before the Appellate Board of the Authority."

Proceedings of 323rd Meeting:

It was discussed in meeting that before proceeding for penalty for prohibitions, as per opinion of the Legal Affair's Division mention in para 14 above, show-cause notice has to be issued to the firm for violation of condition of registration as firm is manufacturing un-approved pack size of their registered product.

Decision of 323rd Meeting of the Board

Registration Board decided to issue show-cause notice under Section 7 (11) (c) to M/s. Sharex Laboratories (Pvt) Ltd. KLP Road Sharex Colony, P.O Box No. 11, Sadiqabad District Rahim Yar Khan for violation of condition of registration.

As per above decision of the Board, Show-Cuase notice has been issued to the firm and reply of the firm is as under:

i. They have submitted that they have been manufacturing Tracodil Syrup (Ammonium Chloride Syrup) since 1965. When the Drug Act 1976 got implemented, they were issued a Registration Letter dated 06-11-1977 for Ammonium Chloride Syrup having registration number 003158. In this letter no pack size and no retail price was mentioned.

ii. On 16-08-1979, another letter was issued by Ministry of Health granting them the named of Tracodil Syrup for their registered product Ammonium Chloride Syrup Reg.No.003158.

iii. On 27-11-1988, a letter was issued for Tracodil Syrup where 60ml, 120ml and 450ml pack sizes were mentioned with MRP. It is important to mention that this product was de-controlled for pricing till 2000. At that time firm was manufacturing Tracodil Syrup in 400ml pack size and continued producing in the same pack size. As the price was decontrolled at that time, fixing MRP was not used to be an issue at that time.

iv. Firm continued producing and submitting Ephedrine HCl consumption record of Tracodil Syrup till early 2017 until the Assistant Director (CD) mentioned it in her letter dated 20-04-2017. It is to clarify that the consumption record the Ephedrine HCl was absolutely correct and no discrepancy was found as far as the consumption of Ephedrine was concerned.

v. They have further submitted that no mal intention what so ever was involved in the production of "Tracodil Syrup" 400ml as consumption record for Ephedrine HCl was submitted according to 400ml pack size. As this is 55-year-old registered product and at that time there were not much regulations and price was also de-controlled, this product somehow mistakenly kept manufactured in this pack size.

vi. They have requested to kindly forgive this mistake of their, as they are in this business for around 6 decades and never been involved in any unlawful activity.

Now, firm has been called for personal hearing.

Proceedings of 329th meeting:

M/s. Sharex Laboratories, Sadiqabad was called for personal hearing. Mr. Muhammad Ishfaq, production pharmacist, appeared before Registration Board and stated that they were manufacturing pack size of 400ml as till 2000, MRP of their product was decontrolled.

Decision: Registration Board deferred the case for further deliberation.

Case No.03: Cancellation Registration of Drugs in lieu of cancellation of DML/Surrender of Sections

Central Licensing Board in its 287th meeting held on 04-06-2022 approved "Syrup Section" in place of "Liquid Vial (Infusion) Section" of M/s. Caraway Pharmaceuticals, Plot No. 12 Street No. N-3 National Industrial Zone, Rawat under Drug Manufacturing License No. 000629 (Formulation).

Accordingly, M/s. Caraway Pharmaceuticals was issued show cause notice.

Now, firm has been called for personal hearing.

Proceedings of 329th meeting:

M/s. Caraway Pharmaceuticals, Rawat was called for personal hearing. Syed Tauqeer Ali (COO) and Mr. Murad Ali (QCM) appeared before Registration Board and stated that they are shifting of their liquid infusion products for toll manufacturing to M/s. Linear Pharma.

Decision: Registration Board decided to refer the case to PR Section of PE&R Division.

Case No. 04: Registration of Drug(s)

Registration Board in its different meetings approved following products in the name of firms mentioned against each and registration letters are pending due to reasons also mentioned against each. Shortcoming letters as well as reminder letters were issued to these firms but response of the firm is still pending. Detail of products along with meeting number of the Board is as under:

Sr. No.	Name of Product	Name of Registration Holder	Reason for non-issuance of Registration Letter	Meeting of Registration Board

1.	Bpride Tablets	M/s. Shaigan Pharmaceuticals,14 Km, Adyala Road, Post Office Dahgal, Rawalpindi	Submission of alternate brand names and fee for change of specs	296
2.	MOXILEX Tablet 400mg	M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore.	Verification of fee challan is required, Fee for change of specifications, BNR	296
3.	Tramax 50mg Injection	M/s Vision Pharmaceuticals, Plot No. 22 & 23, Industrial Triangle Kahuta Road, Islamabad.	Fee for change of title is required.	296
4.	Orbic- C 500 Tablet	M/s Aneeb Pharmaceuticals Pvt Ltd., 24-Km Bedian Road, Lahore	Clarification of formulation required as chewable tablet is approved in RRA	296
5.	Pharmedic Vitamin C 500mg Tablet	M/s Pharmedic Laboratories Pvt Ltd.,16-km, Multan Road Lahore	Clarification of formulation required as chewable tablet is approved in RRA	296
6.	Logestrel tablet 0.75mg	M/s Fredmann Pharmaceuticals, Plot No.82-83, B, Old Industrial Area, Mirpur, AJK.	Approval for steroidal hormone section from Licensing Division before issuance of Registration letter	297
7.	Tegaser tablet 2mg	M/s Well & Well Pharma (Pvt.) Ltd., Plot No. 7, Street No. S- 8, National Industrial Zone, Rawat, Islamabad	Submission of alternate brand names and fee for change of specs	297
8.	Tegaser tablet 6mg	M/s Well & Well Pharma (Pvt.) Ltd., Plot No. 7, Street No. S- 8, National Industrial Zone, Rawat, Islamabad	Submission of alternate brand names and fee for change of specs	297
9.	Febogen 80mg Tablets	M/s Genesis Pharmaceuticals Pvt Ltd., Plot No. 25, Sunder Industrial Estate, Sunder, Lahore	Fee for change of Specs	307
10.	Misoben 200mcg Tablet	M/s Benson Pharmaceuticals Plot # 3, Main road RCCI industrial estate Rawat	Fee for change of Specs	307
11.	Mecowin Injection 500mcg	M/s Winilton Pharmaceuticals (Pvt.) Ltd., Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad.	Fee for change of Specs	316
12.	Irowin 100mg Injection	M/s Winilton Pharmaceuticals (Pvt.) Ltd., Plot # 45, Street # S-5, National Industrial Zone, Rawat, Islamabad.	Fee of Rs. 75,000 for standardization of label claim.	316

13.	J-Lac .3.355g /5ml Syrup	M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan	Submission of GMP Certificate/DML of API Manufacturer and Stability Study of Lactitol	316
14.	ONDATRO Syrup 4mg/5ml	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 35-A, Small Industrial Estate, Taxila.	Fee for correction in label claim	317
15.	ZOLONAF Capsule 150 mg	M/s Dynatis Pakistan Pvt Ltd., Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore	Submission of alternate brand names	317
16.	Wilxime 400mg capsules	M/s. Winilton pharmaceutical (Pvt) Ltd. Plot No.45, Street S-5, National Industrial Zone, Rawat-Islamabad	Submission of alternate brand names	317
17.	Wilxime suspension 100mg/5ml	M/s. Winilton pharmaceutical (Pvt) Ltd. Plot No.45, Street S-5, National Industrial Zone, Rawat-Islamabad	Submission of alternate brand names	317
18.	Wilxime DS suspension 200mg/5ml	M/s. Winilton pharmaceutical (Pvt) Ltd. Plot No.45, Street S-5, National Industrial Zone, Rawat-Islamabad	Submission of alternate brand names	317
19.	Wilpine 500mg injection	M/s. Winilton pharmaceutical (Pvt) Ltd. Plot No.45, Street S-5, National Industrial Zone, Rawat-Islamabad	Submission of alternate brand names	317
20.	Wilpine 1gm injection	M/s. Winilton pharmaceutical (Pvt) Ltd. Plot No.45, Street S-5, National Industrial Zone, Rawat-Islamabad	Submission of alternate brand names	317
21.	Wincef 250mg injection (IV)	M/s. Winilton pharmaceutical (Pvt) Ltd. Plot No.45, Street S-5, National Industrial Zone, Rawat-Islamabad	Submission of alternate brand names.	317
22.	Wincef 500mg injection (IV)	M/s. Winilton pharmaceutical (Pvt) Ltd. Plot No.45, Street S-5, National Industrial Zone, Rawat-Islamabad	Submission of alternate brand names	317
23.	Wincef 1gm injection (IV)	M/s. Winilton pharmaceutical (Pvt) Ltd. Plot No.45, Street S-5, National Industrial Zone, Rawat-Islamabad	Submission of alternate brand names	317
24.	Wilbac1gm injection	M/s. Winilton pharmaceutical (Pvt) Ltd. Plot No.45, Street S-5, National Industrial Zone, Rawat-Islamabad	Submission of fee of Rs.75,000/- for correction in formulation as per decision of DRB and alternate brand names.	317

25.	Wilbac 2gm injection	M/s. Winilton pharmaceutical (Pvt) Ltd. Plot No.45, Street S-5, National Industrial Zone, Rawat-Islamabad	Submission of alternate brand names	317

Decision: **Registration Board after through deliberation decided to issued final reminder to above mentioned firms to fulfil above mentioned queries within one month after approval of minutes.**

Case No. 05: **Report on Assessment and Confirmation of Manufacturing Capacity of M/s. Cure Laboratories (Pvt) Ltd, Plot No. 11-12, Street No. NS-2 RCCI, Rawat (DML No. 000897)**

Reference No: F.5-1/2023-Reg-II (M-323) (Misc.)

Inspection Date: 20th March, 2023.

Background: The inspection was conducted on 20.03.2023 in compliance to letter of Assistant Director (Reg-II) vide No.5-1/2023-Reg-II(M-323) (Misc.) dated 07.02.2023

Composition of Panel:

i. Muneeb Ahmed Cheema, Deputy Director PE&R, DRAP Islamabad.
ii. Adil Saeed, Deputy Director PEC-IX, DRAP Islamabad.

Scope of Inspection:

The inspection was conducted for assessment and confirmation of manufacturing capacity of M/s Cure Laboratories (Pvt) Ltd, Plot # 11-12, Street # NS-2,RCCI, Rawat for following sections;

i. Dry Powder Injection (Cephalosporin).
ii. Dry Powder Suspension (Cephalosporin).
iii. Capsule (Cephalosporin).

Manufacturing record/data of last Quarter of 2022 **(1st September 2022 to 31st December 2022)** and 1st Quarter of year 2023 (**1st January, 2023 to March, 2023 till date**) was evaluated for aforementioned purpose. The details of capacity calculations are as under:

Registered Products				
	Dry Powder Injection (Cephalosporin) Section	Dry Powder Suspension (Cephalosporin) Section	Capsules (Cephalosporin) Section	Total
Total registered products of manufacturer	41	17	13	71
Registered Products on Contract from the manufacturer	Nil	02	01	03
Total	41	19	14	74

A. CAPACITY OF DRY POWDER FOR INJECTION (CEPHALOSPORIN) SECTION.

Manufacturer's total Registrations	*Manufacturer's Pending applications*	*Contract Products Registrations*	*Contract products Pending applications*
41	Nil	Nil	11

STEP WISE CAPACITY OF EACH PROCESS				
	Process/Step 1: **Vial Washing**	**Process/step 2: Depyrogenation Capacity**	**Process / step 3: Filling and Sealing Capacity**	**Process/ Step 4: Packing Capacity**

Per day (8 hours working shift)	21,600 Vials	18,000 Vials	21,600 Vilas	30,000 Vials
Per month (22 working days)	475,200 Vials	396,000 Vials	475,000 Vials	660,000 Vials

Capacity calculated with respect to the depyrogenation being capacity limiting step

QUARTER WISE CAPACITY UTILIZED			
Quarter	**Actual Production**	**Capacity w.r.t capacity limiting step**	**Capacity utilized in %**
2nd (1st April-30th June 22)	175,083 vials	1,425,000	12.3%
3rd (1st July- 30th sept 22)	213,837 vials	1,425,000	15%
4th (1st Oct – 31st Dec 22)	178,933 vials	1,425,000	12.6%
1st (1st Jan – 31st March 2023)	140,575 vials	1,425,000	9.9%
Average Capacity Utilized			12.45%

Manufacturing Capacity Utilized (average): 12.45%
Manufacturing Capacity Available (average): 87.55%

B. CAPACITY OF DRY POWDER FOR SUSPENSION (CEPHALOSPORIN) SECTION.

Manufacturer's total Registrations	*Manufacturer's Pending applications*	*Contract Products Registrations*	*Contract products Pending applications*
17	Nil	02	06

STEP WISE CAPACITY OF EACH PROCESS				
	Process/Step 1: **Bottle Blowing**	Process/step 2: **Mixing**	Process / step 3: **Filling**	Process/ Step 4: **Packing**
Per day (8 hours working shift)	14,400 Bottles	200 Kg	16,800 Bottles	30,000 Bottles
Per month (22 working days)	316,800 Bottles	4400 Kg	369,600 Bottles	660,000 Bottles

Capacity calculated with respect to the Bottle Blowing being capacity limiting step

QUARTER WISE CAPACITY UTILIZED			
Quarter	**Actual Production**	**Capacity w.r.t capacity limiting step**	**Capacity utilized in %**
2nd (1st April-30th June 22)	45,682 bottles	1,108,800	4.12%
3rd (1st July- 30th sept 22)	31,031 bottles	1,108,800	2.8%
4th (1st Oct – 31st Dec 22)	44,438 bottles	1,108,800	4%
1st (1st Jan – 31st March 2023)	79,730 bottles	1,108,800	7.2%
Average Capacity Utilized			4.53 %

Manufacturing Capacity Utilized (average): 4.53%
Manufacturing Capacity Available (average): 95.47%

C. CAPACITY OF CAPSULE (CEPHALOSPORIN) SECTION.

Manufacturer's total Registrations	*Manufacturer's Pending applications*	*Contract Products Registrations*	*Contract products Pending applications*
13	Nil	01	02

STEP WISE CAPACITY OF EACH PROCESS

	Process/Step 1: **Mixing**	**Process/step 2: Filling**	**Process / step 3: Blistering**	**Process/ Step 4: Packing**
Per day (8 hours working shift)	100kg	172,800	24,000 Strokes 03 Blisters/Stroke	40,000
Per month (22 working days)	2200kg	3,801,600	528,000	880,000

Capacity calculated with respect to the filling being capacity limiting step

QUARTER WISE CAPACITY UTILIZED			
Quarter	**Actual Production**	**Capacity w.r.t capacity limiting step**	**Capacity utilized in %**
2nd (1st April-30th June 22)	45,411 capsules	11,404,800	0.4%
3rd (1st July- 30th sept 22)	295,455 caps	11,404,800	2.6%
4th (1st Oct – 31st Dec 22)	79,299 caps	11,404,800	0.7%
1st (1st Jan – 31st March 2023)	88,309 caps	11,404,800	0.8%
Average Capacity Utilized			1.125%

Manufacturing Capacity Utilized (average 1.125%
Manufacturing Capacity Available (average): 98.875%

D. CAPACITY OF QUALITY CONTROL DEPARTMENT

Quality Control Equipment Details		
S.No	Equipment	Quantity
1.	HPLC	02
2.	UV Spectrophotometer	01
3.	pH Meter	01
4.	Polarimeter	01
5.	Dissolution Apparatus	01
6.	Balance	01
7.	Moisture analyzer	01
8.	Cold Incubator	01
9.	Hot Incubator	01
10.	Stability Chamber (Accelerated)	01
11.	Stability Chamber (Real time)	01
12.	Glass Filtration Assembly	01
13.	S.S Filtration Assembly	01

1. HPLC Capacity Calculation
Quarter Wise(Maximum 4 tests/day)TOTAL No of HPLC= 2

QUARTER	Average Capacity of HPLC	Performed	Capacity Utilized %	Capacity Available %
1st (1st Feb – 30th Apr 22)	264	84	31.81	68.19
2nd (1st May – 30st July 22)	264	59	22.34	77.66
3rd (1st Aug – 31st Oct 22)	264	95	35.98	64.02
4th (1st Nov – 31th Jan 23)	264	65	24.62	75.38
			Average capacity Available:	**71.31%**

2. Capacity Calculation for sterility testing
Quarter Wise (Average 5 tests/day)

Quarter	Capacity	Test Performed	Capacity Utilized %	Capacity Available %
1st (1st Feb – 30th Apr 22)	330	41	12.42	87.58

2nd (1st May – 30st July 22)	330	20	6.06	93.94
3rd (1st Aug – 31st Oct 22)	330	32	9.69	90.31
4th (1st Nov – 31th Jan 23)	330	54	16.36	83.64
			Average capacity available:	**88.86%**

3. Bacterial Endotoxin Test Capacity Calculation
Quarter Wise (Average 8 tests / day)

Quarter	Capacity	Test Performed	Capacity Utilized %	Capacity Available %
1st (1st Feb – 30th Apr 22)	528	53	10.03	89.97
2nd (1st May – 30st July 22)	528	22	4.16	95.84
3rd (1st Aug – 31st Oct 22)	528	47	8.91	91.09
4th (1st Nov – 31th Jan 23)	528	116	21.94	78.06
			Average capacity available:	**88.74%**

Ms. Maria Burki Plant Manager/ Production Incharge, Mr. Tasawar Hussain Shah QC Manager and Mr. Umair Aslam QA Manager assisted during the inspection. The details are given below;

1. Raw Material Store:

The raw material store of cephalosporin facility was inspected in detail and following observations were noted.

i. Humidity of RMS at time of inspection was 64% and HVAC system was not operational, which was turned on during inspection.

ii. Boxes of some materials were checked randomly (e.g. Cefixime micronized batch CFEM220042, Cefixime compacted batch CFEC220097 and Magnesium stearate) and it was observed that the poly bags were not sealed to protect the material from environmental factors.

iii. Containers of Cefixime micronized (batch CFEM220042, analysis No. RM0024/QC/API/23 GRN No. 01278) and Cefixime compacted (batch CFEC220097, analysis No. RM0023/QC/API/23 GRN No. 01278) did not contain label of manufacturer. In QC their analysis documents were checked and found that they both were released for use on UV analysis rather HPLC testing which is pharmacopoeial requirements. The firm produced a COA of M/s Covalent Laboratories India of aforesaid API's but couldn't provide their clearance documents.

iv. There was discrepancy between entries of dispensing log book and raw materials stock registers. Some entries in dispensing log book were missing. The storage and documentation practices of the firm for raw materials were found very poor.

2. Production Area:

a. Dry Powder Injection:

The section was not operational at the time of inspection. The production Incharge described the manufacturing process which includes:

i. Vial washing with de-ionized water.

ii. Loading in DHS for sterilization. After sterilization they were

iii. Transfer to filling line through HEPA fitted trolley for filling and capping.

It was noted that firm is using deionized water for final rinsing of vials rather WFI. Moreover, the batch size was not standardized and it was observed that the firm is manufacturing multiple strengths of finished product having different batch numbers and batch sizes as per market demand while using single API container.

b. Dry Suspension:

The section was not operational at the time of inspection. In dry suspension area 200kg mixer was present and again it was observed that batch size was not standardized. Biodroxil 125mg batch No. 23010 was of 7734 units and batch No. 22029 was of 3703 units. Some batches were so small that their mixing in a 200kg mixer is not possible. Humidity of the area was not controlled.

c. Capsule:

The section was not operational at the time of inspection. There was no hygrometer in mixing area. The capacity of mixer in capsule section was 100kg. Again the batch size was not standardized. Roxykef 500mg Capsule batch 22023 had a size of 5607 capsules and batch No. 22003 of same product had a size of 47546 capsules. The mixture to fill 5607 capsules was approximately equal to 3.3kg. Mixing of material of 3.3kg in 100kg mixer is not possible and when it was inquired during inspection the firm informed that they are performing manual mixing in poly bags for such small batches.

There was only one pharmacist looking after all 3 sections of cephalosporin facility and also dispensing of raw materials.

3. In-process quarantine:

There was no in-process quarantine area in cephalosporin manufacturing facility. Quarantine area was established in Finished Goods Store (FGS). In quarantine area following observations were noted;

i. Unlabelled filled vials were present in various boxes. The boxes had labels indicating Vakxon 500mg IM injection batch No. 22115 manufactured in November 2022.

ii. Unlabelled filled vials were also present in other boxes which even did not bear labels. The firm claimed that these are ceftriaxone vials of above batch however they couldn't establish their identity.

iii. Unlabelled dry suspension bottles were also present in boxes having aluminium caps mentioning Herbion. The boxes had labels indicating Biodroxil Suspension 200mg/5ml

Upon inquiry the firm informed that above mentioned unlabelled filled products were placed in quarantine due to the shortage of labelling and packaging material. However as per QC record these batch were passed for release to the market.

4. Finished Goods Store:

The FGS was located in basement of the manufacturing facility. It was common for whole facility.

5. Packing material store:

The foils used for blistering were placed in uncontrolled environment and their polybags were not closed.

6. Quality Control:

a. Main Quality Control Lab:

The firm had 2 HPLC systems and one UV-Vis spectrophotometer. The firm did not had following instruments which are necessary for testing of products being manufactured:

i. FTIR
ii. Liquid particle Counter (LPC)
iii. TOC analyser

b. Microbiology Lab:

The firm had an established microbiology laboratory. Betalactamase enzyme, ATCC strains, LAL test lysate etc were present. Air particle counter was also available.

It was also noted that firm was releasing the API for manufacturing and finished products in the market on UV testing only. Two stability chambers were available for accelerated and real time stability studies of finished products. In accelerated stability chamber, samples of Biodroxil 200mg/5ml were available, the aforesaid product was registered in year 2022 in name of M/s Herbion Pharma Islamabad for contract manufacturing by the firm. The firm informed that they are conducting the accelerated and real time stability

on request of registration holder, however on the other side without completion of study for six months the same product was manufactured on continuous basis and huge stock for market release was available in FGS.

7. Water System:

The firm had double RO system connected with ion exchange cartridges. Firm also had water distillation system but it was not functional. Firm was using deionised water for washing of vials and final rinse of equipments used in sterile manufacturing. Hot loop was not present.

Recommendations & Conclusion:

Keeping in view the above practices, following is being recommended by the panel;

i. Immediate sampling of finished products specifically cephalosporin injectable products available with the firm and released in market.
ii. Panel GMP inspection as it was observed that since grant of DML in 2019, no panel GMP inspection has been conducted so far.
iii. Improvement in raw material storage and documentation practices.
iv. Standardization of batch sizes with process validations.
v. Hiring of at least three more pharmacists to supervise manufacturing and dispensing activities.
vi. Installation of water distillation system for bulk WFI.
vii. Provision of in-process quarantine area in cephalosporin manufacturing facility
viii. Installation of FTIR, TOC analyser and LPC in QC lab.
ix. Installation of hygrometers and improvement of environmental controls.

Despite of the fact firm possess sufficient manufacturing and testing capacity, however keeping in view the storage, documentation, production and testing practices of the firm recorded above, the panel **DO NOT RECOMMEND** to allow contract manufacturing till the compliance of above recommendations and their verification.

Decision: **Registration Board on basis of the findings of above presented inspection report decided to defer the registration applications of contract manufacturing from M/s. Cure Laboratories (Pvt) Ltd, Plot No. 11-12, Street No. NS-2 RCCI, Rawat till any further decision. Moreover, Registration Board decided to refer the above inspection report to QA&LT Division for further necessary action.**

Post Registration-I Section

Case No.01: Change in Specifications/ Standardization of Formulations

Sr.#	Required Documents as per approved SOP
i.	Copy of registration letter and last renewal status
ii.	Document in support of proposed change
iii.	Analytical reports as per monograph of FPP
iv.	Undertaking that: i. The change is made exclusively to comply with the pharmacopeia of Reference Regulatory ii. No case is pending at any forum / court of law regarding this product.

	iii.	In case of any quality complaint/ OOS result observed by the marketing authorization holder as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately.
	iv.	The provided information/ documents are true/ correct.

The following firms have requested for change in specifications Pharmaceutical Form/ registration letter of their registered products as per following details:

A. <u>Fresh cases</u>

M/s. Pfizer Pakistan Limited, B-2, SITE, Karachi					
Sr. No.	**Reg. No.**	**Name of Product with existing composition, Specifications**	**Name of Product with proposed Change in Specifications**	**Initial Date of Registration Renewal Application**	**Fee /R&I Date**
1.	089096	Myrin tablet Each tablet contains: Ethambutol Hcl…300mg Rifampicin…150 Isoniazid…75mg **(USP Specifications)**	Myrin tablet Each tablet contains: Ethambutol Hcl…300mg Rifampicin…150 Isoniazid…75mg **(Manufacturer Specifications)**	21-05-2018 Last Renewal 17-05-2023	Fee Rs 10,000/- deposited dated 15-05-2022 R&I Dy. No. 6453 dated 07-03-2023

Myrin Tablet

(Rifampicin, Ethambutol HCl & Isoniazid Tablet)

S. No.	**Test**	**Pfizer specification**	**USP / B.P / Eur. Ph Specification**	**International Pharmacopoeia Specification**	**Justification/Comment**
01	Description	Meets Test	N/A	N/A	N/A
02	Loss on Drying	NMT 5.0%	N/A	N/A	In house testing method has more stringent release limit. (NMT 3.0%).
03	Weight Variation	± 5% of Average Weight	N/A	± 5% of Average Weight	Perform as per general chapter at FG stage.
04	Disintegration	NMT 30 Minutes.	N/A	NMT 30 Minutes.	N/A
05	Identification	By HPLC	N/A	By TLC/HPLC	N/A

06	Assay	Rifampicin Isoniazid Ethambutol	90.0 % - 110.0% 90.0 % - 110.0% 90.0 % - 110.0%	N/A	Rifampicin Isoniazid Ethambutol	90.0 % - 110.0% 90.0 % - 110.0% 90.0 % - 110.0%	
07	Dissolution	Rifampicin Isoniazid Ethambutol	NLT 75% in 45 minutes. NLT 75% in 45 minutes. NLT 75% in 45 minutes.	N/A	Not part of specific monograph.		Dissolution test is additional in Pfizer specification along with disintegration test.
08	Dose Uniformity	L1 NMT15.0		L1 NMT 15 L2 NMT 25 (General Chapter)	Not applicable.		Dose uniformity test is additional in Pfizer release specification.
09	Related Compounds	Related Compound by HPLC		N/A	Related Compound by HPLC		N/A

2.	089094	Rin 150mg Each tablet contains: Rifampicin…150 Isoniazid…75mg **(USP Specifications)**	Rin 150mg tablet Each tablet contains: Rifampicin…150 Isoniazid…75mg **(Manufacturer Specifications)**	21-05-2018 Last Renewal 17-05-2023	Fee Rs 10,000/- deposited dated 15-05-2022 R&I Dy. No. 6453 dated 07-03-2023

Rin Tablet

(Rifampicin & Isoniazid Tablet)

S. No.	Test	Pfizer specification	USP / B.P / Eur. Ph Specification	International Pharmacopoeia Specification	Justification/Comment
01	Description	Meets Test	N/A	N/A	N/A
02	Loss on Drying	NMT 5.0%	N/A	N/A	In house testing method has more stringent release limit. (NMT 4.5%).

03	Weight Variation	± 5% of Average Weight	N/A	± 5% of Average Weight	Perform as per general chapter at FG stage.
04	Disintegration	NMT 30 Minutes.	N/A	NMT 30 Minutes.	N/A
05	Identification	By HPLC	N/A	By TLC/HPLC	N/A
06	Assay	Rifampicin 90.0 % - 115.0% Isoniazid 90.0 % - 115.0%	N/A	Rifampicin 90.0% - 110.0% Isoniazid 90.0% - 110.0%	
07	Dissolution	Rifampicin NLT 75% in 45 minutes. Isoniazid NLT 75% in 45 minutes.	N/A	Not part of specific monograph.	Dissolution test is additional in Pfizer specification along with disintegration test.
08	Dose Uniformity	L1 NMT15.0	L1 NMT 15.0 L2 NMT 25 (general chapter)	Not applicable.	Dose uniformity test is additional in Pfizer release specification.
09	Related Compounds	Related Compound by HPLC	N/A	Related Compound by HPLC	N/A

3.	089093	Myrin Forte tablet Each tablet contains: Ethambutol Hcl…275mg Rifampicin…150 Isoniazid…75mg **(USP Specifications)**	Myrin Forte tablet Each tablet contains: Ethambutol Hcl…275mg Rifampicin…150 Isoniazid…75mg **(Manufacturer Specifications)**	21-05-2018 Last Renewal 17-05-2023	Fee Rs 10,000/- deposited dated 15-05-2022 R&I Dy. No. 6453 dated 07-03-2023

Myrin Forte Tablet

(Isoniazid, Rifampicin & Ethambutol HCl Tablet)

S. No.	Test	Pfizer specification	USP / B.P / Eur. Ph Specification	International Pharmacopoeia Specification	Justification/Comment
01	Description	Meets Test	N/A	N/A	N/A
02	Loss on Drying	NMT 5.0%	N/A	N/A	In house testing method has more stringent release

					limit. (NMT 4.5%).
03	Weight Variation	± 5% of Average Weight	N/A	± 5% of Average Weight	Perform as per general chapter at FG stage.
04	Disintegration	NMT 30 Minutes.	N/A	NMT 30 Minutes.	Perform as per general chapter at FG stage.
05	Identification	By HPLC	N/A	By TLC/HPLC	N/A
06	Assay	Rifampicin 90.0 % - 110.0% Isoniazid 90.0 % - 110.0% Ethambutol 90.0 % - 110.0%	N/A	Rifampicin 90.0 % - 110.0% Isoniazid 90.0 % - 110.0% Ethambutol 90.0 % - 110.0%	
07	Dissolution	Rifampicin NLT 75% in 45 minutes. Isoniazid N/A Ethambutol N/A	N/A	Not part of specific monograph.	Dissolution test is additional in Pfizer specification along with disintegration test.
08	Dose Uniformity	L1 NMT15.0	L1 NMT 15 L2 NMT 25 (general chapter)	Not applicable.	Dose uniformity test is additional in Pfizer release specification.
09	Related Compounds	Related Compound by HPLC	N/A	Related Compound by HPLC	N/A

Remarks: -	The firm has submitted all relevant as per SOPs.
Decision of 101st PRVC:	**The Chairman Registration Board on the recommendation of the Committee referred the case to Registration Board for further deliberations.**
Decision:	**Drug Registration Board did not accede the request of the firm as the applied specifications are less stringent than the official pharmacopeia**

Sr. No.	Reg. No.	Name of Product with existing composition, Specifications	Name of Product with proposed Change in Specifications	Initial Date of Registration Renewal Application	Fee Submission/ R & I Date
I	**II**	**III**	**IV**	**V**	**VI**
II.	**M/s. Sanofi-Aventis Pakistan Limited, Plot No. 23, Sector 22, Korangi Industrial Area, Karachi.**				
4.	045390	Tritace 10mg Tablets Each Tablets contains: Ramipril…10mg (Manufacturer's Specifications)	Tritace 10mg Tablets Each Tablets contains: Ramipril…10mg **(As Per Innovators' Specifications)**	13-07-2007 **Last renewal** 22-04-2021	Fee Rs 10,000/- deposited dated 08-11-2021 R&I No. 28983 dated 22-10-2021
5.	019564	Tritace 2.5mg Tablet Each Tablet contains: Ramipril…2.5mg	Tritace 2.5mg Tablet Each Tablet contains: Ramipril…2.5mg	08-07-1997	-do-

		(Manufacturer's Specifications)	(**As Per Innovators' Specifications)**	**Last renewal** 06-10-2022	
6.	019565	Tritace 5mg Tablet Each Tablet contains: Ramipril…5mg (Manufacturer's Specifications)	Tritace 5mg Tablet Each Tablet contains: Ramipril…5mg (**As Per Innovators' Specifications)**	08-07-1997 **Last renewal** 06-10-2022	-do-

Specification comparison with Pharmacopeial monograph

Tests	**Innovator Specifications**	**USP Specifications**	**BP Specifications**	**Remarks**	
Identification of Ramipril	Rt(sample)≅ Rt (standard)	Infrared spectroscopy: Meet the requirements. The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay.*	The infrared absorption spectrum of the residue, Appendix II A, is concordant with the *reference spectrum of Ramipril* (RS 417).	Specification is same as USP and BP	
Uniformity of mass	NMT 15	NMT 15	NMT 15	Similar limit	
Dissolution	NLT 75% in 30 minutes	NLT 80%	NLT 70%	More stringent than BP. Less stringent than USP	
Degradation Product					
-Ramipril Diketopiperazine	NMT 5.0%	NMT 6.0%	NMT 6.0%	Stringent than USP and BP	
-Individual by-product (known other than Ramipril diketopiperazine)	NMT 0.5%		NMT 0.5%	Similar limit as BP.	
-Individual by product (unknown)	NMT 0.2%	NMT 0.2%	NMT 0.5%	Similar limit as USP. More stringent than BP.	
- Sum of by-products	NMT 6.0%	NMT 1.0%	NMT 6.0%	Less stringent than USP	
Assay	90 -105%	90.0 to 105.0%	90.0 to 105.0%	Similar limit	
Microbiological quality					
Total aerobic microbial count	≤ 103 CFU/g	≤ 103 CFU/g	≤ 103 CFU/g	Similar limit	
Total combined yeast/molds count	≤ 102 CFU/g	≤ 102 CFU/g	≤ 102 CFU/g	Similar limit	
Escherichia coli	No. *E.Coli* / g	No. *E.Coli* / g	No. *E.Coli* / g	Similar limit	
Remarks: The analytical procedures/specifications are performed as per Innovator specifications. This product is manufactured in Italy and exported to SRA countries (e.g., France) including Pakistan with similar specifications (i.e., Innovator specifications).					
Remarks:	The firm has stated that their specifications are less stringent than pharmacopoeial specifications.				

Decisions: - **Drug Registration Board did not accede the request of the firm as the applied specifications are less stringent than the official pharmacopeia**

Sr. No.	**Reg. No.**	**Name of Product with existing composition, Specifications**	**Name of Product with proposed Change in Specifications**	**Initial Date of Registration Renewal Application**	**Fee Submission/ R & I Date**
I	**II**	**III**	**IV**	**V**	**VI**
II.	**M/s. Sanofi-Aventis Pakistan Limited, Plot No. 23, Sector 22, Korangi Industrial Area, Karachi.**				
7.	019567	Amaryl 1.0mg tablets Each tablet contains: Glimepiride…1mg (Manufacturer's Specifications)	Amaryl 1.0mg tablets Each tablet contains: Glimepiride…1mg (**As Per Innovators' Specifications)**	08-07/1997 **Last renewal** 04-06-2021	Fee Rs 10,000/- deposited dated 16-09-2022

					R&I No. 26270 dated 16-09-2022
8.	019568	Amaryl 2.0mg tablets Each tablet contains: Glimepiride…2mg (Manufacturer's Specifications)	Amaryl 2.0mg tablets Each tablet contains: Glimepiride…2mg (**As Per Innovators' Specifications)**	08-07/1997 **Last renewal** 04-06-2021	-do-
9.	021094	Amaryl 3.0mg tablets Each tablet contains: Glimepiride…3mg (Manufacturer's Specifications)	Amaryl 3.0mg tablets Each tablet contains: Glimepiride…3mg (**As Per Innovators' Specifications)**	22-05-1998 **Last renewal** 04-06-2021	-do-
10.	021095	Amaryl 4.0mg tablets Each tablet contains: Glimepiride…4mg (Manufacturer's Specifications)	Amaryl 4.0mg tablets Each tablet contains: Glimepiride…4mg (**As Per Innovators' Specifications)**	22-05-1998 **Last renewal** 04-06-2021	-do-

Specification comparison with Pharmacopeial monograph

Tests	**Innovator Specifications**	**USP Specifications**	**BP Specifications**	**Remarks**
Identification of Glimepiride.	In the Assay, the principal peak in the chromatogram obtained with standard solution has the same retention time as that of the principal peak in the chromatogram obtained with sample solution.	A. The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay. B. The UV absorption spectra of the major peak of the Sample solution exhibit maxima and minima at the same wavelengths as those of the Standard solution, as obtained in the Assay.	A. The infrared absorption spectrum of the residue, Appendix II A, is concordant with the *reference spectrum* of *glimepiride* (*RS 463*). B. In the Assay, the retention time of the principal peak in the chromatogram obtained with solution (1) is similar to that of the principal peak in the chromatogram obtained with solution (2).	ID B (USP) is not performed by Sanofi ID A (BP) is not performed by Sanofi Less stringent than USP and BP
Uniformity of mass	NMT 15	NMT 15	NMT 15	Similar limits
Dissolution	NLT 80% in 15 minutes	NLT 80% in 15 minutes	NLT 75% in 45 minutes	Stringent than BP
Degradation Product				
- Glimepiride-sulfonamide	NMT 2.0%	NMT 2.5%	NMT 2.0%	Stringent than USP
Glimepiride related compound C	Not Performed	NMT 0.5%	-	Less stringent as this test is not performed by Sanofi
-Others each	NMT 0.5%	NMT 0.5%	NMT 0.2%	Stringent BP limits
- Related substances total	NMT 2.5%	NMT 3.5%	NMT 1.0%	Less stringent than BP

Assay content of Glimepiride.	92.50 -105.00%	90.0 -110.0%	95.00 -105.00%	Less stringent than BP
Microbiological quality				
Total aerobic microbial count	≤ 103 CFU/g	≤ 103 CFU/g	≤ 103 CFU/g	Similar limits
Total combined yeast/molds count	≤ 102 CFU/g	≤ 102 CFU/g	≤ 102 CFU/g	Similar limits
Escherichia coli	No. *E.Coli* / g	No. *E.Coli* / g	No. *E.Coli* / g	Similar limits
Remarks: The analytical procedures/specifications are performed as per Innovator specifications. This product is manufactured in Italy and exported to SRA countries (e.g., France) including Pakistan with similar specifications (i.e., Innovator specifications).				
Remarks:	The firm has stated that their specifications are less stringent than pharmacopoeial specifications.			
Decision:	**Drug Registration Board did not accede the request of the firm as the applied specifications are less stringent than the official pharmacopeia**			

Sr. No.	**Reg. No.**	**Name of Product with existing composition, Specifications**	**Name of Product with proposed Change in Specifications**	**Initial Date of Registration Renewal Application**	**Fee Submission/ R & I Date**
I	**II**	**III**	**IV**	**V**	**VI**
II.	**M/s. Sanofi-Aventis Pakistan Limited, Plot No. 23, Sector 22, Korangi Industrial Area, Karachi.**				
11.	023617	Telfast-D tablets Each tablet contains: Fexofenadine Hcl…60mg Pseudoephedrine Hcl….120mg (Manufacturer's Specifications)	Telfast-D tablets Each tablet contains: Fexofenadine Hcl…60mg Pseudoephedrine Hcl….120mg **(As Per Innovators' Specifications)**	12-05-1999 **Last renewal** 28-06-2021	Fee Rs 10,000/- deposited dated 16-09-2022 R&I No. 26270 dated 16-09-2022

Specification comparison with Pharmacopeial monograph

Tests	**Innovator Specification**	**USP Specifications**	**Remarks**
Identification of Fexofenadine HCl and Pseudoephedrine HCl	(Rt (reference) ≈ Rt(sample) for both active substances)	A. The retention times of the major peaks of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the *Assay*. B. By TLC	ID B is not performed by Sanofi. Hence less stringent than USP specifications.
Uniformity of mass	NMT 15	NMT 15	Similar Limit
Dissolution - Fexofenadine HCl	NLT 75% in 45 minutes	NLT 80% (*Q*) in 45 minutes	Less stringent than USP

Dissolution - Pseudoephedrine HCl In 45 minutes In 180 minutes In 300 minutes In 720 minutes	 ≤36% 41 – 69% 52 - 85% ≥ 76%	 NMT 36 45–69 61–80 NLT 80	Less Stringent than USP
Degradation Product			
-Ephedrone HCl	NMT 0.2%	-	Impurity profile is different in USP
-MDL 102038	NMT 0.3%	-	
-MDL 46016	NMT 0.2%	-	
- Total other degradants	NMT 0.2%	NMT 0.2%	
-Total degradants	NMT 0.6%	NMT 0.5%	
Water Content	1.2 – 6.0 %	-	More stringent than USP as this test is not part of USP specifications
Assay content of Pseudoephedrine HCl	93.0 -107.0%	93.0– 107.0%	Similar limit
Assay content of Fexofenadine HCl	93.0– 107.0%	93.0– 107.0%	Similar limit
Microbiological quality			
Total aerobic microbial count	≤ 103 CFU/g	≤ 103 CFU/g	Similar limit
Total combined yeast/molds count	≤ 102 CFU/g	≤ 102 CFU/g	Similar limit
Escherichia coli	No. *E.Coli* / g	No. *E.Coli* / g	Similar limit

Remarks: The analytical procedures/specifications are performed as per Innovator specifications. This product is manufactured in France and exported to SRA countries (e.g., Australia) including Pakistan with similar specifications (i.e., Innovator specifications).

Remarks: The firm has stated that their specifications are less stringent than pharmacopoeial specifications.

Decision: Drug Registration Board did not accede the request of the firm as the applied specifications are less stringent than the official pharmacopeia

Post Registration-II Section

Case 01. M/s Gray's Pharmaceuticals Rawat: Deferred Cases in 316th Meeting of Registration Board.

It is submitted M/s Grays Pharmaceuticals Plot No. 2 Street N-3 National Industrial Zone Rawat has requested for issuance letters of transfer of registration of below mentioned products registered in their name:

Sr. No.	Reg. No.	Brand Name	Composition
1.	030655	Ciprogray 250mg Tablets	Each tablet contains; Ciprofloxacin 250mg
2.	030654	Ciprogray 500mg Tablets	Each tablet contains; Ciprofloxacin 500mg

2. The matter of shifting of these registered products from facility at plot No. 442, St. No. 7 Sector I-9/2 Industrial Area Islamabad to new facility at Plot No. 2, Street N-3, National Industrial Zone Rawat was considered in 233rd meeting of Registration Board and the board decided to accede to the request of firm subject to fulfillment of latest Fee requirement and confirmation of sections, required for each category of drugs.

3. The letter of transfer of registration to new facility couldn't be issued and matter was again presented in 316th meeting of registration board for consideration as under;

Sr. No	Reg. No.	Brand Name & Composition	Initial date of Registration PRV (If any)	RRA status	Remarks of RRR	Remarks of PR- II
	I	II	II I	V	VI	VII
51.	030655	Ciprogray 250mg tablet Each tablet contains Ciprofloxacin..... 250mg	26-07-2003	Film coated tablet is available in RRA	The renewal application for the year 2018 is submitted on 15th July 2019 and is submitted after due date	The formulation shall be corrected as "Film coated tablet" and firm
52.	030654	Ciprogray 500mg tablet Each tablet contains Ciprofloxacin..... 500mg	26-07-2003	Film coated tablet is available in RRA	but within one year w.r.t initial date of registration. Firm may be advised to submit differential fee under SRO 1005(I)/2017 for consideration of products for regularization of registration.	shall also submit the reference of finish product specifications as per decision of 295th meeting of Registration Board with prescribed fee.

4. The board in its 316th meeting decided to deferred the request of firm for submission of differential fee as per SRO 1005(I)/2017 for regularization of registration. Incompliance of decision of 316th meeting of Registration Board, the firm has submitted fee of Rs165,000/- per product. Initially for renewal, the firm had submitted Rs. 10,000/- per product on 15.07.2019.

5. The firm M/s Grays Pharmaceuticals Plot No. 2, Street N-3, National Industrial Zone Rawat, Islamabad vide letter dated 11.04.2023 has intimated that they have submitted fee of Rs. 165,000/- per product as per Rule 27 of the Drugs (LR&A) Rules 1976.

6. The current renewal status of the 2 products mentioned above is tabulated below;

S. No.	Product	Registration No. & Date of Registration	Renewals
1	Ciprogray 250mg tablet Each tablet contains Ciprofloxacin…….250mg	030655 26.07.2003	Renewals submitted on 26.07.2008 26.07.2013 15.07.2019

			Rs. 165000/- submitted on 11.04.2023 vide Slip No. 8983651701
2	Ciprogray 500mg tablet Each tablet contains Ciprofloxacin…….500mg	030654 26.07.2003	Renewals submitted on 26.07.2008 26.07.2013 15.07.2019 Last renewal Rs. 165000/- submitted on 11.04.2023 vide Slip No. 19208912

7. The matter is placed before the board for regularization of registration and transfer of registration from M/s Gray's Pharmaceuticals, Plot No. 442, St. No. 7 Sector I-9/2 Industrial Area Islamabad (DML No. 000518) to new facility at M/s Gray's Pharmaceuticals, Plot No. 2, Street N-3, National Industrial Zone Rawat (DML No. 000518)

Decision: **The Board deliberated the matter at length. Considering the facts narrated above, the board decided to cancel the above registrations in name of M/s Gray's Pharmaceuticals, Plot No. 442, Street No. 7, Sector I-9/2, Industrial Area Islamabad (DML No. 000518) and grant them in name of M/s Gray's Pharmaceuticals, Plot No. 2, Street No. N-3, National Industrial Zone Rawat (DML No. 000518) subject to confirmation of renewal status under Rule 27 of the Drugs (LR&A) Rules 1976 amended vide SRO 1005(I)/2017 dated 05.10.2017. The firm shall also submit the fee if required under the afore said provisions.**

Case 02: **Cancellation of Registration of Drugs: Norigest Injection (Norethisterone Enanthate) Reg. No. 000693- Locally Manufactured.**

The cases for change of specifications (to retain manufacturers/ innovator's specifications) of Nova Ject Injection and Norigest Injection of M/s Bayer Pakistan (Pvt.) Ltd. 108 Kot Lakhpat Industrial Estate Lahore were approved in 85th meeting of Post Registration Variation Committee (PRVC) held on 01.09.2022.

2. During issuance of letter it was observed that formulation of both prodcuts is same. Details of these products is given below;

S. No.	Product Name & Formulation	Registration No.
1	**Nova ject Injection:** Each ml Contains: - Norethisterone enanthate…200mg	019823
2	**Norigest Injection** Each ml Contains: - Norethisterone enanthate …….200mg **(Innovator's Specifications)**	000693

2. The letter for change of specifications of Norigest Injection Reg No. 000693 was issued on 20.09.2022. The letter for change of specifications of product Nova Ject Reg. No. 019823 was withheld due to duplicate formulation.

3. The matter was discussed with the technical person of M/s Bayer Pakistan (Pvt.) Ltd. 108 Kot Lakhpat Industrial Estate Lahore and they have now requested for cancellation of registration of product **Norigest Injection Reg. No. 000693** vide letter No. BPPL-DRAP-23-038 dated 10.05.2023.

4. The firm M/s Bayer Pakistan (Pvt.) Ltd. 108 Kot Lakhpat Industrial Estate Lahore intends to retain the brand name Nova Ject Injection and have requested for issuance of letter for its change of specifications as per decision of 85th meeting of PRVC.

4. The matter is placed before the Board for consideration.

Decision: **The Board acceded to the request of firm for withdrawal of Registration of Product Norigest Injection Reg No. 000693. Further the relevant section shall issue letter for change of specifications of Nova ject Injection Reg No. 019823 as per decision of 85th meeting of post registration variation committee.**

Case 03. : **Change of Specifications: Noctamide Tablets and Primolut N Tablets.**

The firm M/s Bayer Pakistan (Pvt.) Ltd. 108 Kot Lakhpat Industrial Estate Lahore has requested to retain manufacturers specification of their products Noctamide and Primolut N.

2. The matter was discussed in 74th 100th and 101st meetings of Post Registration variation committee and was referred to registration board for consideration. The details of PRVC cases is given below;

S. No.	Reg. No.	Product & Formulation	Requested change	Renewals	Fee
1.	000677	Primolut N Tablet Each tablet contains Norethisterone.....5mg	Primolut N Tablet Each tablet contains Norethisterone.....5mg **(Innovator Specifications)**	12-01-1984 **Last renewal** 10-01-2019	Fee Rs. 10,000 deposited dated 19-07-2021
2.	006900	Noctamid Tablet Each Tablet contains: - Lormetazepam.....1mg	Noctamid Tablet Each Tablet contains: - Lormetazepam.....1mg **(Innovator Specifications)**	12-05-1984 **Last renewal** 10-01-2019	Fee Rs. 10,000 deposited dated 28-06-2021

Decision of 74th PRVC

Post Registration Variation Committee considered the case in its 74th Meeting. The Committee deferred the case for clarification of "Q" value. Which should not be less than 75% in any case as per the recommendations of United States Pharmacopoeia (USP) General Chapter Dissolution, Dissolution testing in BP finished products monographs for solid oral dosage forms and The International Pharmacopoeia Ninth Edition, 2019. Dissolution testing of tablets and capsules

Reply by the firm

The firm has submitted the replies to fulfillment of their deficiencies. In the reply firm has quoted Appendix XII B. Dissolution of the British Pharmacopoeia. The para of this Appendix of BP is reproduced below;

"Where one tablet or capsule is directed to be placed in the appraratus, for each of the six tablets or capsules tested the amount of active ingredient in solution is not less than 70% of the prescribed or stated amount, unless otherwise specified in the monograph, except that if one fails this requirement a further six may be tested individually and all must comply."

The firm has further stated as under;

"Based on above cited points, Bayer inhouse specification for dissolution test [limit 75% (Q+5%), Q=70%] is fully in line with B.P for product- Noctamid tablets and no change is required"

Same reply was submitted for Primolut N tablets

Decision of 100th PRVC:

The Chairman Registration Board on recommendation of the Committee referred the case to Registration Board for further deliberation.

Remarks: -

The Head of Quality of M/s Bayer Pakistan (Pvt.) Ltd Ms. Alia Shahzad visited PE&R Division for discussion on matter of the specifications of their 2 products.

Noctamid tablet;

The product monograph is only available in British Pharmacopoeia. The BP Monograph does not mention dissolution test of the product so general chapter of dissolution was referred to for it. As per general chapter the dissolution shall not be less than 70%. The dissolution specifications of M/s Bayer are in line with British Pharmacopoeia general chapter. Rest of the specifications of M/s Bayer are more stringent than BP. In view of this the firm requested to give manufacturer/ innovator's specifications for their product Noctamid Tablet.

Noctamid Tablet

Each tablet contains:-

Lormetazapam… 1mg

(Reg. No. 006900)

Sr. No.	Test Parameters	Bayer's Product Specification	B.P 2021 - Monograph
1	**Appearance**	White round tablet. Slightly Convex on both sides, and marked "CF" in	---

		regular hexagon on one side & reverse side scored.	
2	**Tablet Friability**	weight loss: ≤1.0%	---
3	**Disintegration**	max. 15 min	---
4	**Uniformity of Mass**	≥ 90 % of the tablets 111.0 to 129.0 mg , no tablet < 102.0 mg or > 138.0 mg (≥18/20±7.5%,≤ 2/20±15%, No tablet >±15%)	---
5	**Identification of Lormetazepam (TLC)**	To Pass (The spot of sample must match the spot of reference in terms of Rf value and intensity of fluorescence quenching.)	The principal spot in the chromatogram obtained with sample solution corresponds in position and colour to that in the chromatogram obtained with reference solution.
6	**Identification of Lormetazepam**	To Pass (HPLC : The retention times of the lormetazepam peak in the chromatograms of the sample and reference must only differ from each other by a maximum of 5%.	I.R: Infrared absorption spectrum concordant with the reference spectrum of lormetazepam (RS 207).
7	**Related substances and degradation products of lormetazepam***	Release: N.A Shelf life: individual < 0.5%, total ≤ 1.0%	BP uses **Isocratic elution** for determination of related substances by l**imit test** & only one identified related substance (Lorazepam). In the chromatogram obtained with Sample solution: the area of any secondary peak is not greater than 0.5 times the area of the principal peak in the chromatogram obtained with Reference solution (0.5%); the sum of the areas of any secondary peaks is not greater than the area of the peak in the chromatogram obtained with Reference solution (1%). Disregard any peaks with a retention time of less than half that of lormetazepam.
8	**Lormetazepam: (content uniformity)** (HPLC Method)	Acceptance value of 10 samples. 0.850 to 1.150 mg per tablet (85% to 115%) If the requirement is not met proceed as per Ph. Eur. 2.9.40, USP <905> Uniformity of dosage units – content uniformity".	Limit as specified in the Uniformity of content B.P. Appendix XII C3 [Ph. Eur. 2.9.4]
9	**Assay of Lormetazepam** (HPLC Method)	0.950 to 1.050 mg per tablet (95% to 105%)	95.0 to 105.0% of the stated amount.
10	**Dissolution Of Lormetazepam**	Q = 70%, t = 30 min level 1 = individual values of 6 tablets ≥ 75% (Q + 5%);	---

		level 2 = mean value of all 12 tablets tested (level 1 + level 2) ≥ 70%, and no tablets < 55% (Q - 15%);	
		level 3 = mean value of the total 24 tablets tested (level 1 + level 2 + level 3) ≥ 70%, ≤ 2 tablets < 55% (Q - 15%) and no tablet < 45% (Q - 25%)	
11	**Microbial Contamination**** (agar plate method)	Total number of colony forming, aerobic units (TAMC): 10^3 per g Max. acceptable limit 2000 per g); Total combined yeasts / moulds count (TYMC): max. 10^2 p er g Max. acceptable limit 200 per g); Absence of Escherichia coli determined in 1 g	---

Primolut N Tablet (Norethisterone… 5mg):

In case of Norethisterone Tablets, monographs are available in both BP and USP. The specifications initially given by the firm had dissolution limits (Q=65%+5 = 70%). The limits of dissolution in USP monograph of Norethisterone tablet are NLT 80% (Q).
The firm vide letter No. BY2853 dated 23.05.2023 has stated that they have revised the acceptance criteria for dissolution test of their product Primolut N tablet. The dissolution acceptance criteria is now stated as NLT 80% which is similar to USP. The rest of the specifications are given below;

Product specifications - Primolut N Tablet:

S.No.	Test Parameters	Bayer Specifications	BP 2021 Monograph Acceptance criteria	USP 2021 Monogrpah Acceptance Criteria
1	Appearance	White round tablet. Slightly Convex on both sides and marked "AN" in regular hexagon on one side & reverse side plain.	---	---
2	Tablet Friability (Eur.Ph. 2.9.7)	≤1.0%	---	---
3	Disintegration (Eur.Ph. 2.9.1)	max. 15 min	---	---
4	Uniformity of Mass (Eur.Ph. 2.9.5)	≥ 90 % of the tablets 111.0 to 129.0 mg, no tablet < 102.0 mg or > 138.0 mg (≥18/20±7.5%, ≤ 2/20±15%, No tablet >±15%)	---	---

5	Identification of Norethisterone (TLC)	Passes Test	TLC: The principal spot spots of sample and reference match with respect to position and color under UV light at 365nm.	IR: The IR absorption spectrum of a potassium bromide dispersion prepared from the residue so obtained exhibits maxima only at the same wavelengths as that of a similar preparation of USP Norethindrone RS.
6	Identification of Norethisterone (HPLC)	Passes Test	---	---
7	Dissolution Of Norethisterone	Individual values of 6 tablets ≥ 80% (Q + 5%); Q = 75 level 2 = mean value of all 12 tablets tested (level 1 + level 2) ≥ 75%, and no tablets < 60% (Q - 15%); level 3 = mean value of all 24 tablets tested (level 1 + level 2 +level 3) ≥ 75%, and no tablets < 50% (Q - 25%);	---	NLT 80% (Q) of the labeled amount of norethindrone is dissolved.
8	**Assay** (HPLC Method)	4.60 - 5.40 mg per 120 mg tablet 92 – 108%	**90.0 – 110.0%**	**90.0 – 110.0%**
9	**Content Uniformity Of Norethisterone** (HPLC Method)	acceptance value ≤ 15.0% for 10 samples [4.25 - 5.75 mg per tablet (85% to 115%)] if acceptance value > 15.0%, repeat the test with additional 20 tablet: acceptance value from 30 tablets ≤ 15.0% and no individual content < 75% or > 125% from the reference value M	---	Uniformity of dosage units (905): Meet the requirements The requirements for dosage uniformity are met if the acceptance value of the first 10 dosage units is less than or equal to L1%. If the acceptance value is > L1%, test the next 20 units, and calculate the acceptance value. The requirements are met if the final acceptance value of the 30 dosage units is ≤ L1%, and no individual content of any dosage unit is less than [1 − (0.01) (L2)]M nor more than [1 + (0.01) (L2)]M as specified in the Calculation of Acceptance Value under Content Uniformity or under Weight Variation. Unless otherwise specified, **L1 is 15.0 and L2 is 25.0**

10	**Microbial Purity: Microbial Enumeration Tests** (Eur. Ph. 2.6.12, USP <61> , JP 4.05)	Total number of colony forming, aerobic units (TAMC): 10^3 per g (max. 2000cfu); Total combined yeasts / moulds count (TYMC): 10^2 per g (max. 200cfu);	---	---
	Test for specific microorganisms (Eur. Ph. 2.6.13, USP <62>), JP 4.05)	Absence of Escherichia coli determined in 1 g	--	--

3. Matter is placed before the board for consideration of change of specifications to innovator's Specifications.

Decision: **Keeping in view the fact that product monographs are available in pharmacopoeia, the Registration Board did not accede to the request of firm for grant of innovator specifications. The firm shall apply afresh for pharmacopoeial specifications and relevant section shall process the case accordingly.**

EXPORT FACILITATION DESK

Case No.01: Registration of Drug (s) of M/s Nabi Qasim Industries (Pvt.) Ltd, 17/24, Korangi Industrial Area, Karachi, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from letter No. F 2-20/85-Lic dated 27-04-2020
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 27-05-2022
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1.	Blokner Lyophilized Powder for solution (I.V) Injection 25mg Each vial contains: Atracurium Besylate USP.....25mg	Purchase order from Tanzania	Dy. No. 387(03.05.2023) Rs.75,000/- (16.03.2023)
2.	Blokner Lyophilized Powder for solution (I.V) Injection 100mg	Purchase order from Tanzania	Dy. No. 401(09.05.2023) Rs.75,000/- (16.03.2023)

	Each vial contains: Atracurium Besylate USP.....100mg		
3.	Blokner Lyophilized Powder for solution (I.V) Injection 50mg Each vial contains: Atracurium Besylate USP.....50mg	Purchase order from Tanzania	Dy. No. 402(09.05.2023) Rs.75,000/- (16.03.2023)
4.	Blokner Lyophilized Powder for solution (I.V Injection 250mg Each vial contains: Atracurium Besylate USP.....250mg	Purchase order from Tanzania	Dy. No. 403(09.05.2023) Rs.75,000/- (16.03.2023)
Remarks: The Applied products are lyophilized. RRA and me-too reference of lyophilized Atracurium is not available. The applied formulations are RRA approved as liquid injections. Me-too of 100mg and 250mg is not available in liquid ampoule either.			

Decision: **Registration board while considering the purchase order from the importing country i.e., Tanzania and availability of same strength in RRA in liquid injection form, decided to approve the applied products Blokner Lyophilized Powder for Injection 25mg, 50mg, 100mg & 250mg for export to Tanzania only.**

Case No.02: Registration of Drug (s) of M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area Karachi, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from letter No. F 2-11/2005-Lic dated 15-06-2021
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 12-02-2020
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1.	Cold Care Syrup Each 5ml contains: Paracetamol.....120mg Chlorpheniramine maleate.....2mg Pseudoephedrine.....10mg	Purchase order from Uganda	Dy. No. 412(10.05.2023) Rs.30,000/- (27.02.2023)
2.	Cold Care Capsule Each capsule contains: Paracetamol.....400mg Caffeine.....30mg Chlorpheniramine maleate.....4mg Pseudoephedrine.....30mg	Purchase order from Uganda	Dy. No. 413(10.05.2023) Rs.30,000/- (27.02.2023)
Remarks: Me-too and RRA reference of these products is not available. Firm has provided export order of Uganda and images of products registered in Uganda.			

Decision: **Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**

Case No.03: Registration of Drug (s) of M/s Vision Pharmaceuticals (Pvt.) Ltd, Plot No. 22, Industrial Triangle Kahuta Road Islamabad, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from letter No. F 1-26/2009-Lic dated 07-06-2021
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 22-06-2022
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1.	Visosol-R IV Infusion 1000ml Each 1000ml contains: Dextrose Anhydrous.....50g Sodium chloride.....5.5g Potassium Chloride.....0.38g Magnesium Chloride.....0.155g Sodium Acetate Trihydrate.....6.81g Water for Injection.....q.s 1000ml **Electrolytes in 1L:** Sodium (NA+).....143.3mmol Potassium (K+).....5mmol Magnesium (Mg+).....1.63mmol Chloride (C1-).....102.4mmol Acetate (C2H302-).....50mmol	Purchase order from Philippine	Dy. No. 414(17.05.2023) Rs.75,000/- (02.05.2023)
2.	Visosol-M IV Infusion 1000ml Each 1000ml contains: Dextrose Anhydrous.....50g Sodium chloride.....1.42g Potassium Chloride.....0.97g Magnesium Chloride.....0.157g Sodium Acetate Trihydrate.....2.18g Water for Injection.....q.s 1000ml **Electrolytes in 1L:** Sodium (Na+).....40mmol/L Potassium (K+).....13mmol/L Magnesium (Mg+).....1.65mmol/L Chloride (C1-).....40mmol/L Acetate (C2H302-).....16.02mmol/L	Purchase order from Philippine	Dy. No. 415(17.05.2023) Rs.75,000/- (02.05.2023)
Remarks: The firm has submitted reference of Philippines National Formulary wherein these formulations are available. The export order is also of Philippines.			

Decision: **Registration board while considering the purchase order from the importing country i.e., Philippines and availability of same formulations in National Formulary of Philippines, decided to approve the applied products Visosol-R IV Infusion 1000ml & Visosol-M IV Infusion 1000ml for export to Philippines only.**

Case No.03: Registration of Drug (s) of M/s Maxitech Pharma (Pvt.) Ltd, Plot No. F-178, S.I.T.E. Phase-II, Super Highway Karachi, for export purposes only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents

Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5;
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from letter No. F 2-12/2012-Lic dated 25-11-2016
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Inspection report renewal of DML dated 07-07-2021
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Dy.No.(EFD)/Fee with date
I	II	III	IV
1.	Prednivate-N Lotion Each ml contains: Methylprednisolone acetate.....2.5mg Neomycin sulphate.....2.5mg	Myanamar	Dy. No. 458(19.05.2023) Rs. 75,000/- (01.09.2021)
Remarks: The firm was asked to provide export order and evidence of RRA approva. The firm has submitted export order of M/s Medisure Biotech, Rangon Myanmar. The firm has submitted RRA reference of health Canada (Neo-medrol) The status of RRA reference is cancelled due to marketing reasons.			

Decision: **Registration board while considering the purchase order from the importing country i.e., Myanamar and fact that same formulation was marketed in Canada and was withdrawn due to marketing issues and not due to any safety or efficacy issues, decided to approve the applied product Prednivate-N Lotion for export purpose only.**

Case. No. 4: Formulations Containing more than 100mg Tramadol: Case Meeting with Nigeria and the Islamic Republic of Pakistan.

A summary of case meeting with the Government of Nigeria and the Global Rapid Interdiction of Dangerous Substances (GRIDS) program was forwarded by Mr. Muhammad Arif Chaudhary, Additional Director, Control Drugs Division. The meeting was attended by following officers of the Authority;

i. Mr. Ahmad din Ansari, Director Division of controlled drugs DRAP Islamabad.
ii. Mr. M. Arif Chaudhry, Additional Director Division of Controlled Drugs, DRAP Islamabad.

2. On the basis of proceedings of the meeting, above mentioned officers of the Authority have given following recommendations;

"It is submitted that in the light of discussion made during the meeting and stance of Nigerian Authorities, it is recommended that DRP may revise its policy for the already registered products containing "Tramadol" over 100mg and all the products registered with strength over 100mg may be withdrawn (even if for export purpose) after following due process of law. It is further recommended that policy regarding export of products containing synthetic opioid may be revised to make it in line with status of the material in importing country. The concerned authority of the importing country may also be taken on board for verification of import orders or request for registration of new strength as in case of Tramadol to avoid any sort of scam in future"

3. The list of products registered for export purpose containing tramadol more than 100mg is prepared as per available record and given below;

LIST OF TRAMADOL FORMULATIONS REGISTERED FOR EXPORT PURPOSE

Sr. No.	Name of Firm	Reg. No.	Brand Name & composition	Date of issue
1.	**M/s. Universal Pharma (Pvt) Ltd. 131-A, Hayatabad Industrial Estate, Peshawar.**	**007674-Ex**	**Tramadol ER 200mg** **Each Extended Release tablet contains:** **Tramadol HCl.....200mg**	**-do-**
2.	M/s. Friends Pharma (Pvt) Ltd.,31-KM, Ferozepur Road Lahore.	007689-Ex	Profend tablet 300mg Each extended release tablet contains: Tramadol HCl ……...300mg	-do-
3.		007690-Ex	Profend tablet 400mg Each extended release tablet contains: Tramadol HCl…..……400mg	-do-
4.	**M/s Medicraft Pharmaceuticals (Pvt) Ltd.126-B Industrial Estate, Hayatabad Peshawar.**	**007857-Ex**	**Tremomed SR 200mg tablet** **Each prolong released tablet contains:** **Tramadol HCl.....200mg**	**-do-**
5.	**M/s Unison Chemical works Lahore**	**008063-Ex**	**Tymil ER 200mg Tablet** **Each film coated extended release tablet contains:** **Tramadol Hydrochloride…….200mg**	**June, 2019**
6.	**Rakaposhi Pharma Peshawar**	**008265-Ex**	**Madol SR Tablet** **Each sustained release tablet contains:** **Tramadol HCl…….200mg**	**September, 2019**
7.	**Medicon Peshawar**	**008266-Ex**	**Tee-Doll SR 200mg Tablet** **Each Prolong release tablet contains:** **Tramadol HCl…….200mg**	**-do-**
8.	**Panacea Pharma Islamabad**	**008273-Ex**	**Tromser ER 200 Tablet** **Each extended release tablet contains:** **Tramadol HCl……200mg**	**-do-**
9.	M/s Reign Pharmaceuticals PCSIR KLC (Pvt) Ltd. Karachi.	008287-Ex	Reign's Tramadol 200mg tablet Each tablet contains: Tramadol Hydrochloride…..200mg	-do-
10.	**Amros Karachi**	**008341-Ex**	**Tramadol SR 200mg Tablet** **Each sustained release tablet contains:** **Tramadol HCl…….200mg**	**-do-**
11.	**Z.Janz Peshawar**	**008489-EX**	**Tramadol SR Tablet 200mg** **Each sustained release tablet contains:** **Tramadol HCl……200mg**	**-do-**
12.	**Sigma pharma Karachi**	**008513-EX**	**Tred SR 150mg Tablet** **Each prolong release tablet contains:** **Tramadol Hydrochloride.....150mg**	**-do-**
13.		**008514-EX**	**Tred SR 200mg Tablet** **Each prolong release tablet contains:** **Tramadol Hydrochloride.....200mg**	**-do-**
14.	M/s Inventor Pharma, Plot No. K/196, S.I.T.E (SHW), Phase-II, Karachi	008566-EX	Relax 225mg tablet Each film coated tablet contains: Tramadol Hydrochloride……0225mg	-do-
15.	M/s Rakaposhi Pharmaceutical (Pvt) Ltd., 97-K, Hayatabad Industrial Estate,	008567-EX	Tamol-xx Each tablet contains: Tramadol HCl……225mg	-do-

	Peshawar			
16.	M/s Medicraft Pharmaceuticals Pvt Ltd. 126-B, Industrial Estate, Peshawar	008576-EX	Tremomed 225mg tablet Each film coated tablet contains: Tramadol HCl.....225mg	-do-
17.	M/s Mafins Pharma, Plot No. A-5, S.I.T.E., Super Highway Industrial Area, Karachi	008620-EX	TRAMOL 200MG TABLETS Each film coated tablet contains: Tramadol HCl…….200mg	-do-
18.	**M/s Medisure Laboratories Pakistan (Pvt.) Ltd. A-115, S.I.T.E, Super Highway, Karachi**	**008636-EX**	**TRAMADOL SR 200MG TABLET** **Each sustained release tablet contains:** **Tramadol HCl……....200mg**	**-do-**
19.	M/s Honig Pharmaceutical Laboratories, 14KM, Adyala Road, Rawalpindi	008692-EX	Royden 225mg tablet Each film coated tablet contains: Tramadol HCl……..225mg	-do-
20.	M/s Alina Combine Pharmaceuticals (Pvt) Ltd. A-127, S.I.T.E Super Highway, Karachi	008698-EX	T-Dol 200mg tablet Each tablet contains: Tramadol HCl……..200mg	-do-
21.	M/s Weather Folds Pharmaceuticals, Plot No.69/2, Phase-II, Industrial Area Hattar	008747-EX	Pharmdol 225mg tablet Each film coated tablet contains: Tramadol Hydrochloride……225mg	-do-
22.	M/s Delta Pharma (Pvt) Ltd., Plot No.9, Nowshera Industrial, Estate (S.I.Z) Risalpur KPK	008748-EX	Tonolix Tablet Each film coated tablet contains: Tramadol HCl……200mg	-do-
23.	**M/s Mediate Pharmaceutical (Pvt) Ltd. 150-151, sector 24, Korangi Industrial Area, Karachi**	**008783-EX**	**Medi-Trol SR 200mg tablet** **Each sustained release tablet contains:** **Tramadol Hydrochloride……200mg**	**-do-**
24.		**008784-EX**	**Medi-Trol SR 200mg capsule** **Each sustained release capsule contains:** **Tramadol Hydrochloride……200mg**	**-do-**
25.	M/s Fedro Pharmaceutical Labs. (Pvt) Ltd. 149-Industrial Estate, Hayatabad Peshawar	008792-EX	Tramanil 200mg tablet Each film coated tablet contains: Tramadol HCl……200mg	-do-
26.	Star Lab. Lahore	008977-EX	New Royal-225 tablet Each film coated tablet contains: Tramadol HCl……225mg	May, 2020
27.	Sigma Pharma Karachi	009033-EX	Tromodol 200mg Tablet Each tablet contains: Tramadol HCl.....200mg	-do-
28.	Medimarker's Lab. Hyderabad	009042-EX	Tradol 225mg tablet Each film coated contains: Tramadol Hydrochloride…..225mg	-do-
29.		009122-EX	Votadol Tablet 50mg Each film coated Tablet contains: Tramadol HCl……..…..50mg	-do-
30.	M/s Sigma Pharma	009164-EX	Tred tablet 200mg Each film coated tablet contains:	-do-

	International (Pvt) Ltd.		Tramadol HCl……..……..200mg	
31.	Plot No.E-50, NWIZ Port Qasim Karachi	009165-EX	Tred tablet 225mg Each film coated tablet contains: Tramadol HCl……..……..225mg	-do-
32.	M/s Trigon Pharmaceuticals (Pvt) Ltd. 8-Km Thokar Raiwind Road, Lahore	009318-EX	TRAMACUTE 200mg Tablet Each film coated tablet contains: Tramadol HCl ……200mg	-do-
33.		009319-EX	TRAMACUTE 225mg Tablet Each film coated tablet contains: Tramadol HCl …….225mg	-do-
34.	**M/s Welwrd Pharmaceuticals, Hattar**	**009372-EX**	**WELMADOL 100mg** **Each Extended Release tablet contains:** **Tramadol Hydrochloride …….100mg**	**-do-**
35.	Sigma pharma International Karachi	009390-EX	Tred Tablet Each film coated tablet contains: Tramadol HCl……150mg	-do-
36.	**Cunningham Pharma Lahore**	**009432-EX**	**CURADOL SR 200mg Tablets** **Each sustained release tablet contains:** **Tramadol HCl** **……200mg**	**Sep, 2020**
37.	M/s MTI Medical Lahore	009438-EX	Trampol 200mg Tablets Each film coated tablet contains: Tramadol HCl ……...200mg	-do-
38.		009439-EX	Trampol 225mg Tablets Each film coated tablet contains: Tramadol HCl ……...225mg	-do-
39.	M/s Arreta Pharma Rawat	009484-EX	TARMAX 225mg Tablet Each film coated tablet contains: Tramadol HCl…….....225mg	-do-
40.	Rakaposhi Peshawar	009514-EX	Tablet RN-DOL 200mg Each tablet contain: Tramadol HCl……200mg	-do-
41.	**M/s Bio-Mark Pharmaceutical Lahore**	**009533-EX**	**TRMPR SR Tablet** **Each Sustained Release Tablet Contains:** **Tramadol Hydrochloride……..200mg**	**Oct, 2020**
42.	M/s Dew-Max Pharmaceuticals Rawalpindi	009534-EX	NITRAM 225mg Tablets Each film coated tablet contains: Tramadol Hydrochloride ..……..225mg	-do-
43.	M/s Pharmatec Pakistan Karachi	009567-EX	Tarmol-X 225mg tablet Each tablet contains: Tramadol HCl ……225mg	-do-
44.	M/s Hiranis Pharmaceuticals Karachi	009603-Ex	HITRAM Tablet 300mg Each Extended Release Tablet Contains: Tramadol Hydrochloride……..…..300mg	-do-
45.		**009604-Ex**	**HITRAM Tablet 200mg** **Each Extended Release Tablet Contains:** **Tramadol** **Hydrochloride…..……..200mg**	**-do-**
46.		009605-Ex	HITRAM Tablet 225mg Each film coated Tablet Contains: Tramadol Hydrochloride ……....225mg	-do-
47.	M/s Seraph Pharmaceutical Islamabad	009618-Ex	Super Royal King Tablet 200mg Each Film Coated Tablet Contains:	-do-

			Tramadol (HCl)…….....200mg	
48.	M/s Seraph Pharmaceutical Islamabad	009623-Ex	Super Royal King Tablet 225mg Each Film-Coated Tablet Contains: Tramadol HCl …….....225mg	-do-
49.	M/s Pharma Lord Layyah	009702-Ex	NEW ROYAL Tablet Each film coated tablet contains: Tramadol Hydrochloride.....225mg	-do-
50.	M/s Medisure laboratories Karachi	009781-EX	NAMADOL SR 225mg Tablet Each Sustained Release Tablet Contains: Tramadol HCI.....225mg	Nov, 2020
51.	M/s Rotex Pharma Islamabad	009789-EX	VOLPAN Tablet Each Film Coated Tablet Contains: Tramadol Hydrochloride.....225mg	-do-
52.	M/s Isis Pharmaceutical & Chemical Works Karachi	009853-EX	TRAMAKING Tablet Each Film Coated Tablet Contains: Tramadol HCI.....200mg	-do-
53.		009854-EX	TRAMACOLE Royal Tablet Each Film Coated Tablet Contains: Tramadol HCI.....225mg	-do-
54.		009855-EX	TRAMADOL Tablet Each Film Coated Tablet Contains: Tramadol HCI.....200mg	-do-
55.	M/s Hygeia Pharma Rawalpindi	010148-EX	TAMOL-X 225mg Tablets Each Film Coated Tablet Contains: Tramadol Hydrochloride……225mg	-do-
56.	M/s Honig Pharma Lab. Rawalpindi	010185-EX	Trama King Tablets Each film coated tablet contains: Tramadol HCI.....200mg	-do-
57.	M/s Swiss Pharmaceutical Karachi	010233-EX	Royal King 225mg Tablets Each film coated tablet contains: Tramadol Hydrochloride..... 225mg	-do-
58.	M/s Pliva Pakistan Karachi	010242-EX	Tramadol 200mg Tablets Each film coated tablet contains: Tramadol Hydrochloride USP…….200mg	-do-
59.		010243-EX	Tramadol 225mg Tablets Each film coated tablet contains: Tramadol Hydrochloride USP…….225mg	-do-
60.		**010244-EX**	**Tramadol ER Tablets 150mg** **Each film coated extended release tablet contains:** **Tramadol Hydrochloride BP…….150mg**	**-do-**
61.		010324-EX	TAKADOL 200mg Tablet Each film coated tablet contains: Tramadol Hydrochloride……..200mg	-do-
62.		010325-EX	TAKADOL 225mg Tablet Each film coated tablet contains: Tramadol Hydrochloride.....225mg	-do-
63.	**M/s Welmark Pharmaceuticals, Plot No. 122, Block B, Phase V, Industrial Estate, Hattar.**	**010508-EX**	**Torax SR 200mg Tablet** **Each sustained release film coated tabletcontains:** **Tramadol HCl.....200mg**	**-do-**
64.	M/s Kanel Pharma,	010541-EX	Sonel-225mg Tablet Each film coated tablet contains:	-do-

	Plot No. 6, Street SS-3, National Industrial Zone, RCCI Rawat,RWP		Tramadol HCl….....225mg	
65.	M/s Saydon Pharmaceutical Industries Pvt. Ltd, 77-A Hayatabad Industrial Estate, Peshawar	010547-EX	Trafast 225mg Tablet Each film coated tablet contains: Tramadol HCI.....225mg	March 2021
66.	M/s Karsons Pharmaceuticals, Plot No. 01, Street No. SS-3, National Industrial Zone, Rawat, Rawalpindi,	010605-EX	Tramadol 225mg tablet Each film coated tablet contains: Tramadol Hydrochloride.....225mg	-do-
67.	M/s Avensis Pharmaceuticals, Plot No. F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim, Karachi.	010606-EX	Tramadol 225mg tablet Each film coated tablet contains: Tramadol Hydrochloride.....225mg	-do-
68.		010607-EX	Tramadol 200mg tablet Each film coated tablet contains: Tramadol Hydrochloride.....200mg	-do-
69.	M/s Amros Pharmaceuticals, Plot No. A-96, S.I.T.E. Super Highway, Karachi,	010634-EX	Tramadol 120mg capsule Each capsule contains: Tramadol hydrochloride…….120mg	-do-
70.	M/s Rotex Pharma (Pvt.) Ltd, Plot No. 206&207 Industrial Triangle Kahuta Road, Islamabad,	010652-EX	Volpan 200mg Tablet Each film coated tablet contains: Tramadol HCl.....200mg	-do-
71.	M/s Medisure Laboratories Pakistan (Pvt.) Ltd, A-115, S.I.T.E. Super Highway, Karachi.	010701-EX	TramakingTablet 225mg Each sustained release tablet contains: Tramadol HCI 225mg	-do-
72.		**010702-EX**	**Tramaking Tablet 200mg** **Each Sustained release tablet contains:** **Tramadol HCI** **.....200mg**	**-do-**
73.	M/s Iqra Pharmaceuticals, Plot No. 2, street No. S-9, RCCI Industrial Estate, Rawat, Rawalpindi,	010708-EX	Tramadol-IR 225mg Tablets Each film coated tablet contains: Tramadol Hydrochloride.....225mg	April 2021
74.	M/s Pharma Lord (Pvt.) Ltd, 12-Km, Lahore Road, Layyah,	010747-EX	Lord Royal Tablet Each film coated tablet contains: Tramadol Hydrochloride.....225mg	-do-
75.	M/s Focus & Rulz Pharmaceuticals (Pvt.) Ltd, 44-Industrial Triangle Road, Islamabad,	010888-EX	Tramapain-XX 225mg tablets Each film coated tablet contains: Tramadol HCI.....225mg	-do-
76.		010889-EX	Predol 225mg tablet Each film coated tablet contains: Tramadol HCI.....225mg	-do-
77.	M/s Universal Pharmaceuticals (Pvt.) Ltd, 131-A, Hayatabad Industries Estate,	010890-EX	Tramapain-XX 225mg Tablet Each film coated tablet contains: Tramadol HCI.....225mg	-do-

	Peshawar,			
78.	M/s Medisure Laboratories Pakistan (Pvt.) Ltd, A-115, S.I.T.E. Super Highway, Karachi.	010953-EX	Namadol 225mg tablet Each tablet contains: Tramadol HCI 225mg	-do-
79.		010954-EX	Tymol 225mg tablet Each tablet contains: Tramadol HCI 225mg	-do-
80.	M/s Safe Pharmaceuticals (Pvt.) Ltd, Plot No. C-1, 20, Sector 6-B, North Karachi Industrial Area, Karachi,	010969-EX	Tramadol 225mg tablet Each film coated tablet contains: Tramadol HCL.....225mg	June, 2021
81.	M/s Avensis Pharmaceuticals, Plot No. F-24/1, Eastern Industrial Zone Port Muhammad Bin Qasim, Karachi,	010982-EX	Tramaking tablet 225mg Each film coated tablet contains: Tramadol HCI 225mg	-do-
82.	M/s Friends Pharma (Pvt.) Ltd, 31-Km Ferozepur Road, Lahore,	010983-EX	Tamal-225mg tablet Each film coated tablet contains: Tramadol Hydrochloride.....225mg	-do-
83.	M/s Wimits Pharmaceuticals, Plot No. 129, sunder Industrial Estate Raiwind Road, Lahore,	010996-EX	T-mol 200mg tablet Each film coated tablet contains: Tramadol HCl.....200mg	-do-
84.	M/s Amros Pharmaceuticals, Plot No. A-96, S.I.T.E. Super Highway, Karachi,	011071-EX	Tramaking 225mg tablet Each film coated tablet Tramadol HCl.....225mg	-do-
85.	M/s Avensis Pharmaceuticals, Plot No. F-24/1, eastern Industrial Zone, Port Muhammad Bin Qasim, Karachi.	011111-EX	Tramaking Capsule 120mg Each capsule contains: Tramadol HCI 120mg	-do-
86.	M/s Honig Pharmaceutical Laboratories, 14-Km, Adyala Road Rawalpindi,	011124-EX	Tramadol Capsule Each capsule contains: Tramadol HCI 120mg	-do-
87.	M/s Pharma Lord (Pvt.) Ltd, 12-Km, Lahore Road, Layyah,	011159-EX	Tramalor tablet Each tablet contains: Tramadol Hydrochloride.....225mg	July, 2021
88.		011160-EX	TDOL tablet Each tablet contains: Tramadol Hydrochloride.....225mg	-do-
89.	M/s Mission	011168-EX	Tramol-X tablet Each film coated tablet conations;	-do-

	Pharmaceuticals, A-94, S.I.T.E. Super		Tramadol Hydrochloride.....225mg	
90.	Highway Karachi,	011169-EX	Tramol 200mg tablet Each film coated tablet contains: Tramadol Hydrochloride.....200mg	-do-
91.	M/s Amros Pharmaceuticals, Plot No. A-96, S.I.T.E. Super Highway Karachi,	011184-EX	New Royal 225mg tablet Each film coated tablet contains: Tramadol HCI.....225mg	-do-
92.	M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattarband Road, Thokar Niaz Baig, Multan Road Lahore,	011214-EX	FSDOL 225mg tablet Each film coated tablet contains: Tramadol Hydrochloride.....225mg	-do-
93.	M/s Medisure Laboratories Pakistan (Pvt) Ltd, A-115, S.I.T.E. Super Highway, Karachi.	011216-EX	Tramadol 225mg tablet Each tablet contains: Tramadol HCI 225mg	-do-
94.	M/s Medisure Laboratories Pakistan (Pvt) Ltd, A-115, S.I.T.E. Super Highway, Karachi.	011317-EX	Temol 225mg tablet Each tablet contains: Tramadol HCl.....225mg	-do-
95.	M/s Safina Pharmaceuticals (Pvt.) Ltd, 17-Km, Lahore Sheikhupura Road, Distt, Sheikhupura,	011368-EX	Saftram 225mg tablet Each film coated tablet contains: Tramadol Hydrochloride.....225mg	September, 2021
96.	M/s Lawari International, Valley Road gulkada Sharif, Swat,	011455-EX	Ladol X 225mg Tablet Each film coated tablet contains: Tramadol HCI.....225mg	-do-
97.	M/s Fahmir Pharma (Pvt.) Ltd, Main Mandiwala Stop, 26-Km, Lahore Jaranwala Road, Tehsil Sharaqpur sharif, Distt, Sheikhupura,	011499-EX	Tramir XX 200mg tablet Each film coated tablet contains: Tramadol HCI.....200mg	-do-
98.				
99.	M/s AAA Health Pharmaceutical Laboratories, Plot No. 9-A, Street No. N-5, RCCI Rawat,	011535-EX	Kadrol 225mg tablet Each film coated tablet contains: Tramadol HCI.....225mg	-do-
100.	M/s Medicraft Pharmaceuticals (Pvt.) Ltd, 126-B, Industrial Estate, Hayatabad, Peshawar,	011567-EX	Tramol-X 225mg capsule Each capsule contains: Tramadol HCI.....225mg	-do-
101.	M/s Medisure Laboratories Pakistan (Pvt.) Ltd, A-115, S.I.T.E. Super Highway, Karachi.	011572-EX	Temol XX tablet Each sustained release tablet contains: Tramadol HCI……..……..225mg	-do-
102.	M/s Maxitech Pharma (Pvt.) Ltd,	011573-EX	Matradol SR 225mg tablet	-do-

	Plot No. F-178 S.I.T.E. Phase-II Super Highway, Karachi,		Each sustained release film coated tablet contains: Tramadol Hydrochloride.....225mg	
103.	M/s Swat Pharmaceuticals, Valley Road, Sherari Gulkada No. 3, Saidu Sharif Swat Khyber PakhtoonKhwa,	0116005-EX	Tomal-X 225mg Tablet Each tablet contains: Tramadol HCI.....225mg	-do-
104.	M/s Fahmir Pharma (Pvt.) Ltd, Main Mandiwala Stop, 26-Km, Lahore Jaranwala Road, Tehsil Sharaqpur sharif, Distt, Sheikhupura,	011619-EX	Tramir XXX 225mg Tablet Each film coated tablet contains: Tramadol HCI.....225mg	-do-
105.	M/s Pliva Pakistan (Pvt.) Ltd, Plot No. B-77 Hub Industrial Trading Estate, Hub Baluchistan,	011646-EX	Tramadol 120mg Capsule Each capsule contains: Tramadol Hydrochloride BP.....120mg	November, 2021
106.	M/s MBL Pharma, Plot No. B-77/A, Hub Industrial Trading Estate, Baluchistan,	011647-EX	Ramadol 200mg Tablet Each film coated tablet contains: Tramadol Hydrochloride.....200mg	-do-
107.		011648-EX	Ramadol 225mg Tablet Each film coated tablet contains: Tramadol Hydrochloride.....225mg	-do-
108.	M/s Palpex Pharmaceuticals (Pvt.) Ltd, Plot No. FD-46-A8, Street-I, Sector-38, Korangi Creek Industrial Park, Karachi,	011677-EX	Tomol-X 225mg Tablet Each film coated tablet contains: Tramadol HCI.....225mg	-do-
109.	M/s Convell Laboratories, Saidu Sharif, Swat,	011751-EX	Tramavel 225mg Tablet Each film coated tablet contains: Tramadol HCI.....225mg	December, 2021
110.	M/s Trigon Pharmaceuticals (Pvt.) Ltd., 8-Km, Thokar Raiwind Road,Lahore	011830-EX	Tamol-X 225mg Tablets Each film coated tablet contains: Tramadol HCl.....225mg	-do-
111.	M/s Honig Pharmaceutical Laboratories,14-Km, Adyala Road,Rawalpindi	011854-EX	Tramaking 225mg Tablets Each film coated tablet contains: Tramadol HCl ……225mg	Jan-22
112.	M/s Medicraft Pharmaceuticals (Pvt.) Ltd., 126-B, Industrial Estate,	011873-EX	Tramapain-XX 225mg Tablets Each tablet contains: Tramadol HCl ……..225mg	-do-
113.	Hayatabad, Peshawar	011874-EX	Tymol-X 225mg Tablets Each tablet contains: Tramadol HCl ……..225mg	-do-
114.	M/s Palpex Pharmaceuticals (Pvt.) Ltd.,FD-46-A8, Street-I, Sector 38, Korangi Creek Industrial Park,Karachi	011913-EX	Tee-Doll 225 Tablets Each film coated tablet contains: Tramadol HCl…….225mg	-do-

115.	M/s Trigon Pharmaceuticals (Pvt.) Ltd.,8-Km, Thokar Raiwind Road, Lahore	011929-EX	PolmeX 225mg Tablets Each film coated tablet contains: Tramadol HCl……225mg	-do-
116.	M/s Swera Pharmaceuticals, Plot No.27, Street No.S-4, Industrial Area,Rawat	012033-EX	Roymax 225mg Capsules Each capsule contains: Tramadol HCl……..…225mg	-do-
117.	M/s Trigon Pharmaceuticals (Pvt.) Ltd., 8-Km Thokar Raiwind Road, Lahore	012070-EX	Royden 225mg Tablets Each film coated tablet contains: Tramadol HCl ……225mg	-do-
118.	M/s Quaper (Pvt.) Ltd., 26-A, Small Industrial Estate, Lahore Road,Sargodha	012091-EX	Q-Tamol 225mg Tablets Each film coated tablet contains: Tramadol Hydrochloride……..225mg	-do-
119.	M/s English Pharmaceutical Industries,Link Kattar BundRoad, Thokar Niaz Baig, Multan Road,Lahore	012102-EX	Trepol 225mg Tablets Each film coated tablet contains: Tramadol Hydrochloride ……..…..225mg	Feb-22
120.	M/s Fahmir Pharma (Pvt.) Ltd., Main Mandiwala Stop, 26-Km, Lahore-Jaranwala Road, Tehsil Sharaqpur Sharif, District Sheikhupura.	012124-EX	Tramir 120mg Capsules Each capsule contains: Tramadol HCl……120mg	-do-
121.	M/s Amson Vaccines & Pharma (Pvt.) Ltd.,Plot No.154, Kahuta Triangle,Islamabad	012149-EX	Amsotrol 225mg Tablets Each film coated tablet contains: Tramadol HCl ……225mg	-do-
122.	M/s Trigon Pharmaceuticals (Pvt.) Ltd., 8-Km Thokar Raiwind Road, Lahore	012204-EX	Tramaking 225mg Tablets Each film coated tablet contains: Tramadol HCl ……225mg	Mar-22
123.	M/s Cure Laboratories (Pvt.) Ltd., Plot No.11 & 12, Street No. NS-2, National Industrial Zone, Rawat-Rawalpindi	012245-EX	Tramadol-X 225 Tablets Each film coated tablet contains: Tramadol HCl ……225mg	-do-
124.	M/s Pharma Lord (Pvt.) Ltd., 12-Km, Lahore Road, Layyah	012249-EX	Tymol-X 225mg Tablets Each tablet contains: Tramadol Hydrochloride……..225mg	-do-
125.	M/s Medicraft Pharmaceuticals (Pvt.) Ltd, 126-B, Industrial Estate, Hayatabad, Peshawar	012359-EX	Tremomed 225mg Tablets Each film coated tablet contains: Tramadol HCl ……..……225mg	-do-
126.		012360-EX	Tramaking 225mg Tablets Each film coated tablet contains: Tramadol HCl ……..…....225mg	-do-
127.	M/s Cure Laboratories (Pvt.) Ltd, Plot No. 11&12, Street No. NS-2, National Industrial	012516-EX	Tymol-X 225 mg Tablet Each tablet contains:	-do-

	Zone Rawalpindi,		Tramadol HCl.....225mg	
128.	M/s Medicraft Pharmaceuticals (Pvt.) Ltd, 126-B, Industrial Estate, Hayatabad, Peshawar,	012589-EX	Tremomed 250mg Tablets Each film coated tablet contains: Tramadol HCl ……250mg	-do-
129.	M/s Pharma Lord (Pvt.) Ltd, 12-Km, Lahore Road, Layyah,	012616-EX	Tramaking 225mg Tablet Each film coated tablet contains: Tramadol Hydrochloride.....225mg	June-22
130.	M/s Jawa Pharmaceuticals (Pvt.) Ltd, 112/10, Quaid-e-Azam Industrial Estate Kot Lakhpat, Lahore,	012818-EX	T-Doll 225mg Tablet Each tablet contains: Tramadol HCl.....225mg	-do-
131.	M/s Magns Pharmaceuticals, Plot No. 7-B, Value Addition City, Sahianwala Road, Khurrainwala, Faisalabad,	012843-EX	Magtrol 225mg Tablets Each film coated tablet contains: Tramadol HCl.....225mg	-do-
132.	M/s Pharma Lord (Pvt.) Ltd, 12-Km, Lahore Road, Layyah,	012864-EX	Tramacute 225mg Tablet Each tablet contains: Tramadol Hydrochloride.....225mg	September-22
133.		012865-EX	Namadol 225mg tablet Each tablet contains: Tramadol Hydrochloride.....225mg	-do-
134.		012866-EX	Tee-Doll 225mg tablet Each tablet contains: Tramadol Hydrochloride.....225mg	-do-
135.	M/s Orta Laboratories (Pvt.) Ltd, 24-Km, Multan Road Off Defence Road Mohlanwal, (Near Bahria Town Bridge) Lahore,	012890-EX	Tamul-X 225mg Tablet Each film coated tablet contains: Tramadol Hydrochloride.....225mg	-do-
136.	M/s Linta Pharmaceuticals (Pvt.) Ltd, Plot No. 3, Street No. S-5, National Industrial Zone Rawat,	012939-EX	Taymol-X 225mg Tablets Each film coated tablet contains: Tramadol HCl……225mg	-do-
137.	M/s Roryan Pharmaceutical Industries (Pvt.) Ltd, 85/B, Hayatabad Industrial Estate, Peshawar,	012990-EX	Ro-Tram 225mg Tablet Each tablet contains: Tramadol HCl.....225mg	-do-
138.	M/s Pharma Lord (Pvt.) Ltd, 12-Km, Lahore Road, Layyah,	012993-EX	Temol-XX 225mg Tablet Each tablet contains: Tramadol Hydrochloride.....225mg	-do-

139.	M/s Medisure Laboratories Pakistan (Pvt) Ltd, A-115, S.I.T.E. Super Highway, Karachi.	013037-EX	Tamral 250mg tablet Each tablet contains: Tramadol HCl…….250mg	-do-
140.	M/s Medicraft Pharmaceuticals (Pvt.) Ltd, 126-B, Industrial Estate, Hayatabad, Peshawar,	013049-EX	Tamol-X 225mg tablet Each tablet contains:- Tramadol HCl……..225mg	October-22
141.	**M/s Don Valley Pharmaceuticals (Pvt.) Ltd, 31-Km, Main Ferozepur Road, Lahore,**	**013174-EX**	**Trama 200mg Tablets** **Each extended release tablet contains:** **Tramadol** **HCl.....200mg**	**November-22**
142.	M/s Pharma Lord (Pvt.) Ltd, 12-Km, Lahore Road, Layyah,	013186-EX	Tamol-X 225mg Tablet Each tablet contains: Tramadol Hydrochloride.....225mg	-do-

4. It should be noted that strengths of 150mg and 200mg of tramadol are approved by MHRA as prolonged release formulations (capsules) and up to 300mg as extended release tablets by USFDA.

5. The matter is placed before the Board for consideration and decision please.

Decision: **The Board referred the matter to Expert Working Group for the review of "Human Formulations of Pharmaceutical Drug Products" for review of formulations containing more than 100mg Tramadol in light of report meeting with the Government of Nigeria and the Global Rapid Interdiction of Dangerous Substances and availability of sustained release formulations in reference regulatory authorities.**

Case No. 01: Registration of Drugs under the Drugs Act, 1976-Virtual Inspection Reports of Manufacturer Abroad.

Following veterinary products approved in various meeting of Registration Board subject to inspection of manufacturer abroad as per import policy.

S. No.	Name of Importer/ Manufacturer & meeting number	Name of Drug/ Composition/	Panel of Inspector(s)/ Date of inspection
1.	M/s. Chakwal Pharma International, OTI Plaza, Basement Ground, 1st ,2nd & 3rd floor, 210 Lalazar Commercial Market, Thokar Niaz Baig, Raiwind Road, Lahore./ Manufacturer & Marketing Authorization Holder:- M/s. Medivet sa, route de korbous km 58020 Soliman, Tunisia.	Triclazole 10% Oral Suspension Each 100ml contains:- Triclabendazole……..10g **(M-297)**	(i)Mr. Manzoor Ali Bozdar, Director (HOTC), DRAP, Islamabad. (ii)Mr. Muneeb Cheema, Deputy Director (RRR), DRAP, Islamabad.
2.	M/s. Chakwal Pharma International O.T.I Plaza Basement Ground, 1st, 2nd & 3rd floor, 210-Lalazar Commercial Market Thokar Niaz Baig, Raiwind Road, District Lahore./ **Manufacturer & Marketing Authorization Holder:-** M/s. Medivet, Korbous Road 5Km Soliman, 8020 Tunisia.	**(i)** Anthelben S 2.5% Oral Suspension Each 100ml contains:- Albendazole……2.5gm **(ii)** Cydox 500 Oral Powder Each 100gm of final product contains:- Doxycycline Hyclate…….50g **(iii)** Amoxidol 80% Oral Powder Each 100gm contains:- Amoxicillin Trihydrate….80g **(M-308)**	
3.	M/s. Chakwal Pharma International O.T.I Plaza Basement Ground, 1st, 2nd & 3rd floor, 210-Lalazar Commercial Market Thokar Niaz Baig, Raiwind Road, District Lahore./ **Manufacturer & Marketing Authorization Holder:-** M/s MEDIVET s.a, Korbous Road, Km 5, 8020 Soliman, Tunisia.	**(i)** Oxyfen Oral Suspension 2.265g/100ml Each 100ml contains:- Oxfendazole …….. 2.265g **(ii)** Roxyl Oral Solution 10.0g/100ml Each 100ml contains:- Enrofloxacin …….10g **(M-308)**	
4.	M/s. Chakwal Pharma International, OTI Plaza, 210-Lalazar Commercial Market, Thokar Niaz Baig, Raiwind Road, Lahore./ Manufacturer & Marketing	Flumexyl 50% Oral Solution Each 100ml contains:- Flumequine……...50g **(M-316)**	

	Authorization Holder: - M/s. Medivet sa, route de Korbous Km 5 Soliman, 8050, Tunisia.		

Accordingly, an inspection was carried out by inspection panel dated 4th & 5th January 2023 and final remarks of the panel are as under:-

FINAL REMARKS:

The following observations were noted during the virtual inspection:

i. The firm i.e., M/s Medivet SA, Route de Korbous Km 5-8020 Soliman Tunisia was manufacturing Penicillins products along with other general products in the same facility however as per international regulatory practices, dedicated facilities are required for production of penicillin drug products.
ii. The temperature and humidity was not maintained/ controlled at the time of inspection.
iii. The firm did not possess stability chambers for real time stability testing. The finished product samples were placed in ware house in a separate area for real time stability where the temperature and humidity was not maintained/controlled.
iv. The firm did not possess microbiology laboratory for microbiological testing.

In view of above the panel **do not recommend** the registration of above products.

Decision:- In view of the shortcomings highlighted and the recommendations given by the inspection panel, the Board decided to reject the registration application(s) of above mentioned drugs manufactured by M/s. Medivet sa, route de korbous km 58020 Soliman, Tunisia as per recommendations of the panel.

Case No. 02: Registration of Drugs under the Drugs Act, 1976-Virtual Inspection Reports of Manufacturer Abroad.

Following veterinary products approved in various meeting of Registration Board subject to inspection of manufacturer abroad as per import policy.

S. No.	Name of Importer/ Manufacturer & meeting number	Name of Drug/ Composition/	Panel of Inspector(s)/ Date of inspection
1.	M/s. Chakwal Pharma International O.T.I Plaza basement ground, 1st, 2nd, 3rd Floor, 210 Lalazar Commercial, Market Thokar Niaz Baig, Raiwand Road, Lahore./ Manufacturer:- M/s. DORCAS, Zone Industrialle de Kondar, 4020 Sausse, Tunisia. Marketing Authorization Holder:- M/s. MEDIVET, Korbous Road, Km 5 8020 Soliman, Tunisia.	Ivermectyl 1% Injectable Solution (Veterinary) Each 100ml contains:- Ivermectin……....1g **(M-307)**	(i)Mr. Manzoor Ali Bozdar, Director (HOTC), DRAP, Islamabad. (ii)Mr. Muneeb Cheema, Deputy Director (RRR), DRAP, Islamabad.
2.	M/s. Chakwal Pharma International O.T.I Plaza Basement Ground, 1st, 2nd & 3rd floor, 210-Lalazar Commercial Market Thokar Niaz Baig, Raiwind Road,	Ivermectyl F Injectable Solution Each 100ml contains:- Ivermectin……1gm Clorsulon…….10gm	

	District Lahore./ **Manufacturer:-**M/s. Dorcas, zone industrielle Kondar, 4020 Sousse, Tunisia. **Marketing Authorization Holder:-** M/s Medivet, Korbous Road 5Km soliman, 8020 Tunisia.	**(M-308)**	

Accordingly, an inspection was carried out by inspection panel dated 1st & 2nd February 2023 and final remarks of the panel are as under:-

FINAL REMARKS:

The following observations were noted during the virtual inspection:

i. The firm i.e., M/s Dorcas, Zone Industrielle de Kondar 4020 Sousse, Tunisia was manufacturing veterinary and human injectable drugs in the same facility. The firm was also manufacturing steroidal injectable drugs along with the general injectable drugs in the same production facility which is not recommended as per international regulatory practices.

ii. The firm was not performing quality control testing of the raw materials and quality release of finished products. It was informed during inspection that aforesaid quality tests are being performed by M/s Medivet SA, Route de Korbous Km 5-8020 Soliman Tunisia. However, during virtual inspection of Medivet SA, Route de Korbous Km 5-8020 Soliman Tunisia the firm didn't mention regarding performance of quality testing of the products being contract manufactured by M/s Dorcas, Zone Industrielle de Kondar 4020 Sousse, Tunisia.

iii. M/s Medivet SA, Route de Korbous Km 5-8020 Soliman Tunisia do not possess microbiology laboratory therefore the sterility testing is questionable.

iv. The firm was not performing the stability testing and during inspection they informed that it is being conducted by M/s Medivet SA, Route de Korbous Km 5-8020 Soliman Tunisia, which requires verification. Moreover, the panel during the virtual inspection of aforesaid facility noted that they did not possess stability chambers for real time stability testing. The finished product samples were placed in ware house in a separate area for real time stability where the temperature and humidity was not maintained/controlled.

In view of above the panel **do not recommend** the registration of products mentioned in Part III of the report.

Decision:- In view of the shortcomings highlighted and the recommendations given by the inspection panel, the Board decide to rejected the registration application(s) of above mentioned drugs manufacturer by M/s. Dorcas, Zone Industrielle Kondar, 4020 Sousse, Tunisia as per recommendations of the panel.

Case No. 03: Registration of Drugs under the Drugs Act, 1976-Virtual Inspection Reports of Manufacturer Abroad.

Following veterinary products approved in various meeting of Registration Board subject to inspection of manufacturer abroad as per import policy.

S. No.	Name of Importer/ Manufacturer & meeting number	Name of Drug/ Composition/	Panel of Inspector(s)/ Date of inspection
1.	M/s. Huzaifa International, Commercial Area, Aziz	(i) Henzole-10% Suspension Each 100ml contains:-	(i)Mr. Manzoor Ali Bozdar, Director (HOTC), Drug

	Bhatti Town, Sargodha./ M/s. Shandong Soocom Animal Remedy Co., Ltd. Xundakang Road No. 666 of Agricultural High & New Technology Development Zone of Jinan, China.	Albendazole…….10g **(M-297)** (ii) Florfenicol-30% Injection Each 100ml contains:- Florfenicol…….30g **(M-297)**	Regulatory Authority of Pakistan, Islamabad. (ii)Mr. Muneeb Cheema, Deputy Director (RRR), Drug Regulatory Authority of Pakistan, Islamabad.

Accordingly, an inspection was carried out by inspection panel dated 03rd March, 2023 and final remarks of the panel are as under:-

FINAL REMARKS:

Based on the preceding's of virtual inspection, documents reviewed and videos of the unit seen, the panel has reached to the conclusion that the firm has basic systems to manufacture veterinary drugs. However, panel of the view that matter needs to be placed before the Registration Board for following reasons:

***"There was sheer breach of trust and misrepresentation by the firm that on one hand firm was saying that they not manufactured Albendazole-10% Suspension & Florfenicol-30% Injection since long. But on the other hand the stock of Albendazole-10% Suspension & Florfenicol-30% Injection was found in the finished goods store with* urdu labelling".**

Decision:-

Registration Board deliberated the matter and decided to remand back the case to inspecting panel for clear and candid recommendation.

Case No.04:- Request of M/s. Star Laboratories (Pvt) Ltd, Lahore for Correction of Composition of already Registered Veterinary Drug.

M/s. Star Laboratories (Pvt) Ltd, Lahore has requested for correction of composition of already registered veterinary drug as per detail mentioned against each:-

S. No.	Regn. No.	Product Granted Composition / Pack Size	Demanded Composition/ Pack Size	Remarks/ Diary No. R&I & Initial date of Regn./Renewal Trail
I	II	III	IV	V
1.	026430	Teragen Aerosol Spray **Each gm contains:-** Oxytetracycline HCI…40mg Gentian Violet……...4mg **(200gm)**	Teragen Aerosol Spray **Each ml contains:-** Oxytetracycline HCI…40mg Gentian Violet……...4mg **(200ml)**	Dy. No. 12267-R&I dated 18-05-2023. 21st September, 2000 17th August, 2020

M/s. Star Laboratories (Pvt) Ltd, Lahore has deposited the required fee of **Rs.30,000/-** for correction of composition and submitted following supporting documents:-

(i) Copy of Registration letter/ renewal trail.

Decision:- Registration Board deliberated the matter and decided to approved the correction as per following details:

Regn.	Existing Composition /	Corrected Composition/

No.	Pack Size	Pack Size
026430	Teragen Aerosol Spray **Each gm contains:-** Oxytetracycline HCI…40mg Gentian Violet……...4mg **(200gm)**	Teragen Aerosol Spray **Each ml contains:-** Oxytetracycline HCI…40mg Gentian Violet……...4mg **(200ml)**

Case No.05:- Request of M/s. Selmore Pharmaceuticals (Pvt) Ltd, Lahore for Revise Formulation of already Registered Veterinary Drug.

M/s. Selmore Pharmaceuticals (Pvt) Ltd, Lahore has requested for revise formulation of already registered veterinary drug as per detail mentioned against each:-

S. No.	Regn. No.	Product Granted Composition / Pack Size	Demanded Composition/ Pack Size	Remarks/ Diary No. R&I & Initial date of Regn./Renewal Trail
I	II	III	IV	V
1.	029661	Scour-X Oral Suspension Each 100ml contains:- Sulphadiazine……..3.550gm Sulphadimidine…...2.840gm Neomycin Sulphate……..0.180gm **Hyoscine Methylbromide….0.004gm** Pectin……..0.710gm Kaolin……..…..10.330gm Vitamin B-1……0.015gm Vitamin B-2……0.022gm	Scour-X Oral Suspension Each 100ml contains:- Sulphadiazine……..3.550gm Sulphadimidine…...2.840gm Neomycin Sulphate……..0.180gm **Hyoscine N butylbromide….0.004gm** Pectin……..0.710gm Kaolin……..…..10.330gm Vitamin B-1……0.015gm Vitamin B-2……0.022gm	Dy. No. 12028-R&I dated 16-05-2023. 22-07-2003 Registration Board granted the renewal w.e.f. 22-07-2018 to 21-07-2023

M/s. Selmore Pharmaceuticals (Pvt) Ltd, Lahore has deposited the required fee of **Rs.5000 + 25000/- = Rs.30,000/--** for correction of composition and submitted following supporting documents:-

(i) Copy of Registration letter/ renewal trail.
(ii) Me-too status of Scour-X Oral Suspension.
(iii) Previous requests.

Decision:- Registration Board deliberated the matter and decided to approved the composition as per following details:

S. No.	Regn. No.	Existing Composition	Approved Composition
2.	029661	Scour-X Oral Suspension Each 100ml contains:- Sulphadiazine……..3.550gm Sulphadimidine…...2.840gm Neomycin Sulphate……..0.180gm **Hyoscine Methylbromide….0.004gm** Pectin……..0.710gm Kaolin……..…..10.330gm Vitamin B-1……0.015gm Vitamin B-2……0.022gm	Scour-X Oral Suspension Each 100ml contains:- Sulphadiazine……..3.550gm Sulphadimidine…...2.840gm Neomycin Sulphate……..0.180gm **Hyoscine N butylbromide….0.004gm** Pectin……..0.710gm Kaolin……..…..10.330gm Vitamin B-1……0.015gm Vitamin B-2……0.022gm

Case No. 06: Registration of Drugs under the Drugs Act, 1976-Virtual Inspection Reports of Manufacturer Abroad.

Following veterinary products approved in 308th meeting of Registration Board subject to inspection of manufacturer abroad as per import policy.

S. No.	Name of Importer/ Manufacturer & meeting number	Name of Drug/ Composition/	Panel of Inspector(s)/ Date of inspection
1.	M/s. Medicinia Corporation, 234, Sunny Plaza, Hasrat Mohani Road, Karachi. / Manufacturer & Marketing Authorization Holder:- M/s. Reyoung Pharmaceutical Co., Ltd., No.1, Ruiyang Road, Yiyuan County, Shandong Province, China.	**(i)** Amoclave Tablet 375mg Each film coated tablet contains:- Amoxicillin as Trihydrate…250mg Potassium Clavulanate as Clavulanic Acid……...125mg **(ii)** Amoclave Tablet 625mg Each film coated tablet contains:- Amoxicillin as Trihydrate……500mg Potassium Clavulanate as Clavulanic Acid……...……..125mg **(iii)** Amoclave Tablet 1000mg Each film coated tablet contains:- Amoxicillin as Trihydrate……..875mg Clavulanic Acid as Potassium Clavulanate ……..125mg **(M-308)**	(i)Mr. Abdullah Abro, Deputy Director (Controlled Drugs), DRAP, Islamabad. (ii)Mr. Muhammad Kashif, Deputy Director (Biological), DRAP, Islamabad. **13h & 14th February, 2023**

Accordingly, an inspection was carried out by inspection panel dated 13h & 14th February, 2023 and final remarks of the panel are as under:-

Conclusion & Recommendations:

Based on the proceedings of virtual inspection, documents reviewed and videos of the unit seen, the panel has reached to the conclusion that the firm has basic systems to manufacture tablets and appeared to comply the cGMP requirements. Hence, the panel recommends that the registration of the applied products namely registration of applied products namely Amoclave Tablet (375mg,625 and 1000mg) may be granted to M/s. Medicinia Corporation, 234, Sunny Plaza, Hasrat Mohani Road, Karachi Karachi,

However, the panel strongly recommends on-site inspection in order to verify/ascertain the Good Manufacturing Practices (GMP) of the firm **within one year** as virtual inspection can never replace/in-person inspection.

Inspection report was placed before the Registration Board in its 327th meeting and Board decided as under:

"Registration Board deliberated the matter and decided to remand back the case to inspecting panel for clear and candid recommendation"

Accordingly, letter was issued to the panel members and the panel reply is as under:

S.No.	Conclusion & Recommendations	Explanation
1.	Based on the proceedings of virtual inspection, documents reviewed and videos of the unit seen, the panel has reached to the conclusion that the	The panel clearly recommended that the firm has basis system to manufactured tablets and appeared to comply the

	firm has basic systems to manufacture tablets and appeared to comply the cGMP requirements. Hence, the panel recommends that the registration of the applied products namely Amoclave Tablet (375mg,625 and 1000mg) may be granted to M/s. Medicinia Corporation, 233, Sunny Plaza, Hasrat Mohani Road, off. 1.1 Chundrigar Road, Karachi.	cGMP requirements. The registration of the applied products namely Amoclave Tablet (375mg, 625 and 1000mg) may be granted to M/s. Medicinia Corporation, 233, Sunny Plaza, Hasrat Mohani Road, off. 1.1 Chundrigar Road, Karachi. **Panel has neither barred grant of registration nor given conditional approval.**
2.	However, the panel strongly recommends on-site inspection in order to verify/ascertain the Good Manufacturing Practices (GMP) of the firm **within one year** as virtual inspection can never replace/in-person inspection.	Panel has emphasized for on-site inspection as it is the best way to determine the compliance of GMP standards, so waiver of on-site inspection shall not exceed more than one year. However, in public health emergencies and other situations when it not feasible for inspectors to travel then for a temporary time on-site inspections may be waived but not more than one year.

Decision:-

Registration Board deliberated the matter and decided to remand back the case to inspecting panel for clear and candid recommendation.

Case No. 07:- Reconstitution of Expert Working Group on Veterinary Drugs

Drug Registration Board in its 281st meeting held on 11-13th April, 2018 has constituted expert working group on veterinary drugs regarding matters related to veterinary drugs.

Decision of 281st meeting of RB: -

The Board observed that the constitution of the veterinary expert Committee notified under Section 10 of Drugs Act, 1976 vide SRO No.81(I)/2015 dated 26-01-2015 needs to be revised for inclusion of relevant expert(s) member(s) of the Board etc. However, since process of revision of constitution may take some time as the approval of Federal Government and other relevant organizations are required before revised Gazette notification, so, in order to avoid pendency/delay in processing of issues relating to veterinary drugs requiring input/recommendation of pertinent veterinary expert, the Board decided to constitute an Expert Working Group on Veterinary Drugs having following composition: -

1.	*Dr. Qurban Ali, Ex-Director General* *National Veterinary Laboratory, Islamabad.* *Expert Member Veterinary Drugs*	*Chairman*
2.	*Animal Husbandry Commissioner or his representative,* *M/o National Food Security & Research, Islamabad.*	*Member*
3.	*Dr.Mazhar-ul-Haq* *Veterinary Pharmacologist* *Arid Agriculture University, Rawalpindi.*	*Member*
4.	*Any other relevant expert(s)*	*As Co-opted member(s)*
5.	*Deputy Director (Reg-I), DRAP*	*Member, Secretary*

The expert working group will provide expert advice / views and recommendations to the Registration Board on matters relating to veterinary drugs referred by the Board including review of existing/new veterinary drug formulations. The group can Co-opt any relevant expert(s) as Co-opted member(s).

The Board further advised that in order to avoid any pendency, the "expert working group" needs be notified immediately without waiting till formal approval of the minutes of 281st

meeting so that the meeting of the expert working group may be called earlier.

Accordingly notification of expert working group was issued on 08th May 2018. Chairman of Expert working Group co-opted Dr. Shabnum Firdous, Secretary PVMC as a co-opted member, and letter for in this regard was issued on 16th June 2022.

After completion of 2nd term Dr. Qurban Ali, (Chairman EWG) was retired as member registration board [under Rule 24 (f) of Drugs (LR&A) Rules, 1976 (Expert Member for Veterinary Drugs)]. Accordingly denotification letter of EWG, after approval from Chairman, Registration Board, was issued on 24th February, 2023 vide letter No. 7-4/2018 (M-281) and endorsed in 325th meeting of Registration Board.

Decision of M-326: - The Board observed that the constitution of the veterinary expert Committee notified under Section 10 of Drugs Act, 1976 vide SRO No.81(I)/2015 dated 26-01-2015 needs to be revised in order to avoid pendency/delay in processing of issues relating to veterinary drugs which require input/recommendation of pertinent veterinary expert, hence Board decided to constitute an Expert Working Group on Veterinary Drugs having following composition: -

1.	*Dr. Qurban Ali,* *Ex-Director General,* *National Veterinary Laboratory, Islamabad.*	*Chairman*
2.	*Dr. Ayesha Yaqoob, Drug Testing Laboratory, Rawalpindi.*	*Member*
3.	*Mst. Najia Saleem, Deputy Director (PE&R), DRAP*	*Member*
4.	*Any other relevant expert(s)*	*As Co-opted member(s)*
5.	*Assistant Director (I&V-I), DRAP*	*Member, Secretary*

The expert working group will provide expert advice / views and recommendations to the Registration Board on matters relating to veterinary drugs referred by the Board including review of existing/new veterinary drug formulations. The group can Co-opt any relevant expert(s) as Co-opted member(s).
The Board further advised that in order to avoid any pendency, the "expert working group "needs be notified immediately without waiting till formal approval of the minutes of 281st meeting so that the meeting of the expert working group may be called earlier.

Decision: - The Board observed that the constitution of the veterinary expert Committee notified under Section 10 of Drugs Act, 1976 vide SRO No.81(I)/2015 dated 26-01-2015 needs to be revised in order to avoid pendency/delay in processing of issues relating to veterinary drugs which require input/recommendation of pertinent veterinary expert, hence Board decided to constitute an Expert Working Group on Veterinary Drugs having following composition: -

1.	*Dr. Qurban Ali,* *Ex-Director General,* *National Veterinary Laboratory, Islamabad.*	*Chairman*
2.	*Dr. Ayesha Yaqoob, Drug Testing Laboratory, Rawalpindi.*	*Member*
3.	*Mst. Najia Saleem, Deputy Director (PE&R), DRAP*	*Member*
4.	*Dr. Irfan Yousaf* *Dean Faculty of Veterinary and Animal Sciences Pir Meher Ali Shah Arid Agriculture University, Rawalpindi*	*Member*
5.	*Any other relevant expert(s)*	*As Co-opted member(s)*
6.	*Assistant Director (I&V-I), DRAP*	*Member, Secretary*

Case: Deferred cases of Import (Veterinary Drugs)

Name and address of Applicant	M/s Fartal Pharmaceuticals Flat no. 409 shalimar pride plaza near Mehran depo model colony Karachi
Detail of Drug Sale License	Drug License by way of whole sales no. 0458 valid upto 01-Sep-2019

Manufacturer & Marketing Authorization Holder	M/s Laboratorios Microsules Uruguay S.A. Camino al Paso Escobar s/n, Canelones Department Uruguay
Type of Form	**5A**
Diary No. & Date of R& I	Dy. No 419 Dated 21-10-2015
Fee including differential fee	Rs. 100,000/- Dated 21-10-2015
Brand Name +Dosage Form + Strength	Vitmic complement
Composition	Each 100ml contains: Vitamin B1…….0.1gm Vitamin B2…….0.01gm Nicotinamide……..0.1gm Glucose anhydrous…….10gm Sodium Chloride…….0.5gm Potassium chloride……..0.09gm Calcium Chloride Hexahydrate……...0.03gm Magnessium Chloride Hexahydrtae……0.015gm Caffeine…….....0.4gm
Finished Product Specification	In-House
Pharmacological Group	Vitamin suplement
Shelf life	24 months
Demanded Price	Decontrolled.
Pack size	100mL, 250mL
Me-too status	Could not be confirmed
Stability studies	Firm has submitted long term (24 months) at 25^{o}C±2^{0}C, 60±5%RH & accelerated (06 months) stability data at 30^{o}C, 60±5% RH for three batches
Detail of certificates attached	Original legalized of veterinary product registration certificate issued by Ministry of Agriculture and Fisheries Oriental Republic of Uruguay declaring the use of the product in the country, valid till 02-08-2019, Notarized Copy of GMP certificate dated 21-02-2019 expires dated 22-05-2019 is submitted. Notarized copy of Power of attorney from Product License holder is submitted
Remarks of the Evaluator:	Accelerated stability data is not submitted. • As per submitted real time stability data, the assay results of different APIs/ingredients are out of specifications in all 03 batches (Batches: BJ140466, BJ140567, BJ140768) • Evidence of approval of the applied formulation in reference regulatory authorities could not be confirmed. However, the firm has submitted copy of Overseas Site GMP Compliance report (date of inspection: 02/06/2019) wherein the applied product is endorsed to be manufactured by the firm. • As per available database of me-too product, the applied formulation is not registered in Pakistan

Decision of 312th meeting: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting or evidence of applied formulation/drug already approved by DRAP (generic / me-too

status) alongwith registration number, brand name and name of firm.

Submission by firm:

The firm has stated that the availability of the exact formulation as the applied product in reference agencies could not be confirmed as it is a novel product. However, Australian Pesticides and Veterinary

Medicines Authority has provided Australian GMP certificate.

The provided copy of GMP certificate No. M-7908 contains a list of products including the applied product Vitmic Complemento

Decision of 316th meeting: Registration Board deferred the case for clarification from the firm regarding pharmacological role of Caffeine in applied formulation and then will be forwarded to Dr. Qurban Ali (member Registration Board) for review of applied formulation.

Evaluation by PEC:

Dr. Qurban Ali via e.mail to Incharge PEC dated 05-03-2023 has forwarded his opinion as under:

Subject: **Vitmic Complemento Inj. M/s Fartal Pharmaceuticals, Karachi; Veterinary Import from M/s Laboratorios Microsules, Uraguay**

Dear Sir/ Madam

The subject cited product is a Routine Application Submitted on Form 5A (Veterinary Import)
– Deferred Cases. The product was considered in 316th meeting of Registration Board and deferred for want of elucidating the role of caffeine in applied formulation and a review.

Whereas the evaluator remarks stand on stability data; the product has been claimed novel and as such its me-too status or status in any reference authority could not be confirmed. The product however had a tag of GMP certification of manufacturer in Uraguay from Australian Pesticide and Veterinary Medicine Authority.

The dosage form is injectable (S/C or I/V) for Bovine (cattle buffaloes), Ovine (sheep, goats), and Equine (Horse) indicated for downer cow syndrome, general wakening, acetonemia and recovery of essential elements loss due to physically demanding sports in equines. The product has not been tagged for withdrawal period due to absence of MRL for any of the ingredients in the product. Moreover, the product is registered for use in animals by Uraguay Ministry of Livestock, Agriculture and Fisheries under Registration Number: A-2301 and is allowed for free sale in the country. The product is registered in Bolivia, Chile, Costa Rica, Ecuador, Mexico, Panama, Paraguay, Peru, Venezuela, and Albania. The product has composition per each 100 ml is as follows:

Active ingredients		***Excipients***	
Anhydrous glucose	*10 g*	*Sodium benzoate*	*0.4 g*
Vit B1 (Thiamine HCl)	*0.1 g*	*Disodium EDTA*	*0.01 g*
Vit B2 (Riboflavin Phosphate Sodium)	*0.01g*	*Nipagin*	*0.08 g*
Nicotinamide	*0.1 g*	*Nipasol*	*0.02 g*
Sodium Chloride	*0.5 g*	*Distilled water*	*q.s ad*

			100 ml
Potassium Chloride	*0.09 g*		
Calcium Chloride	*0.03 g*		
Magnesium Chloride	*0.015 g*		
Caffeine	*0.4 g*		

In formulation, the glucose, essential electrolytes elements and vitamins are known for maintaining bodily muscular and nervous functions; the charged elemental ions are also known important for maintaining balance of internal environment and pH levels besides help in keeping the body sufficiently hydrated.

Pharmacological properties of Caffeine have been made case for study in few animal investigations indicating a stimulating effect on the central nervous system of animals. It enhances and regulates the processes of excitation in the cerebral cortex, strengthens conditioned reflexes, and increases motor activity. The stimulating effect of caffeine leads to increased physical performance reduces fatigue and sleepiness. The drug increases heart activity, diuresis, gas exchange, and water and nitrogen metabolism. The effect is dose dependent.

Use of aforesaid product has also been made part of clinical studies by manufacturer indicating safety, improvement of body condition and desired stimulatory effects achieved in 60 heifers (cattle). For veterinary use, injectable caffeine products (alone or in combinations are few); an Austrian product previously registered in Pakistan namely Novacoc forte did had injectable Caffeine (0.35 g/ 100ml) and Caffeine alone with preservative (Caffeine 75 mg and 120 mg Sodium Benzoate per ml) has been registered in Russia for use.
Keeping in view the situation above, safety of product, novelty in terms of availability of a product for animals in need to recoup post convalescence weakness, management of debility, acetonemia, management of post strenuous exercise of horses through utilizing potential of caffeine has sufficient justification for veterinary use and purpose. The product is therefore, recommended for registration and a consequent availability to the clinical veterinarian.

Decision:-
Keeping in view the above Registration Board deliberated the matter and decided to Approved the product subject to import policy of manufacturer abroad.

Import & Vet-II Section

Case No: 01 <u>REQUEST OF M/S NOVARTIS PHARMA PAKISTAN LIMITED, FOR IMPORT OF GEMCITABINE "EBEWE" 200MG/VIAL AND 1G/VIAL INJECTION.</u>

The firm has submitted as under: -

As we informed you earlier through our letter no NPP-DRAP-27-0238 dated 23-Sep-2021, we, M/s Novartis Pharma (Pakistan) Limited, have divested certain portfolio of our products to AGP Limited [AGP] through its subsidiary OBS AGP (Private) limited. As per the aforesaid divestment

transaction, AGP has successfully acquired a portfolio of 22 pharmaceutical products from Sandoz AG, a company organized under the laws of Switzerland, which are commercialized in Pakistan under the Sandoz brand. Registration of most of these products have been transferred to AGP from Novartis Pharma (Pakistan) Limited [Novartis], while some are still in the process of being transferred.

Accordingly, continuing with transfer of registration process, AGP has received approval from DRAP dated 07-Mar-2O23 for transfer of registration of Gemcitabin "Ebewe" 200mg/vial and 1g/ vial injection in their name. Gemcitabin is an imported chemotherapy drug used to treat different types of cancers.

Novartis being the registration holder of the Products, at that time, places the order for the Products on 21-Nov-2022 for both strengths. On 22-Feb-2022, the manufacturer of Products based in Austria informed about the readiness of the order, and since then, Novartis have been working on the bank contract for the payment of this consignment. Unfortunately, due to the economic challenges in Pakistan, there was a significant delay, and finally the approval was granted on 22-Mar-2023 for Gemcitabine Ebewe 1g injection & 17-Mar-2023 for Gemcitabin Ebewe 200mg injection. Due to this delay, the remaining shelf life of the batch no MV5297 for Gemcitabin Ebewe 200mg injection has reduced to 69.5%, which is lower than the recommended shelf-life limit at the time of drug importation and the registration of the Products has transferred in the name of AGP. Since, the shelf life at the time of import would be low than ' recommended 75% we will also apply for the approval to import the product with short shelf life.

The details of the consignment ordered for Gemcitabin are as follows:

Name of Product	Batch No	Date of manufacturer	Date of Expiry
Gemcitabine Ebewe 200mg injection	MV6297	28.09.2022	3L.08.2024
Gemcitabine Ebewe 1gminjection	MW2306	23.02.2023	31.01.2025

As the importer has changed by virtue of transfer of registration over the course of time, i.e., at the time of ordering it was Novartis and at the time when consignment is expected to be received at the port it is AGP, Novartis will face extreme difficulty in releasing the consignment as deregistration letter has been already issued to Novartis with respect to the products. As previously mentioned, the Products are chemotherapy agents critical for the treatment of cancer patients in Pakistan, and their continuous availability must be ensured in the best interest of patients.

Further, the next ordering cycle with the new registration holder, i.e., AGP, will take another 9 months to receive the stocks, which will lead to a shortage of this medicine in Pakistan.

The Products are ready for shipment, but the import is not possible without DRAP's approval. Therefore, we kindly request your permission to import the Products into Pakistan. Your permission will not only save several cancer patients but also secure the availability of these critical Products during a time when extreme shortages for such cancer treatments are already prevalent in the country.

Decision:- Registration Board deliberated the matter and decided to refer the case to Licensing Authority.

Case.No.02. <u>REQUEST OF M/S PFIZER PAKISTAN LIMITED FOR CHANGE IN REG. STATUS FROM BULK IMPORT TO FINISHED IMPORT WITH CHANGE IN MANUFACTURING SITE-CARPSOL INJECTION 150MG/15ML.</u>

M/s Pfizer Pakistan Ltd, B-2 SITE, Karachi has submitted request for change in registration status from bulk import to finish import with change in manufacturing site for following product:

Reg. No.	Name & Composition of Drug / address	Detail of approved Sites as per approval (01-04-2016)	Detail of approved Sites as per CoPP

013966	Carpsol 150mg/15ml Injection Each ml contains: Carboplatin….10mg	**Name & Address of Manufacturer:** M/s Pfizer (Perth) Pty Ltd, Technology Park 15 Brodie Hall drive, Bentley WA 6102 Australia	Market Authorization Holder: M/s Pfizer Australia Pty Ltd Level 17 151 Clarence Street Sydney NSW 2000 Australia. Manufacturer: Hospira Australia Pty Ltd, 1-5,7-23 and 25-39 Lexia Place, Mulgrave, Victoria, 3170, Australia Finished Import

The firm has submitted the following supporting documents: -

a) Fee of Rs.150,000/- for above product.
b) Copy of registration letter issued on 30-01-1993.
   - Change of name of drug from Deltaplatin Injection 10mg/ml to Carpsol Injection 10mg/ml dated 20-07-1993.
   - Change of title of manufacturer (bulk import with local repacking) on 01-04-2016.
   - Transfer of Registration from M/s Parke Davis & Compnay to M/s Pfizer Pakistan Ltd on 01-06-2011.
   - Renewal Submit on 28-05-2021
   - Due date 01-06-2021.
c) Copy of valid Drug Sale License.
d) Copy of CoPP.
e) Form 5-F
f) Letter of Authorization.

Decision:-
Registration Board deliberated the matter and decided to approve the change in registration status from bulk import to finish import along with change in manufacturing site for following product:

Reg. No.	Name & Composition of Drug / address	Existing approved Sites (01-04-2016)	New approved Sites as per CoPP
013966	Carpsol 150mg/15ml Injection Each ml contains: Carboplatin….10mg	Name & Address of Manufacturer: M/s Pfizer (Perth) Pty Ltd, Technology Park 15 Brodie Hall drive, Bentley WA 6102 Australia	Market Authorization Holder: M/s Pfizer Australia Pty Ltd Level 17 151 Clarence Street Sydney NSW 2000 Australia. Manufacturer: Hospira Australia Pty Ltd, 1-5,7-23 and 25-39 Lexia Place, Mulgrave, Victoria, 3170, Australia Finished Import

Case No.03 **REQUEST OF M/S NOVARTIS PHARMA (PAKISTAN) LIMITED FOR PERMISSION TO IMPORT INTERNATIONAL APCKS OF RITALIN LA 20MG CAPSULE (REG.NO.110548).**

M/s Novartis Pharma (Pakistan) Limited, 15 West Wharf, Dockyard Road, Karachi has stated that product Ritalin LA 20mg (Reg. No.110548) manufactured in USA and manufacturer have informed that due to very specific and limited quantity of product they are unable to provide this medicine in country specific packs.

Details of Product:

S. No.	Reg. No.	Name of Product	Remarks

1.	110548	Ritalin LA Capsules 20mg Each capsule contains:- Methylphenidate hydrochloride……20mg	Reg. Letter date 22.11.2022.

The firm has requested to allow them to print the following components on outer box of product locally at licensed premises i.e. C-21, SITE, Karachi DML No. 000003 as per labeling and packaging rules 1986.

- Urdu text.
- Registration number.
- Maximum retail price.
- Name and address of sole agent.
- 2D Matrix Barcode
- Other information (as per labeling requirements)

The firm has provided the following documents along with the application: -

a. Fee challan of Rs.10,000/- for said product.
b. Copy of registration letter.
c. Copy of valid DML.
d. An undertaking.

Decision: Registration Board acceded to the request for import of already registered products (Ritalin LA Capsules 20mg (Reg. no. 110548) in Standard Export Packs. The Board advised the firm to locally print MRP and Registration Number along with Urdu Text before sale of drug at their Licensed Premises (DML No.000003) to comply requirements as per Drugs (Labelling & Packing) Rules, 1986. This permission shall be valid for two (02) year only. The firm shall submit the future plan regarding the import of Drugs (Labelling & Packing) Rules, 1986 compliant packs.

Case No.04 <u>REQUEST OF M/S NOVARTIS PHARMA (PAKISTAN) LIMITED FOR PERMISSION TO IMPORT INTERNATIONAL APCKS OF SYBRAVA SOLUTION FOR INJECTION (REG.NO.114234).</u>

M/s Novartis Pharma (Pakistan) Limited, 15 West Wharf, Dockyard Road, Karachi has stated that product Sybrava solution for injection (Reg. No.114234) manufacturer informed that due to very specific and limited quantity of product they are unable to provide this medicine in country specific packs.

Details of Product:

S. No.	Reg. No.	Name of Product	Remarks
2.	114234	Sybrava Solution for Injection Pre-filled syringe Each ml contains: Inclisiran Sodium eq. to Inclisiran…189mg	Reg. Letter date 11.04.2023.

The firm has requested to allow them to print the following components on outer box of product locally at licensed premises i.e. C-21, SITE, Karachi DML No. 000003 as per labeling and packaging rules 1986.

- Urdu text.
- Registration number.
- Maximum retail price.
- Name and address of sole agent.
- 2D Matrix Barcode
- Other information (as per labeling requirements)

The firm has provided the following documents along with the application: -

a. Fee challan of Rs.10,000/- for said product.
b. Copy of registration letter.
c. Copy of valid DML.
d. An undertaking.

Decision: Registration Board acceded to the request for import of already registered products (Sybrava Solution for Injection (Reg. no. 114234) in Standard Export Packs. The Board advised the firm to locally print MRP and Registration Number along with Urdu Text before sale of drug at their Licensed Premises (DML No.000003) to comply requirements as per Drugs (Labelling & Packing) Rules, 1986. This permission shall be valid for two (02) year only. The firm shall submit the future plan regarding the import of Drugs (Labelling & Packing) Rules, 1986 compliant packs.

Case.No.05: Request of M/s. Amgomed, Islamabad for Registration of Drug.

M/s Amgomed case was presented in different meetings of Registration Board (M-295,M-287) Registration Board in its 262nd meeting approved the following products of M/s. Amgomed, Islamabad for import from Korea as per details mentioned alongside;

S. No	Name of importer / manufacturer	Name & Composition of Drug(s)	Demanded Pack size & Price	Decision of Board
1.	M/s Amgomed, Islamabad. **Manufacturer:** M/s Dong Kook Pharmaceutical Co. Ltd. 33-19, yongso 2-gil, Gwanghyewon-myeon, Jincheon-gun, Chungcheongbuk-do, Republic of Korea.	Diluent for Lorelin depot 3.75 mg Each ampoule (2ml) contains: D-Mannitol..100mg Sodium Carboxymethylcellulose…10mg Polysorbate 80……2mg Water for Injection…..q.s.	Free of Cost.	Approved
2.	M/s Amgomed, Islamabad. **Manufacturer:** M/s Dong Kook Pharmaceutical Co. Ltd. 33-19, yongso 2-gil, Gwanghyewon-myeon, Jincheon-gun, Chungcheongbuk-do, Republic of Korea.	Lorelin depot 3.75 mg Injection Leuprolide acetate 3.75mg Injection	As per SRO	Approved

While issuance of registration letter it has been observed the above mentioned product "Lorelin Depot 3.75mg injection" has already been granted registration in favor of M/s. Medisure Pharma International, Karachi from the same source having registration number **027357**.

Accordingly M/s. Amgomed, Islamabad was informed about the above stated position. The firm informed that the principle has already cancelled/terminated the sole agency agreement from the name of M/s. Medisure Pharma International, Karachi in 2013 (provided copy of that cancellation letter dated 16-03-2013) for the reasons that M/s. Medisure Pharma International, Karachi has never imported a single vial since the time of registration i.e 2002 and violation of conditions of agreement.

It is pertinent to mention that the inspection of the above mentioned manufacturer has been carried out dated 21st -22nd June, 2018 by nominated panel comprised of Mr.Malik Irshad Hussain (Member Policy Board), Mr.Sayyad Hussain (Deputy Director, DRAP).

Decision of 287th meeting:-

Registration Board decided to issue show cause notice to the firm M/s. Medisure Pharma International, Karachi as to why not the registration of product Lorelin depot 3.75 mg Injection may not be cancelled because of the termination of their sole agency agreement by M/s. Dong Kook Pharmaceutical Co. Ltd, Korea, as reported by M/s. Amgomed, Islamabad.

Fresh Proceedings:

In the light of Registration Board decision a Show Cause Notice has been served to the firm on 21st June, 2019 but no reply has been received. Furthermore, a reminder (No.F.1-40/2007-Reg-I-Pt) through registered post has been issued on on 26th August, 2019 to the firm (C-145, K.D.A. Scheme No.1 Off Karsaz Road, Karachi) with advised to submit reply within seven days after issuance of this letter, the same has been received back with failed delivery status. Afterwards, on 18th September 2019 the reminder letter handed

over to firm's representative (Mr. Atta) & till the date no reply from M/s Medisure Pharma International, Karachi has been received.

Decision of M-292:

Registration Board advised to issue final showcase notice to M/s Medisure Pharma International Karachi and in case of no reply, case will be considered by Registration Board.

Fresh Proceedings:

M/s Medisure Pharma International has submitted their reply as under: -

M/s Medisure Pharma International is a respectable commercial pharmaceutical organization committed to provide best quality products registered and accredited from all concerned departments of Government of Pakistan.

M/s Medisure Pharma International is fully honored and respects the land of laws, to fulfil the Pakistan regulations and fully comply with the Drug Laws. Accordingly, a per mandate and requirements of Drugs Act, 1976 and Drugs (Licensing, Registration & Advertising) Rules, 1976, the Medisure Pharma International entirety is to follow the regulations.

The aforesaid product is currently registered with M/s Medisure Pharma International and has a valid registration number. Subsequent to registration, we are regularly maintaining its registration and last renewal was filed in DRAP in June 2017.

We are not aware about the letter of cancellation of sole agency agreement whit M/s Dong Kook Pharmaceutical Co., Ltd, 33-19, Yongso 2-gil, Gwnghewon-myeon, Jincheon-gun, Chungcheongbuk –do, Republic of Korea and even not have been officially informed regarding termination of sole agency agreement from M/s Dong Kook Pharmaceutical Co., Ltd.

We are also wondering that how DRAP pharmaceutical evaluation cell accepted and included the case in Drug Registration Board (M-287) meeting without taking consideration of No Objection Certificate (NOC) from existing Marketing Authorization Holder which is the basic requirement of DRAP Post Registration Variation SOP of Marketing Authorization transfer from one importer to another importer.

Decision OF 295TH Meeting: Registration Board advised to M/s Medisure Pharma International to submit fresh Sole Agency Agreement/Authorization Letter in their name from Product License holder for above mentioned products.

Fresh Proceedings:

The above decision was conveyed to the firm on 7th August, 2020 and reply form firm is not received till yet.

M/s Medisure Laboratories Pakistan file Constitutional Petition No.D-5539 dated 02-12-2020 in the High Court of Sindh, Karachi Federal of Pakistan and others.

Decision M-297:

Registration Board referred the case to Legal affair division to seek their opinion regarding issuance of show cause notice in the light of Constitutional Petition No. D-5539 dated 02-12-2020 in the High Court of Sindh, Karachi Federal of Pakistan and others.

Fresh Proceedings: -

Comments of Legal Affair Division.

As per available facts/ record of the case, M/s Medisure Pharma International filed constitutional Petition No.5539/2020 wherein till date the court has not granted any status quo order. Therefore, the Registration Board may issue show cause notice to the firm under relevant provisions of the Drug Act, 1976.

Decision of M-308 (21-22 June 2021): -

Keeping in view the above position, Registration Board decided as follow:-

a) **Approved the cancellation of registration of Lorelin depot 3.75mg Injection (Reg.No. 027357) from the name of M/s Medisure Pharma International, Karachi.**
b) **Approved the registration of Lorelin depot 3.75mg Injection (Reg.No. 027357) in the name of M/s Amgomed, Islamabad as per policy for imported finished drug registration (in accordance with details of composition and manufacturer as per CoPP).**
c) **A reference shall be sent to Costing & Pricing Division for their comments regarding MRP of the said products.**

As per decision of the Board cancellation letter of Lorelin depot 3.75mg Injeciton (Reg. No. 027357) issued to M/s Medisure and registration letter issued to M/s Amgomed) dated 20-04-2022.

2nd strength of the same class of product was approved in the same meeting
The detail is as under:

S. No	Name of importer / manufacturer	Name & Composition of Drug(s)	Demanded Pack size & Price
1.	M/s Amgomed, Office no. 4, 1st floor, Ghousia Plaza, Jinnah Avenue blue area, Islamabad **Manufacturer & Product License Holder:** M/s Dongkook Pharmacetuical Co., Ltd., 33-19, Yongso 2-GIL, Gwanghyewon-Myeon, Jincheon-Gun, Chungcheongbuk-Do, Korea.	Lorelin Depot 7.5mg Subcutaneous injection Each vial contains: Leuprolide acetate…7.5mg Gonadotropin releasing hormone analogue 3 years	As per SRO
Decision M-308: Approved with innovator's specifications and as per Policy for inspection of Manufacturer abroad and verification of local storage facility.			
2.	**-do-**	Diluent for Lorelin Depot 7.5mg Subcutaneous injection Each ampoule of 2ml contains: D-mannitol……...100mg Sodium carboxymethylcellulose...10mg Polysorbate 80……..2mg Water for injection……q.s	As per SRO
Decision M-308:- Approved with innovator's specifications as diluent of Lorelin Depot 7.5mg Subcutaneous injection (S No.32). Approval is as per Policy for inspection of Manufacturer abroad and verification of local storage facility.			

Current status of Petition No.5539/2020 is dismissed.

ORDER SHEET

IN THE HIGH COURT OF SINDH, KARACHI.

C.P No. D-5539 of 2020

Dated Order with signature of Judge.

Priority
1. For hearing of Misc. No.23605/2020
2. For hearing of Main Case.

20.09.2022.

Mr. Rashid Mureed, Advocate for the Petitioner.
Kazi Abdul Hameed Siddiqui, D.A.G. Syed Hakim Masood, FID, DRAP, Karachi

YOUSUF ALI SAYEED, J- The Petitioner has invoked the jurisdiction of this Court under Article 199 of the Constitution soas to assail two letters issued by the Drug Regulatory Authority of Pakistan ("**DRAP**") regarding the cancellation of the Petitioner'sregistration in respect of certain pharmaceutical products, with it being averred that the Petitioner had responded to a Show-Cause Notice that had been issued by DRAP on the subject and it being sought that DRAP be restrained from taking any coercive action in pursuance of the impugned letters without considering the representation of the Petitioner.

As it transpires, the comments submitted on behalf of DRAP reflects that the principal of the Petitioner had apparently intimated DRAP that it had cancelled/terminated the Petitioner's agency in relation to the subject products and appointed a third party as its agent/representative, with the matter thus being placed before the Registration Board and a decision being taken to issue the show cause notice to the Petitioner. Thereafter, the ensuing proceedings taking place during pendency of this Petition had culminated in a decision by the Registration Board that if the Petitioner desired to preserve its registration for the given products, it ought to submit a fresh license agreement/authorization letter from the proprietor, and such decision was open to challenge by way of an appeal under section9 of Drug Act 1976 before the Appellate Board.

When asked, learned counsel for the Petitioner could notcontrovert the veracity of what had been stated in the comments. Under the given circumstances, it is manifest that subsequent events have overtaken the Petition, which accordingly stands dismissed along with the pending miscellaneous application, leaving the Petitioner at liberty to pursue the alternate remedy available, if so desired.

Decision: -
Keeping in view the above position, Registration Board decided as follow:-

a) **Approved the cancellation of registration of Lorelin depot 7.5mg Injection from the name of M/s Medisure Pharma International, Karachi.**
b) **Approved the registration of Lorelin depot 7.5mg Injection in the name of M/s Amgomed, Islamabad as per policy for imported finished drug registration (in accordance with details of composition and manufacturer as per CoPP).**
c) **A reference shall be sent to Costing & Pricing Division for their comments regarding MRP of the said products.**

Case.No.6: REQUEST OF M/S AGP LIMITED, KARACHI FOR REGISTRATION OF DRUGS TO THEIR NAME.

M/s AGP Limited, B-23-C, SITE, Karachi has submitted an application for Registration of following already registered products from M/s Novartis Pharma (Pakistan) Ltd, 15 West Wharf Karachi to their name. Detail of each proposed product is as under: -

Product-1: Lectrum Lyophilized for Injection 3.75mg (Reg.No. 043044)		
S. No.	**Name / Detail of Documents**	**Documents / information provided by firm**
1.	Product Name/ Composition	**As per approval** Lectrum Lyophilized for Injection 3.75mg. Each vial contains:- Leuprolide acetate……..3.75mg As per CoPP:

		Lectrum 3.75mg Lyophilized for Injection Each vial contains:- Leuprorelin acetate……..3.75mg Each solvent ampoule contains: Sodium carboxymethylcellulose….7.5mg Mannitol…..75mg Polysorbate 80….1.5mg Water for injection q.s…..1.5ml
	Reg. date / renewal status	Reg. Letter issued on 26-06-2006 (renewal due date 25-06-2021) Renewal submit on 06-05-2021.
	Name and address of Applicant(Transferee)	M/s AGP Limited, B-23-C, SITE, Karachi.
	Name of Transferor	M/s. Novartis Pharma (Pakistan) Ltd, 15 West Wharf, Karachi.
	Detail of Drug Sale License	**DSL No.045 (valid upto 21-09-2023)** **Address:** M/s AGP Limited, B-23-C, SITE, Karachi. **Godown address:** 1. M/s AGP Limited, B-23-C, SITE, Karachi. 2. Burma Oil Mills Limited, TCW Plot No. 1&2 Boat Building Yard Area West Wharf, Karachi.
	Name and address of Manufacturer / Product License Holder	**As per approval** **Manufacturer**: M/s Eriochem S.A., Argentina. **As per CoPP (14219156):** **Product License Holder & Drug Product Manufacturer.** M/s Eriochem S.A., Ruta 12, KM 452 (3107) Colonia Avellaneda, Departamento Parana, Provincia Entre Rios, Republica, Argentina. **Solvent Manufacturer:** M/s MR Pharma, S.A. Estados Unidos 5105, esquina Luis Sullivan N^0 2961, Localidad Area de Propocion EI Triangulo Partido Malvinas Argentinas, Pcia de Buenos Aires, Argentina.
	Name of exporting Country	Argentina
	Diary No. & Date of R& I	Dy. No. 30940 Dated 31/10/2022.
	Finished Product Specification	Not mentioned in Reg. Letter.
	Shelf life	Not mentioned in Reg. Letter. However, as per provided stability data shelf life of product is 2 years
	MRP/Pack Size	Rs.8090/1's (as per Reg. Letter)

Product-2: Lectrum Lyophilized for Injection 7.50mg (Reg.No. 043043)		
S. No.	**Name / Detail of Documents**	**Documents / information provided by firm**
2.	Product Name/ Composition	**As per approval** Lectrum Lyophilized for Injection 7.5mg. Each vial contains:- Leuprolide acetate……..7.5mg As per CoPP: Lectrum 7.5mg Lyophilized for Injection Each vial contains:- Leuprorelin acetate…….7.5mg

		Each solvent ampoule contains: Sodium carboxymethylcellulose….7.5mg Mannitol…..75mg Polysorbate 80….1.5mg Water for injection q.s…..1.5ml
	Reg. date / renewal status	Reg. Letter issued on 26-06-2006 (renewal due date 25-06-2021) Renewal submit on 06-05-2021.
	Name and address of Applicant(Transferee)	M/s AGP Limited, B-23-C, SITE, Karachi.
	Name of Transferor	M/s. Novartis Pharma (Pakistan) Ltd, 15 West Wharf, Karachi.
	Detail of Drug Sale License	**DSL No.045 (valid upto 21-09-2023)** **Address:** M/s AGP Limited, B-23-C, SITE, Karachi. **Godown address:** 1. M/s AGP Limited, B-23-C, SITE, Karachi. 2. Burma Oil Mills Limited, TCW Plot No. 1&2 Boat Building Yard Area West Wharf, Karachi.
	Name and address of Manufacturer / Product License Holder	**As per approval** **Manufacturer**: M/s Eriochem S.A., Argentina. **As per CoPP (14219156):** **Product License Holder & Drug product Manufacturer** M/s Eriochem S.A., Ruta 12, KM 452 (3107) Colonia Avellaneda, Departamento Parana, Provincia Entre Rios, Republica, Argentina. **Solvent Manufacturer:** M/s MR Pharma, S.A. Estados Unidos 5105, esquina Luis Sullivan N^0 2961, Localidad Area de Propocion EI Triangulo Partido Malvinas Argentinas, Pcia de Buenos Aires, Argentina.
	Name of exporting Country	Argentina
	Diary No. & Date of R& I	Dy. No. 30942 Dated 31/10/2022.
	Finished Product Specification	Not mentioned in Reg. Letter
	Shelf life	Not mentioned in Reg. Letter. However, as per provided stability data shelf life of product is 2 years
	MRP/Pack Size	Rs.13,483/1's (as per Reg. Letter)

The firm has submitted the following supporting documents / information for approval of above transfer of registrations: -

a) Fee of Rs.150,000/- for each product.
b) Applications on Form-5F.
c) Copy of Registration letters and renewal trail, detail as mentioned above table.
d) Copy of CoPP issued by Argentina for above products.
e) Original Legalized Termination letter from M/s Eriochem S.A., Argentina in the name of M/s Novartis Pharma (Pakistan) Ltd, 15 West Wharf, Karachi for above products.
f) Original Legalized of Letter of authorization in the name of M/s AGP Limited, B-23-C, SITE, Karachi from M/s Eriochem S.A., Argentina for above products.
g) Original of NOC for transfer of registrations from M/s. Novartis Pharma (Pakistan) Ltd, 15 West Wharf, Karachi **(issued on 10-04-2023).**
h) undertaking

Remarks: M/s AGP Limited, Karachi submit two copies of CoPP as per following details:

As per Initial submitted CoPP copy	**Newly submitted CoPP Copy**
Product License Holder	**Product License Holder & Drug product Manufacturer**
M/s Novartis Argentina S.A Ramallo 1851, Ciudad Autonoma de Buenos Aires, Argentina	

Drug product Manufacturer
M/s Eriochem S.A., Ruta 12, KM 452 (3107) Colonia Avellaneda, Departamento Parana, Provincia Entre Rios, Republica, Argentina.
Solvent Manufacturer:
M/s MR Pharma, S.A. Estados Unidos 5105, esquina Luis Sullivan N^0 2961, Localidad Area de Propocion EI Triangulo Partido Malvinas Argentinas, Pcia de Buenos Aires, Argentina.
1.3
Is this product license to ber placed on the market for use in the exporting country? Yes
1.4
Is this product actually on the market in the exporting country? Yes

M/s Eriochem S.A., Ruta 12, KM 452 (3107) Colonia Avellaneda, Departamento Parana, Provincia Entre Rios, Republica, Argentina.
Solvent Manufacturer:
M/s MR Pharma, S.A. Estados Unidos 5105, esquina Luis Sullivan N^0 2961, Localidad Area de Propocion EI Triangulo Partido Malvinas Argentinas, Pcia de Buenos Aires, Argentina.
1.3
Is this product license to ber placed on the market for use in the exporting country? Yes
1.4
Is this product actually on the market in the exporting country? No

Decision:
Registration Board deliberated the matter and decided that if an imported drug is not on free sale in its respective country of origin / manufacture, such product will be registered in Pakistan if the product manufactured in the applied facility is approved by any of the reference regulatory authorities.

Case No.7: <u>REQUEST OF M/S WYETH PAKISTAN LIMITED FOR WITHDRAW OF REGISTRATION APPLICATION (PRISTIQ 100MG)</u>

M/s Wyeth Pakistan Limited, Room No.2 & 3, PGS ADMIN Block, First Floor, Plot No. B-2, SITE, Karachi has submitted request for withdrawal registration application of Pristiq 100mg tablets (desvenlafaxine succinate) as per following details:

S. No	Status	Product(s) Name	Reason for withdrawal
1.	Approved in M-296	PRISTIQ 100mg Extended Release Tablet Each Extended release tablet Contains: Desvenlafaxine Succinate…..100mg	US-FDA Label, the recommended dosage of Pristiq is 50mg/ day which is already registered. Hence, our marketing and sales team are not interested to pursue Pristiq 100mg Tablet in registration in Pakistan.

Decision:
Registration Board deliberated the matter and decided to ask importer for submission of valid reason for withdrawal registration application.

Case No.08: <u>REQUEST OF M/S AGP LIMITED, KARACHI FOR CANCELLATION OF REGISTRATION OF IMPORTED DRUGS.</u>

M/s AGP Limited, B-23-C, SITE, Karachi has submitted request for cancellation of registration of imported drugs as per following details.

S. No	Reg. No.	Product(s) Name	Reason for De-Reg. (stated by firm)	Alternative registered products
1.	091899	Nevimat Tablet 200mg (Nevirapine)	Manufacturer has decided to discontinued / de-registrar the product in pakistan.	Pivir of M/s Hilton Pharma

2.	099008	Trezav Tablet (Lamivudine / Nevirapine / Zidovudine 150mg/200mg/300mg)	-do-	Zidolam-N Tablet of M/s Araf Pharmaceutidcals

SOP Requirement	Firms Response
Application. Copy of registration letter. Justification. List of alternatives brands/ FPPs available in the country. An undertaking that: No case is pending at any forum / court of law regarding this product. Provided information/ documents are true/ correct.	Application without fee. Copy of registration letter. As mentioned above. As mentioned above. Provided by the firm.

Decision:
Registration Board deliberated the matter and decided to ask importer for submission of valid reason for cancellation of registration of imported drugs.

Case No.09: <u>REQUEST OF M/S NOVARTIS PHARMA (PAKISTAN) LIMITED FOR CANCELLATION OF REGISTRATION OF IMPORTED DRUG.</u>

M/s Novartis Pharma (Pakistan) Limited, 15 West Wharf, Dockyard Road, Karachi has submitted request for cancellation of registration of imported drug as per following details.

S. No	Reg. No.	Product(s) Name	Reason for De-Reg. (stated by firm)	Alternative registered products
1.	052235	Lozal 40mg Powder for Infusion. Each vial of powder for solution for infusion contains: - Omeprazole Sodium eq to 40mg Omeprazole.	Kindly be informed that Sandoz group Portfolio has been divested and we do not want to continue mentioned products as per glocal directivers.	Noctis by M/s Saffron Pharma. Noran by M/s Akson Pharma. Ome-Stoch by M/s Usawa Pharma.

SOP Requirement	Firms Response
Application. Copy of registration letter. Justification. List of alternatives brands/ FPPs available in the country. An undertaking that: No case is pending at any forum / court of law regarding this product. Provided information/ documents are true/ correct.	Application with a fee Rs.7,500/-. Copy of registration letter. As mentioned above. As mentioned above. Provided by the firm.

Decision:

Registration Board deliberated the matter and decided to ask importer for submission of valid reason for cancellation of registration of imported drugs.

Case No.10: REQUEST OF M/S NOVARTIS PHARMA (PAKISTAN) LIMITED FOR CANCELLATION OF REGISTRATION OF IMPORTED DRUGS.

M/s Novartis Pharma (Pakistan) Limited, 15 West Wharf, Dockyard Road, Karachi has submitted request for cancellation of registration of imported drugs as per following details.

S. No	Reg. No.	Product(s) Name	Reason for De-Reg. (stated by firm)	Alternative registered products
1.	083905	Hycamtin Capsule 0.25mg Each capsule contains:- Topotecan….0.25mg	Kindly be informed that Sandoz group Portfolio has been divested and we do not want to continue mentioned products as per global directives.	Not provided
2.	084156	Hycamtin Capsule 1mg Each capsule contains:- Topotecan….1mg		Not provided
3.	084157	Hycamtin Powder for concentrate for solution for infusion Each vial contains:- Topotecan hydrochloride….4mg		Topotel 4mg by M/s Atco Labs Ltd. Potekam by M/s Ghani Brothers. Topokebir by M/s Oncogene Pharma. Topotu by M/s Punjab Medical Services
4.	028455	Foradil suspension aerosol Each puff contains: - Formoterol 12ug.		Rofomist by M/s Atco Labs Ltd. Atimos by M/s Chiesi. Easair by M/s Platinum Pharma.

SOP Requirement	Firms Response
Application.	Application with a fee Rs.7,500/- for each product.
Copy of registration letter.	Copy of registration letter.
Justification.	As mentioned above.
List of alternatives brands/ FPPs available in the country.	As mentioned above.
An undertaking that: No case is pending at any forum / court of law regarding this product. Provided information/ documents are true/ correct.	Provided by the firm.

Decision:
Registration Board deliberated the matter and decided to ask importer for submission of valid reason for cancellation of registration of imported drugs.

Case No.11: REQUEST OF M/S NOVARTIS PHARMA (PAKISTAN) LIMITED FOR CANCELLATION OF REGISTRATION OF IMPORTED DRUGS.

M/s Novartis Pharma (Pakistan) Limited, 15 West Wharf, Dockyard Road, Karachi has submitted request for cancellation of registration of imported drugs as per following details.

S. No	Reg. No.	Product(s) Name	Reason for De-Reg. (stated by firm)	Alternative registered products
1.	066179	Anastrozole Sandoz 1mg film coated tablets Each table contains: Anastrozole….1mg	Kindly be informed that Sandoz group Portfolio has been divested and we do not want to continue mentioned products as per global directives.	
2.	094752	Cisplatin Ebewe 50mg/100ml Concentrate for solution for Infusion Each ml contains: Cisplatin…..0.5mg		
3.	105594	Cisplatin 25mg/50ml Concentrate for Solution for Infusion Each ml contains: Cisplatin……...0.5mg		Topotel 4mg by M/s Atco Labs Ltd. Potekam by M/s Ghani Brothers. Topokebir by M/s Oncogene Pharma. Topotu by M/s Punjab Medical Services
4.	103767	Carboplatin Ebewe 50mg/5ml concentrate for Solution for Infusion. Each ml contains:- Carboplatin …10mg		Rofomist by M/s Atco Labs Ltd. Atimos by M/s Chiesi. Easair by M/s Platinum Pharma.
5.	103768	Carboplatin Ebewe 150mg/15ml concentrate for Solution for Infusion. Each ml contains:- Carboplatin …10mg		
6.	103769	Carboplatin Ebewe 450mg/45ml concentrate for Solution for Infusion. Each ml contains:- Carboplatin …10mg		
7.	078117	Geperprostin 50mg Film Coated Tablets. Each film coated tablets contains:- Bicalutamide …50mg.		
8.	078118	Geperprostin 150mg Film Coated Tablets. Each film coated tablets contains:- Bicalutamide ….150mg.		

SOP Requirement	Firms Response
Application. Copy of registration letter. Justification.	Application with a fee Rs.7,500/- for each product. Copy of registration letter. As mentioned above. As mentioned above.

List of alternatives brands/ FPPs available in the country. An undertaking that: No case is pending at any forum / court of law regarding this product. Provided information/ documents are true/ correct.	Provided by the firm.

Decision:
Registration Board deliberated the matter and decided to ask importer for submission of valid reason for cancellation of registration of imported drugs.

Case No.12: <u>REQUEST OF M/S NOVARTIS PHARMA (PAKISTAN) LIMITED FOR WITHDRAW PENDING APPROVED/UNDER APPROVAL DRUGS.</u>

M/s Novartis Pharma (Pakistan) Limited, 15 West Wharf, Dockyard Road, Karachi has submitted request for withdraw pending approved / under approval drugs as per following details.

S. No	Status	Product(s) Name	Reason for De-Reg. (stated by firm)
1.	Not approved yet	Piperacillin/Tazobactam Sandoz 2.25g & 4.5g powder for solution for injection.	Kindly be informed that due to global divestment of Sandoz we cannot proceed to continue the registration of these products in Pakistan.
2.	Approved in M-313	Fulvestrant Sandoz 250mg/5ml solution for injection	

Decision:
Registration Board deliberated the matter and decided to ask importer for submission of valid reason for withdrawal registration application.

RRR Section

Case No:1 Showcause notices issued under section 42 of Drug Act 1976 and Rule 27 of Drug (LR&A) Rules 1976

M/S ORTA LABORATORIES PVT LIMITED, 24 KM MULTAN ROAD OFF DEFENSE ROAD MOHLANWAL LAHORE					
Sr. No	**Reg. No.**	**Brand Name & Composition**	**Initial date of Registration PRV (If any)**	**Date of application (R&I) Fee submitted**	**Decision**
1.	048083	Prostaloc Tablets Each tablet contains: Flurbiprofen …. 100mg (BP Specifications)	17.01.2008	Dy. No. 2681 dated 27.01.2023 Rs. 15000/- Rs. 10000/- dated 17.01.2018	Renewal is granted w.e.f 17.01.2023 to 16.01.2028. The firm shall apply for description of the product as per Innovator as per decision of 295th meeting of Registration Board.
2.	048084	Dirox Tablets Each tablet contains: Naproxen Sodium …. 550mg (BP Specifications)	17.01.2008	Dy. No. 2681 dated 27.01.2023 Rs. 15000/- Rs. 10000/- dated 17.01.2018	Renewal is granted w.e.f 17.01.2023 to 16.01.2028. The firm shall apply for description of the product as per Innovator as per decision of 295th meeting of Registration Board.

3.	048085	Orpram Tablets Each tablet contains: Escitalopram …. 10mg (Orta's Specifications)	17.01.2008	Dy. No. 2681 dated 27.01.2023 Rs. 15000/- Rs. 10000/- dated 17.01.2018	Renewal is granted w.e.f 17.01.2023 to 16.01.2028. The firm shall apply for description of the product as per Innovator and specifcations as per decision of 295th meeting of Registration Board.
4.	048086	Diclodyn-K Tablets Each tablet contains: Diclofenac Potassium ….. 50mg USP Specifications	17.01.2008	Dy. No. 2681 dated 27.01.2023 Rs. 15000/- Rs. 10000/- dated 17.01.2018	Renewal is granted w.e.f 17.01.2023 to 16.01.2028. The firm shall apply for description of the product as per Innovator as per decision of 295th meeting of Registration Board.
5.	048087	Ortabolamin Tablets Each tablet contains: Mecobalamin …. 500mcg (Orta's Specifications)	17.01.2008	Dy. No. 2681 dated 27.01.2023 Rs. 15000/- Rs. 10000/- dated 17.01.2018	Renewal is granted w.e.f 17.01.2023 to 16.01.2028. The firm shall apply for description of the product as per Innovator and specifcations as per decision of 295th meeting of Registration Board.
6.	048090	Ortabolamin Injection Each vial contains: Mecobalamin …. 500mcg (Orta's Specifications)	17.01.2008	Dy. No. 2681 dated 27.01.2023 Rs. 15000/- Rs. 10000/- dated 17.01.2018	Renewal is granted w.e.f 17.01.2023 to 16.01.2028. The firm shall apply for description of the product as per Innovator and specifcations as per decision of 295th meeting of Registration Board.
7.	048088	Oramox Tablets Each tablet contains: Moxifloxacin …. 400mg (Orta's Specifications)	17.01.2008	Dy. No. 2681 dated 27.01.2023 Rs. 15000/- Rs. 10000/- dated 17.01.2018	Renewal is granted w.e.f 17.01.2023 to 16.01.2028. The firm shall apply for description of the product as per Innovator and specifcations as per decision of 295th meeting of Registration Board.
8.	048089	Ortafer Tablets Each tablet contains: Iron III Hydroxide Polymaltose Complex …. 100mg Folic Acid …. 0.35mg (Orta's Specifications)	17.01.2008	Dy. No. 2681 dated 27.01.2023 Rs. 15000/- Rs. 10000/- dated 17.01.2018	Renewal is granted w.e.f 17.01.2023 to 16.01.2028. The firm shall apply for description of the product as per Innovator and specifcations as per decision of 295th meeting of Registration Board..

Background:

Registration Board in its 326th meeting held on 14-16 March 2023 directed to issue show cause notice to the firm for suspension of registration of above products under section 42 of Drug Act, 1976 and under rule 27 of Drug (LR&A) Rules 1976 considering the fact that the firm has not submitted the prescribed fee (differential fee for year 2018 and 2023) of renewal of registration despite of intimation to the firm vide letter No. 1-65/2018 (RRR) dated 16.02.2023 as indicated in the last column above.

Accordingly, as per decision of the Board the firm has been issued showcause notice vide letter F.No.3-5/2023-RRR(M-326) dated 24th May 2023 and notice for personal hearing on 29th May 2023.

Proceeding of 329th meeting of Registration Board:

In compliance to above letter, Mr. Umair Perviaz, Director of the firm appeared before the Board and informed that they have submitted the differential fee for year 2023 Rs. 15000/- each for above products on 22.02.2023. The Board noted that differential fee for year 2018 is still pending for which the firm repetitive assured to submit in the next week.

The firm has now submitted the balance fee Rs. 15000/- each for year 2018 vide Dy. No. 15053 dated 14.06.2023.

MUHAMMAD HANIF & COMPANY, PLOT NO,D-10, SECTION 4 FISH HARBBUR WEST WHARF ROAD, KARACHI

9.	057157	Enrofloxacin 10% Injection Each ml contains Enrofloxacin…100mg **Manufactured By:** M/s. Hebei Yuanzheng Pharmaceuticals Co. Ltd., China	03-06-2009	Dy. No. 34663 dated 30.11.2022 Rs. 30000/-	Registration Board cancelled the registration of Enrofloxacin 10% Injection (057157) due to non-submission of renewal of registration for year 2019 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
10.	057158	Oxytetracycline 10% Injection Each ml contains Oxytetracycline HCl……100mg **Manufactured By:** M/s. Hebei Yuanzheng Pharmaceuticals Co. Ltd., China	03-06-2009	Dy. No. 34662 dated 30.11.2022 Rs. 30000/-	Registration Board cancelled the registration of Oxytetracycline 10% Injection (057158) due to non-submission of renewal of registration for year 2019 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
11.	039964	Ivermectin Injection Each ml contains: Ivermectin……..100mg **Manufactured By:** M/s. Hebei Yuanzheng Pharmaceuticals Liability Co. Ltd., China	03-09-2005	Dy. No. 34661 dated 30.11.2022 Rs. 30000/-	Registration Board cancelled the registration of Ivermectin Injection (039964) due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.

Background of the case:

Enrofloxacin 10% Injection (057157) and Oxytetracycline 10% Injection (057158):

Registration Board in its 326th meeting held on 14-16 March 2023 directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2019 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976. Accordingly, as per decision of the Board the firm has been issued showcause notice vide letter F.No.3-5/2023-RRR(M-326) dated 24th May 2023 and notice for personal hearing on 29th May 2023.

Ivermectin Injection (039964):

Registration Board in its 326th meeting held on 14-16 March 2023 directed to issue show cause notice to the firm for cancellation of registration due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976. Accordingly, as per decision of the Board the firm has been issued showcause notice vide letter F.No.3-5/2023-RRR(M-326) dated 24th May 2023 and notice for personal hearing on 29th May 2023.

Proceeding of 329th meeting of Registration Board:

In compliance to the above letter, Mr. Shoaib, Manager of the firm appeared before the Board and submitted the copy of submission of fee for year 2017 under SRO 1005 (I)/2017, however they were failed to provide any evidence for submission of renewal for year 2019 and 2020 for above products.

M/S. UNI-TIECH PHARMACEUTICALS (PVT) LTD., PLOT NO. 4/116 SECTOR 21 KORANGI INDUSTRIAL AREA KARACHI. (DML NO.000356)

12.	015888	Water For Injection	14-09-1994 Transfer of Reg: **22.07.2005**	Dy. No. 35222 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Water for Injection (015888) due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
13.	067310	Utine 10mg Tablet Each Tablet contains: Ebastine….10mg	28-12-2010	Dy. No. 35222 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Utine 10mg Tablet (067310) due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
14.	067304	Unilin 50mg Tablet Each tablet contains: Sertraline as HCl…..50mg	28-12-2010	Dy. No. 35222 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Unilin 50mg Tablet (067304) due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
15.	067305	Unilin 100mg Tablet Each Tablet contains: Sertraline as HCl…..100mg	28-12-2010	Dy. No. 35222 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Unilin 100mg Tablet (067305) due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
16.	061142	Unizolid 200mg/100ml Injection Each ml contains: Linezolid……2mg (Manufacturer Specifications)	18-02-2010	Dy. No. 35222 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Unizolid 200mg/100ml Injection (061142) due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
17.	061143	Unizolid 400mg/200ml Injection Each ml contains: Linezolid……2mg (Manufacturer Specifications)	18-02-2010	Dy. No. 35222 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Unizolid 400mg/200ml Injection (061143) due to non-submission of renewal of registration for year 2020 under section

					42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
18.	061144	Unizolid 600mg/300ml Injection Each ml contains: Linezolid……2mg (Manufacturer Specifications)	18-02-2010	Dy. No. 35222 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Unizolid 600mg/300ml Injection (061144) due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
19.	048669	Unimox 400mg/250ml Infusion Each 250ml contains: Moxifloxacin….400mg (Manufacturer Specifications)	15-07-2008	Dy. No. 35222 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Unimox 400mg/250ml Infusion (048669) due to non-submission of renewal of registration for year 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
20.	047469	Unistrofer injection Each 5ml contains: Iron sucrose complex eq. to Elemental Iron……20mg (Manufacturer Specifications)	24-01-2008	Dy. No. 35222 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Unistrofer injection (047469) due to non-submission of renewal of registration for year 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
21.	067298	Sodacarbol 50ml Injection Each ml contains: Sodium Bicarbonate….8.4% (USP Specifications)	28-12-2010	Dy. No. 35222 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Sodacarbol 50ml Injection (067298) due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
22.	048658	U- Glim 3mg Tablet Each Tablet contains: Glimepiride….3mg (USP Specifications)	15-07-2008	Dy. No. 35222 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of U- Glim 3mg Tablet (048658) due to non-submission of renewal of registration for year 2013 and 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
23.	067306	Uprinol 100mg Tablet Each Tablet contains: Allopurinol….100mg	28-12-2010	Dy. No. 35223 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Uprinol 100mg (067306) due to non-

		(USP Specifications)			submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
24.	015889	Neurogen 3ml Injection Each 3ml contains: vitamin B1….100mg, vitamin B6….100mg, vitamin B12….1000mg	14-09-1994 Transfer of Reg: **22-07-2005**	Dy. No. 35223 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Neurogen 3ml Injection (015889) due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
25.	067297	Uni- Trops 1mg Injection Each ml contains: Atropine Sulphate…1mg (USP Specifications)	28-12-2010	Dy. No. 35223 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Uni-Trops 1mg Injection (067297) due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
26.	047468	Xim- Tech 200mg Capsule Each Capsule contains: Cefixime….400mg (USP Specifications)	24-01-2008	Dy. No. 35223 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Xim- Tech 200mg Capsule (047468) due to non-submission of renewal of registration for year 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
27.	048662	Unilol 50mg Tablet Each tablet contains: Atenolol…50mg (USP Specifications)	15-07-2008	Dy. No. 35223 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Unilol 50mg Tablet (048662) due to non-submission of renewal of registration for year 2018 & 2013 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
28.	048663	Unilol 100mg Tablet Each tablet contains: Celecoxib……..100mg	15-07-2008	Dy. No. 35223 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Unilol 100mg Tablet (048663) due to non-submission of renewal of registration for year 2018 & 2013 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.

29.	047048	Cipflke 200mg/100ml Infusion Each 100ml contains: Ciprofloxacin as Lactate…...200mg (USP Specifications)	05-09-2007	Dy. No. 35223 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Cipflke 200mg/100ml Infusion (047048) due to non-submission of renewal of registration for year 2012 & 2017 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
30.	039671	Mortam 1gm Injection Each vial contains: Ceftazidime…..1gm	28-11-2005	Dy. No. 35225 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Mortam 1gm Injection (039671) due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
31.	039670	Mortam 500gm Injection Each vial contains: Ceftazidime….500mg	28-11-2005	Dy. No. 35223 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Mortam 500gm Injection (039670) due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
32.	039669	Mortam 250gm Injection Each vial contains: Ceftazidime….250mg	28-11-2005	Dy. No. 35223 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Mortam 250gm Injection (039669) due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
33.	053277	Amoxicillin 500mg Capsule Each capsule contains: Amoxicillin as Trihydrate….500mg (BP Specifications)	02-12-2008	Dy. No. 35223 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Amoxicillin 500mg Capsule (053277) due to non-submission of renewal of registration for year 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
34.	053274	Amoxicillin 125mg/5ml Suspension Each 5ml contains: Amoxicillin as Trihydrate….125mg (BP Specifications)	02-12-2008	Dy. No. 35223 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Amoxicillin 125mg/5ml Suspension (053274) due to non-submission of renewal of

					registration for year 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
35.	067303	Flucotiech 150mg Capsule Each capsule contains: Fluconazole….150mg (BP Specifications)	28-12-2010	Dy. No. 35223 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Flucotiech 150mg Capsule (067303) due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
36.	048671	Lincofanc 500mg Capsule Each capsule contains: Lincomycin as HCl…..500mg (Manufacturer Specifications)	15-07-2008	Dy. No. 35223 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Lincofanc 500mg Capsule (048671) due to non-submission of renewal of registration for year 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976
37.	015895	Dexone 1ml Ampoule Injection Each ml contains: Dexamethasone sodium phosphate eq. to Dexamethasone…..4mg	14-09-1994 Transfer of Reg: **22-07-2005**	Dy. No. 35225 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Dexone 1ml Ampoule Injection (015895) due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976
38.	047478	U-Gravi 50mg/ml Injection Each ml contains: Dimenhydrate…50mg (Manufacturer Specifications)	24-01-2008	Dy. No. 35225 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of U-Gravi 50mg/ml Injection (047478) due to non-submission of renewal of registration for year 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976
39.	047467	Lumisnag 20/120mg Tablet Each Tablet contains: Artemether….20mg, Lumefantrine….120mg (Manufacturer Specifications)	24-01-2008	Dy. No. 35225 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Lumisnag 20/120mg Tablet (047467) due to non-submission of renewal of registration for year 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976

40.	048665	Uni- Pine 30mg Tablet Each Tablet contains: Nimodipine…...30mg (BP Specifications)	15-07-2008	Dy. No. 35225 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Uni- Pine 30mg Tablet (048665) due to non-submission of renewal of registration for year 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976
41.	067302	Uni- Zide 25mg Tablet Each Tablet contains: Hydrochlorothiazide….25 mg (BP Specifications)	28-12-2010	Dy. No. 35225 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Uni- Zide 25mg Tablet (067302) due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976
42.	048655	Pyriclo Tablet Each Tablet contains: Meclozine HCl….25mg, Pyridoxine HCl….50mg (USP Specifications)	15-07-2008	Dy. No. 35225 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Pyriclo Tablet (048655) due to non-submission of renewal of registration for year 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976
43.	067301	U- Losapot 50mg Tablet Each tablet contains: Losartan Potassium….50mg (USP Specifications)	28-12-2010	Dy. No. 35225 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of U- Losapot 50mg Tablet (067301) due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976
44.	000960-EX	U- Viagra 50mg Tablet Each Tablet contains: Sildenafil as citrate…..50mg	10-05-2008	Dy. No. 35225 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of U- Viagra 50mg Tablet (000960-EX) due to non-submission of renewal of registration for year 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976
45.	048666	Montbliss 4mg Tablet Each Chewable Tablet contains: Montelukast sodium eq. to Montelukast ….4mg (Manufacturer Specifications)	15-07-2008	Dy. No. 35225 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Montbliss 4mg Tablet (048666) due to non-submission of renewal of registration for year 2018 under section 42 of Drug Act 1976 and under rule

					27 of Drug (LR&A) Rules 1976
46.	067299	Unibesylate 5mg Tablet Each Tablet contains: Amlodipine as besylate…..5mg (BP Specifications)	28-12-2010	Dy. No. 35225 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Unibesylate 5mg Tablet (067299) due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976
47.	067300	Unibesylate 10mg Tablet Each Tablet contains: Amlodipine as besylate…..10mg (BP Specifications)	28-12-2010	Dy. No. 35224 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Unibesylate 10mg Tablet (067300) due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976
48.	067310	Zemtiech 30mg Tablet Each tablet contains: Diltiazem…...30mg (BP Specifications)	28-12-2010	Dy. No. 35224 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Zemtiech 30mg Tablet (067310) due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976
49.	061260	Unidrine 30mg Tablet Each tablet contains: Ephedrine HCl…...30mg (Manufacturer Specifications)	07-04-2010	Dy. No. 35224 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Unidrine 30mg Tablet (061260) due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976
50.	015893	Unimethazine Injection Each ml contains: Cyanocobalamin……1000 mg	14-09-1994 Transfer of Reg: Dt: **22-07-2005**	Dy. No. 35224 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Unimethazine Injection (015893) due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976
51.	048656	Bon- Tech 0.25mcg Tablet Each Tablet contains: Alfacalcidol…0.25mcg (USP Specifications)	15-07-2008	Dy. No. 35224 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Bon- Tech 0.25mcg Tablet (048656) due to non-submission of

					renewal of registration for year 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976
52.	048654	U- Gran 15mg Tablet each Tablet contains: Pioglitazone….15mg (USP Specifications)	15-07-2008	Dy. No. 35224 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of U- Gran 15mg Tablet (048654) due to non-submission of renewal of registration for year 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976
53.	067295	Muskodine 2mg Tablet Each tablet contains: Tizanidine…...2mg (USP Specifications)	28-12-2010	Dy. No. 35224 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Muskodine 2mg Tablet (067295) due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976
54.	061046	Unizem 10mg Tablet Each Tablet contains: Diazepam…….10mg (USP Specifications)	11-04-2009	Dy. No. 35224 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Unizem 10mg Tablet (061046) due to non-submission of renewal of registration for year 2019 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976
55.	015890	Unimethazone Injection Each ml contains: Promethazine….2mg	14-09-1994 Transfer of Reg: **22-07-2005**	Dy. No. 35224 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Unimethazone Injection (015890) due to non-submission of renewal of registration for year 2020 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976
56.	053276	Amoxicillin 250mg Capsule Each capsule contains: Amoxicillin…...250mg (BP Specifications)	02-12-2008	Dy. No. 35224 dated 05.12.2022 Rs. 15000/-	Registration Board cancelled the registration of Amoxicillin 250mg Capsule (053276) due to non-submission of renewal of registration for year 2018 under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976
Remarks:					

Accordingly, as per decision of the Board the showcause notice has been issued vide letter F.No.3-5/2023-RRR(M-326) dated 24th May 2023 and notice for personal hearing on 29th May 2023 to the firm.

Proceedings of 329th meeting of Registration Board:

In compliance to above letters, Mr. Vikash Lal, Director of the firm appeared before the Board. The firm failed to submit any evidence for submission of renewal as required vide letter F.No.3-5/2023-RRR(M-326) dated 24th May 2023.

Case No: 2 Renewal application submitted under Rule 27 of Drug (LR&A) Rules 1976 and under SRO 1005(I)/2017.

Sr. No	Reg. No.	Brand Name & Composition	Initial date of Registration PRV (If any)	Date of application (R&I) Fee submitted	Decision
M/S BARRETT HODGSON PAKISTAN PVT LIMITED, F-423, SITE KARACHI					
57.	027336	Alphagan Ophthalmic Solution Each ml contains: Brimonidine Tartrate….2mg **Manufacturer:** M/s Allergan Pharmaceuticals Ireland Castlebar Road Westport Co. Mayo Ireland	11.04.2002	Dy. No. 9191 dated 11.04.2022 Rs. 30000/- Dy. No. 12151 dated 17.05.2023 Rs. 30000/-	Registration Board granted the renewal to Alphagan Ophthalmic Solution (027336) w.e.f 11.04.2022 to 10.04.2027 as per Import Policy for finished drugs. Renewal letter shall be issued after approval of shelf life, specifcations, container closure system (CCS) and other variations applied in concerned section.
Remarks: Shelf life, CCS and specifcations approval is required as same in not incorporated on initial registration letter. Submitted please.					
M/S. ICE BERG PHARMACEUTICALS PVT LIMITED. PLOT NO.144, NOWSHERA INDUSTRIAL ESTATE, RISALPUR, K.P.K-PAKISTAN.					
58.	085224	CB - GET Suspension 100mg/5ml Each 5ml contains: Cefixime trihydrate eq. to Cefixime…...100mg USP Specification	31.08.2017	Dy No.7825-R&I Dated:20.03.2023 Rs. 90,000/- (545636624) Rs.30000/- (65870238706)	Renewal is granted w.e.f 31.08.2022 to 30.08.2027. The renewal letter shall be issued after approval of registration in name of new tittle by PR-I section as per Licensing Division approval vide No. F.3-8/2005-Lic (Vol-I) dated 21.02.2023
59.	085099	IB DROX Capsule Each capsule contains: Cefadroxil monohydrate eq. to Cefadroxil….500mg USP Specification	14/09/2017	Dy No.7820-R&I Dated:20.03.2023 Rs. 30,000/- (321677043347) Rs.60000/- (1124044206)	Renewal is granted w.e.f 14.09.2022 to 13.09.2027. The renewal letter shall be issued after approval of registration in name of new tittle by PR-I

					section as per Licensing Division approval vide No. F.3-8/2005-Lic (Vol-I) dated 21.02.2023
60.	085100	IB DROX Suspension 125mg Each 5ml contains: Cefadroxil monohydrate eq. to Cefadroxil…125mg (USP Specification)	14.09.2017	Dy No.7822-R&I Dated:20.03.2023 Rs. 30,000/- (080173021572) Rs.60000/- (824306912976) Rs. 15000/- dated 07.06.2023 (122874774460)	Renewal is granted w.e.f 14.09.2022 to 13.09.2027. The renewal letter shall be issued after approval of registration in name of new tittle by PR-I section as per Licensing Division approval vide No. F.3-8/2005-Lic (Vol-I) dated 21.02.2023
61.	085101	IB DROX Suspension 250mg Each 5ml contains: Cefadroxil monohydrate eq. to Cefadroxil….250 mg (USP Specification)	14.09.2017	Dy No.7824-R&I Dated:20.03.2023 Rs. 60,000/- (18687110641) Rs.30000/- (19282638353) Rs. 15000/- dated 07.06.2023 (3782203249)	Renewal is granted w.e.f 14.09.2022 to 13.09.2027. The renewal letter shall be issued after approval of registration in name of new tittle by PR-I section as per Licensing Division approval vide No. F.3-8/2005-Lic (Vol-I) dated 21.02.2023
62.	087007	CB -GET Suspension 200mg/5ml Each 5ml contains: Cefixime as trihydrate… 200 mg (USP Specification)	18.12.2017	Dy No.10910-R&I Dated:02.05.2023 Rs. 60,000/-	Renewal is granted w.e.f 18.12.2022 to 17.12.2027. The renewal letter shall be issued after approval of registration in name of new tittle by PR-I section as per Licensing Division approval vide No. F.3-8/2005-Lic (Vol-I) dated 21.02.2023
Remarks: The tittle of the manufacturer has been changed to M/s JSK Medica Pvt Limited Plot No. 144 Nowshera Industrial Estate Risalpur vide Licensing Division approval No. F.3-8/2005-Lic (Vol-I) dated 21.02.2023.					

Case No: 3 Renewal confirmation before approval in name of new tittle i.e. M/s JSK Medica Pvt Limited Plot No. 144 Nowshera Industrial Estate Risalpur

PRV section has forwarded following products for verification of renewal of following products registered in name of Ice Berg Pharmaceuticals Pvt Limited Plot No. 144 Nowshera Industrial Estate Risalpur. The tittle of the aforesaid manufacturer has been changed to M/s JSK Medica Pvt Limited Plot No. 144 Nowshera Industrial Estate Risalpur vide Licensing Division approval No. F.3-8/2005-Lic (Vol-I) dated 21.02.2023. The details are as under:

Sr. No	Reg. No.	Brand Name & Composition	Initial date of Registration PRV (If any)	Date of application (R&I) Fee submitted	Remarks
1.	082786	CB-GET Capsule Each capsule contains: Cefixime Trihydrate eq. to Cefixime…...400mg (USP Specification)	03.10.2017	Dy No.7823-R&I Dated:20.03.2023 Rs. 30000/- (0949086824) Rs.30000/- (145845934068) Rs. 30000/- dated 07.06.2023 (917629213167)	Renewal is granted w.e.f 03.10.2022 to 02.10.2027 The renewal letter shall be issued after approval of registration in name of new tittle by PR-I section as per Licensing Division approval vide No. F.3-8/2005-Lic (Vol-I) dated 21.02.2023
2.	087006	Tenoberg 300mg Tablet Each film coated tablet contains: Tenofovir Disoproxil Fumarate….300 mg (Int. Ph. Specification)	18.12.2017	Dy No.7821-R&I Dated:20.03.2023 Rs.30000/- Rs. 30000/- dated 07.06.2023 (612486536)	Renewal is granted w.e.f 18.12.2022 to 17.12.2027. The renewal letter shall be issued after approval of registration in name of new tittle by PR-I section as per Licensing Division approval vide No. F.3-8/2005-Lic (Vol-I) dated 21.02.2023
3.	085051	IB-CLAR Dry Suspension 125mg/5ml Each 5ml contains: Clarithromycin (27.5%Enteric Coated Taste Masked Pellets) …...125mg (USP Specification) **Source of Pellets:** M/s Vision Pharmaceuticals Plot No. 22-23 Industrial triangle Kahuta Road Islamabad.	14.09.2017	Dy No.7826-R&I Dated:20.03.2023 Rs. 30000/- Rs. 60000/- Rs. 15000/- dated 07.06.2023 (94460000)	Renewal is granted w.e.f 14.09.2022 to 13.09.2027 The renewal letter shall be issued after approval of registration in name of new tittle by PR-I section as per Licensing Division approval vide No. F.3-8/2005-Lic (Vol-I) dated 21.02.2023

Case No: 4 Renewal applications of Contract Manufacturing/ Extension under Rule 27 of Drug (LR&A) Rules 1976 and under SRO 1347(I)/2021

a. M/s. Helix Pharma (Pvt) Ltd., A/56 SITE Mangopir Karachi

It is submitted that below mentioned products were applied by M/s. Helix Pharma (Pvt) Ltd., A/56 SITE Mangopir Karachi for extension in contract manufacturing as per details given below:

I	II	III	IV	V
Sr. No	**Reg. No.**	**Brand Name & Composition**	**Initial date of Registration PRV (If any)**	**Date of application (R&I) Fee submitted**
63.	028931	Tycef Capsule Each capsule contains: Cefixime USP….400mg **Manufacturer:** M/s. Opal Laboratories (Pvt) Ltd., LC/41 SITE Landhi Karachi.	13/08/2002 Approval of contract Mfg: 24.11.2020 Valid till: **23.03.2022**	Rs: 10000/- dated **25.04.2022** Rs: 75000/- dated 25.04.2022 Rs.75000/- dated 29.07.2022
64.	028165	Tycef Pediatric Suspension Each 5ml contains: Cefixime USP….100mg **Manufacturer:** M/s. Opal Laboratories (Pvt) Ltd., LC/41 SITE Landhi Karachi.	10/08/2002 Approval of contract Mfg: 24.11.2020 Valid till: **23.03.2022**	Rs: 10000/- dated **25.04.2022** Rs: 75000/- dated 25.04.2022 Rs.75000/- dated 29.07.2022
65.	048552	Tycef DS Suspension Each 5ml contains: Cefixime Trihydrate eq. to Cefixime….200mg **Manufacturer:** M/s. Opal Laboratories (Pvt) Ltd., LC/41 SITE Landhi Karachi.	20/03/2008 Approval of contract Mfg: 24.11.2020 Valid till: **23.03.2022**	Rs: 10000/- dated **25.04.2022** Rs: 75000/- dated 25.04.2022 Rs.75000/- dated 29.07.2022

Back ground of the case is that the firm was given an approval of contract manufacturing under former contract manufacturing policy of above products from M/s. Opal Laboratories (Pvt) Ltd., LC/41 SITE Landhi Karachi for a period of sixteen months i.e. till 23.03.2022 vide DRAP approval F.296-RB/2020 (PR-I) dated 24.11.2020 with the advice to submit quarterly progress on the activities undertaken by the firm in 296th meeting. The undertaking given by the firm at the time of grant of permission is reproduced as under:

Phase 1: Renovation of general packaging area (tablets and capsules) will be completed by Dec-2020

Phase II: Renovation of blistering, coating &encapsulation will be completed by May 2021.

Phase III: Renovation of Dry Suspension, blending, granulation and packaging will be completed by
November 2021

Phase IV: Renovation of liquid manufacturing, filling and packing will be completed by March 2022.

Phase V: Renovation of oral cephalosporin (capsule and dry powder suspension) will be completed by Feb,2022.

The firm submitted application of extension in contract manufacturing on 25.04.2022 as indicated in Column V above which was placed in before the Renewal Sub Committee in its 8th meeting held on 21st February 2023. Wherein the committee deferred the renewal applications for submission of progress report as per undertaking in 296th meeting of Registration Board.

In response to the above decision of the Committee the firm submitted reply vide Dy. No. 8391 dated 27.03.2023 wherein they have submitted that they have applied for withdrawal of Cephalosporin section due to non-feasibility for manufacturing of cephalosporin registered products. Accordingly, DRAP–Licensing section issued letter No. F.2-20/84-Lic (Vol-V), dated:23rd Oct, 2020 for withdrawal of Cephalosporin section. The firm further submitted that they had applied for contract manufacturing on basis of renovation /upgrade Cephalosporin area but later on we have withdrawn Cephalosporin section as mentioned above. The firm requested to consider the submitted application for renewal of Contract manufacturing for their registered Cephalosporin products & grant us the Contract Manufacturing for 05 years at your earliest on basis of withdrawal of Cephalosporin area.

The case was placed before the Registration Board in its 327th meeting of Registration Board with all the facts mentioned above. The Board is of the view to take assistance of the Legal Affairs Disvion on the matter regarding following:

i. The firm was granted contract manufacturing permission for their registered products as mentioned above for a period of sixteen months based on renovation of their manufacturing facilities with the advice to submit quarterly progress on the activities undertaken by the firm as mentioned above.
ii. However instead of submitting aforesaid report the firm approached the Licensing Disvion and get approval of layout plan for regularization vide letter No. 2-20/84-Lic (Vol-V) dated 23.10.2020 wherein Dry Powder Suspension (Cephalosporin) and Capsule (Cephalosporin) and Warehouse (Cephalosporin) were withdrawn.
iii. It is pertinent to mention that the firm didn't inform the PE&R Disvion of the aforesaid development instead submit an application of contract extension after due date which is mentioned column V of table above.

In view of foregoing Legal Affairs Division was requested to please opine on following:

a. Whether application for extension in contract manufacturing submitted after the due date can be considered under SRO 1347(I)/2021 or the firm has to apply afresh because the permission is valid for sixteen months only.
b. The Legal status of the registrations after the withdrawal of section without the intimation to the PE&R Disvion as per decision of Registration Board in its 29th meeting wherein the firm has to submit quarterly progress on the activities of renovation
c. The legal status of unauthorized manufacturing after the expiry of permission granted till 23.03.2022.

The Legal Affairs Division has responded to above queries and their response is recorded as under:

Sr. No.	Query by PE&R	Response by Legal Affairs
a.	Whether application for extension in contract manufacturing submitted after the due date can be considered under SRO 1347(I)/2021 or the firm has to apply afresh because the permission is valid for sixteen months only.	Rule 20A(2)(a) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as amended vide S.R.O. 1347(I)/2021 stipulates that the provisions of, *inter alia*, rule 27 shall apply *mutatis mutandis* to rule 20A. First proviso of rule 27 as amended vide S.R.O. 1005(I)/2017 provides that an application shall be made within sixty days after the expiry of the registration and when an application has been made as aforesaid the registration shall subject to the orders passed on the application for the renewal continue in force for the next period of five years and a certificate to this effect shall be issued within one month. The application of the firm may be considered under rule 27.
b.	The legal status of the registrations after the withdrawal of section without the intimation to the PE&R Division as per	The permission for contract manufacturing was validly granted in 296th meeting of the Registration Board. Both the contract giver and contract acceptor fulfilled the requisite conditions of rule 20A of the Drugs (Licensing, Registering and Advertising) Rules, 1976 at the

	decision of Registration Board in its 296th meeting wherein the firm has to submit quarterly progress on the activities of renovation.	time of grant of contract manufacturing permission. Registration of products remain intact and valid until otherwise suspended or cancelled by the Registration Board following the procedure laid down in section 7(11) of the Drugs Act, 1976 read with section 41 thereof. It has to be kept in mind that the present case is of contract manufacturing and withdrawal of any section of contract giver having valid DML has no consequences on products manufactured by the contract acceptor on behalf of the contract giver.
c.	The legal status of unauthorized manufacturing after the expiry of permission granted till 23.03.2022.	In case the application submitted by the firm is covered under first proviso of rule 27 of the Drugs (Licensing, Registering and Advertising) Rules, 1976, the registration shall remain valid until explicit orders are passed by the Registration Board.

Decision: **Keeping in view the opinion of Legal Affairs Division recorded above, Registration Board granted the extension in contract manufacturing under Rule 27 of Drug (LR&A) Rules 1976 as per validity mentioned against each below:**

Sr. No	Reg. No.	Brand Name & Composition	Initial date of Registration PRV (If any)	Decision
66.	028931	Tycef Capsule Each capsule contains: Cefixime USP….400mg **Manufacturer:** M/s. Opal Laboratories (Pvt) Ltd., LC/41 SITE Landhi Karachi.	**13/08/2002** Approval of contract Mfg: 24.11.2020	Renewal is granted w.e.f 13.08.2022 to 12.08.2027 The firm shall submit finished product specifcations as per decision of 295th meeting of Registration Board.
67.	028165	Tycef Pediatric Suspension Each 5ml contains: Cefixime USP….100mg **Manufacturer:** M/s. Opal Laboratories (Pvt) Ltd., LC/41 SITE Landhi Karachi.	**10/08/2002** Approval of contract Mfg: 24.11.2020	Renewal is granted w.e.f 10.08.2022 to 09.08.2027 The firm shall submit finished product specifcations as per decision of 295th meeting of Registration Board.
68.	048552	Tycef DS Suspension Each 5ml contains: Cefixime Trihydrate eq. to Cefixime….200mg **Manufacturer:** M/s. Opal Laboratories (Pvt) Ltd., LC/41 SITE Landhi Karachi.	**20/03/2008** Approval of contract Mfg: 24.11.2020	Renewal is granted w.e.f 20.03.2023 to 19.03.2028 The firm shall submit finished product specifcations as per decision of 295th meeting of Registration Board.

b. M/s. Gillman Pharmaceuticals, Plot No. 14/2-A Phase-I & II Industrial Estate Hattar. (DML No.000683)

Sr. No	Reg. No.	Brand Name & Composition	Initial date of Registration PRV (If any)	Date of application (R&I) Fee submitted	Decision
1.	087991	GILSPAN Dry Suspension 200mg/5ml Each 5ml contains Cefixime as Trihydrate….200 mg (JP Specifcations) **Contract Manufacturer:** M/s. EG Pharmaceuticals,13-A Industrial Triangle Kahuta Road Islamabad	09/03/2018	Dy. No: 6632 dated 08.03.2023 Fee not submitted	Registration Board directed to issue show cause notice to the firm for suspension of registration due to non-submission of renewal fee under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
2.	087990	GILSPAN Dry Suspension 100mg/5ml Each 5ml contains Cefixime as trihydrate……100mg (USP Specifcations) **Contract Manufacturer:** M/s. EG Pharmaceuticals,13-A Industrial Triangle Kahuta Road Islamabad	09/03/2018	Dy. No: 6632 dated 08.03.2023 Fee not submitted	Registration Board directed to issue show cause notice to the firm for suspension of registration due to non-submission of renewal fee under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.
3.	087989	GILSPAN Capsule 400mg Each capsule contains Cefixime as Trihydrate……400 mg (USP Specifcations) **Contract Manufacturer:** M/s. EG Pharmaceuticals,13-A Industrial Triangle Kahuta Road Islamabad	09/03/2018	Dy. No: 6632 dated 08.03.2023 Fee not submitted	Registration Board directed to issue show cause notice to the firm for suspension of registration due to non-submission of renewal fee under section 42 of Drug Act 1976 and under rule 27 of Drug (LR&A) Rules 1976.

Remarks:

The firm was informed vide letter No. F. No.3-4/2023 (Renewal) dated 16.05.2023 to submit following:

1. Application on Form 5B as per SOP approved by the Registration Board in its 276th meeting for submission of renewal applications.
2. Prescribed fee Rs.75000/- each as same has not been submitted with renewal application
3. Contract agreement as per contract manufacturing policy notified vide SRO 1347(I)/2021.
4. Evidence of revision of monograph of GILSPAN Capsule 400mg in light of directions of the Registration Board vide its 313rd meeting.

Reply of above is still awaited.

Sr. No.	Assistant Director	Designated No.	No. of Cases
1.	Mr. M. Kashif	DD-I	11
2.	Ms. Haleema Sharif	DD-II	13
3.	Mr. Hafiz Ahsan	DD-III	13
Total			37

Cases of DD (Mr. Muhammad Kashif)

Imported Human Biological product from Reference countries/WHO PQ:

1.	Name, address of Applicant / Importer	**M/s TIMAX LIFE SCIENCES Pvt Ltd.** Address: M-1 FL-37, Block-B, Gulshan-e-Jamal, Karachi.
	Details of Drug Sale License of importer	License No: 0323 Address: M-1, FL-37, Block-B, Gulshan-e-Jamal Karachi Address of go-down: R-172, Block-F, Gulshan-e-Jamal, Karachi. Validity: 05-03-2028
	Name and address of marketing authorization holder (abroad)	M/s Octapharma GmbH, Address: Elisabeth-Selbert-Straße 11 40764 Langenfeld, Germany.
	Name, address of manufacturer(s)	M/s Octapharma Produktionsgesellschaft Deutschland mbH Wolfgang-Marguerre-Allee 1, 31832 Springe, Germany.
	Name of exporting country	Germany
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Valid original legalized CoPP No. 20090301 dated 03-09-2020 issued by Bezirksregierung Düsseldorf Postfach 300865 40408 Düsseldorf Germany. GMP: Legalized GMP Certificate Ref # 41401/H-43 dated 12-02-2020.
	Details of letter of authorization / sole agency agreement	New Legalized Letter of Authorization Number 78/2022 issued dated July 28th 2022 valid till 27-07-2027 & Legalized Sole Agency Agreement (copies are attached)
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)

	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 3117 Dated: 27-01-2021
	Details of fee submitted	Deposit Slip # 2035154 of Rs.100,030/- (One lac thirty only) Dated 21-01-2021
	The proposed proprietary name / brand name	ALBUNORM 20% 50ML
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Human Albumin Albunorm 20% is a solution containing 200g / L of total protein of which at least 96% is human albumin.
	Dosage form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Blood Product
	Finished product specifications	Ph. Eur. Specifications
	Proposed Pack size	50ml glass Vial
	Proposed unit price	Retail price equivalent to Grifols current prices.
	Shelf Life	36 months
	Storage Conditions	2°C -25°C
	The status in reference regulatory authorities	Available in Germany, France, Belgium, Austria, Switzerland.
	For generic drugs (me-too status)	AlbuRx 20% 50ml of Hakimsons (Reg # 083695)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per EEC guidelines. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	M/s Octapharma Froduktionsgesellschaft Deutschland mbH Wolfgang-Marguerre-Allee 1, 31832 Springe, Germany
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of fractionation process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance derived from human plasma.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study 60 months final data are available for the long-term conditions at 5°C ±3°C, 25°C±2°C/60% RH±5% and 30°C±2°C/75% RH±5%. 6 months final data are presented for the accelerated condition at 40°C±2°C/75% RH±5%.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, fractionation process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted that the data from the product Fractionation process consistently yields drug product that meets the predetermined acceptance criteria for all quality attributes and the in-process tests are suitable to monitor the fractionation process.
	Container closure system of the drug product	50 ml glass Infusion Vial with sealed cap.
	Stability study data of drug product, shelf life and storage conditions	36 months at +2°C to 25°C, **not to be frozen and protected from light.** The stability study report FFH-1104 comprises a total of 12 batches. Stability was investigated under the following storage conditions: • Long term conditions for 60 months at 5°C ±3°C, 25°C±2°C/60% RH±5% and 30°C±2°C/75% RH±5%, • Accelerated conditions for 6 months at 40°C±2°C / 75% RH±5%.
	Module-IV	Albunorm was registered in the European Union as a bibliographic (well established use) application according to Article 10a of Directive 2001/83/EC. According to this regulation results of preclinical and clinical trials have been replaced by references to published scientific literature. For this reason, no complete Module 4 has been included in the dossier for Albunorm. An overview and summary for preclinical and clinical literature data can be found in Module 2 of the dossier.
	Module-V	By definition, when a medicinal product is given intravenously, its bioavailability is 100%, so for plasma-derived products of human origin, that are given intravenously, clinical studies to investigate the products' bioavailability are not requested. This statement is supported by the European Medicines Agency (EMA) - Guideline on Similar

		Biological Medicinal Products, CHMP/437/04, 2005: "The standard generic approach (demonstration of bioequivalence with a reference medicinal product by appropriate bioavailability studies) is normally applied to chemically derived medicinal products. Due to the complexity of biological/biotechnology-derived products the generic approach is scientifically not appropriate for these products."
	Remarks	The firm has not performed any non-clinical or clinical studies. It is evident from public assessment reports of different products approved in RRAs like Australia, Germany that these products were authorized on the basis of well-established use and no new non-clinical or clinical studies were performed.
	Decision: Keeping in view the legalized CoPP indicating product availability in the country of origin, Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.	
2.	Name, address of Applicant / Importer	M/s TIMAX Life Sciences Pvt Ltd., Address: M-1 FL-37, Block-B, Gulshan-e-Jamal, Karachi
	Details of Drug Sale License of importer	License No: 0323 Address: M-1, FL-37, Block-B, Gulshan-e-Jamal Karachi Address of warehouse-2: R-172, Block-F, Gulshan-e-Jamal Karachi Validity: 05-03-2028
	Name and address of marketing authorization holder (abroad)	M/s Octapharma GmbH, Registration Address: Elisabeth-Selbert-Straße 1140764 Langenfeld, Germany
	Name, address of manufacturer(s)	M/s Octapharma Froduktionsgesellschaft Deutschland GmbH Wolfgang-Marguerre-Allee 1, 31832 Springe, Germany
	Name of exporting country	Germany
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Valid original legalized CoPP No. 20090301 dated 03-09-2020 issued by Beziksregierung Düsseldorf Postfach 300865 40408 Düsseldorf Germany. GMP: Valid legalized GMP Certificate Ref # 41401/H-43
	Details of letter of authorization / sole agency agreement	New Legalized Letter of Authorization Number 78/2022 issued dated July 28th 2022 valid till 27-07-2027 & Legalized Sole Agency Agreement (copies are attached)
	Status of the applicant	☐ Manufacturer ☒ Importer

		☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 3118 Dated: 27-01-2021
	Details of fee submitted	Deposit Slip # 2035155 of Rs.100030/- (One lac thirty only) Dated 21-01-2021
	The proposed proprietary name / brand name	ALBUNORM 20% 100ML
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Human Albumin Albunorm 20% (Human Albumin 20%) is a solution containing 200g /L of total protein of which at least 96% is human albumin.
	Dosage form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Blood Product
	Finished product specifications	Ph. Eur. Specifications
	Proposed Pack size	100ml glass Vial
	Proposed unit price	Retail price equivalent to Grifols current prices.
	Shelf Life	36 months
	Storage Conditions	+ 2°C -25°C
	The status in reference regulatory authorities	Available in Germany, France, Belgium, Austria, Switzerland.
	For generic drugs (me-too status)	AlbuRx 20% 100ml of Hakimsons (Reg # 087404)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per EEC guidelines. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	M/s **Octapharma** Froduktionsgesellschaft Deutschland GmbH Wolfgang-Marguerre-Allee 1, 31832 Springe, Germany.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of fractionation process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and

		justification of specification, reference standard, container closure system and stability studies of drug substance derived from human plasma.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study 60 month data are available for the long-term conditions at 5°C ± 3°C, 25°C ± 2°C/60% RH±5% and 30°C±2°C/75% RH±5%. 6 month data are presented for the accelerated condition at 40°C±2°C/75% RH±5%.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, fractionation process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted that the data from the product Fractionation process consistently yields drug product that meets the predetermined acceptance criteria for all quality attributes and the in-process tests are suitable to monitor the fractionation process.
	Container closure system of the drug product	100 ml glass Vial with sealed cap.
	Stability study data of drug product, shelf life and storage conditions	36 months at +2°C to 25°C, **not to be frozen and protected from light.** The stability study report FFH-1104 comprises a total of 12 batches. Stability was investigated under the following storage conditions: • Long term conditions for 60 months at 5°C ±3°C, 25°C±2°C/60% RH±5% and 30°C±2°C/75% RH±5%, • Accelerated conditions for 6 months at 40°C±2°C / 75% RH±5%.
	Module-IV	Albunorm was registered in the European Union as a bibliographic (well established use) application according to Article 10A of Directive 2001/83/EC. According to this regulation, results of preclinical and clinical trials have been replaced by references to published scientific literature. For this reason, no complete Module 4 has been included in the dossier for Albunorm. An overview and summary for preclinical and clinical literature data was present in Module 2 of the dossier.

	Module-V	By definition, when a medicinal product is given intravenously, its bioavailability is 100%, so for plasma-derived products of human origin, that are given intravenously, clinical studies to investigate the products' bioavailability are not requested. This statement is supported by the European Medicines Agency (EMA) - Guideline on Similar Biological Medicinal Products, CHMP/437/04, 2005: "The standard generic approach (demonstration of bioequivalence with a reference medicinal product by appropriate bioavailability studies) is normally applied to chemically derived medicinal products. Due to the complexity of biological/biotechnology-derived products the generic approach is scientifically not appropriate for these products."
	Remarks	The firm has not performed any non-clinical or clinical studies. It is evident from public assessment reports of different products approved in RRAs like Australia, Germany that these products were authorized on the basis of well-established use and no new non-clinical or clinical studies were performed.
	Decision: Keeping in view the legalized CoPP indicating product availability in the country of origin, Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.	
3.	**Name, address of Applicant / Importer**	**M/s TIMAX Life Sciences Pvt Ltd.,** Address: M-1 FL-37, Block-B, Gulshan-e-Jamal, Karachi.
	Details of Drug Sale License of importer	License No: 0323 Address: M-1, FL-37, Block-B, Gulshan-e-Jamal Karachi Address of warehouse-2: R-172, Block-F, Gulshan-e-Jamal Karachi Validity: 05-03-2028
	Name and address of marketing authorization holder (abroad)	M/s Octapharma GmbH Registration Address: Elisabeth-Selbert-Straße 1 1 40764 Langenfeld, Germany
	Name, address of manufacturer(s)	M/s Octapharma Froduktionsgesellschaft Deutschland mbH Wolfgang-Marguerre-Allee 1, 31832 Springe, Germany.
	Name of exporting country	Germany
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	Valid original legalized CoPP No. 20090301 dated 03-09-2020 issued by Beziksregierun g Düsseldorf Postfach 300865 40408 Düsseldorf Germany Valid legalized GMP Certificate Ref # 41401/H-43
	Details of letter of authorization / sole agency agreement	New Legalized Letter of Authorization Number 78/2022 issued dated July 28th 2022 valid till 27-07-2027 &

		Legalized Sole Agency Agreement (copies are attached)
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 3119 Dated: 27-01-2021
	Details of fee submitted	Deposit Slip # 2035156 of Rs.100030/- (One lac thirty only) Dated 21-01-2021
	The proposed proprietary name / Brand name	ALBUNORM 25% 50ML
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Human albumin: Albunorm 25% (Human Albumin 25%) is a solution containing 250g /L of total protein of which at least 96% is human albumin.
	Dosage form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Blood Product
	Reference to Finished product specifications	Ph. Eur. Specifications
	Proposed Pack size	50ml glass Vial
	Proposed unit price	Retail price equivalent to Grifols current prices.
	Shelf Life	36 months
	Storage Conditions	+ 2°C - 25°C
	The status in reference regulatory authorities	Available in Germany, France, Belgium, Austria, Switzerland.
	For generic drugs (me-too status)	Uman Albumin 25% by M/s Popular International
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	M/s **Octapharma** Produktionsgesellschaft Deutschland mbH Wolfgang-Marguerre-Allee 1, 31832 Springe, Germany
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general

		properties, solubilities, physical form, manufacturers, description of fractionation process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance derived from human plasma.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study 60 months final data are available for the long-term conditions at 5°C ±3°C, 25°C±2°C/60% RH±5% and 30°C±2°C/75% RH±5%. 6 months final data are presented for the accelerated condition at 40°C±2°C/75% RH±5%.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, fractionation process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted that the data from the product Fractionation process consistently yields drug product that meets the predetermined acceptance criteria for all quality attributes and the in-process tests are suitable to monitor the fractionation process.
	Container closure system of the drug product	50 ml glass Infusion Vial with sealed cap.
	Stability study data of drug product, shelf life and storage conditions	36 months at +2°C to 25°C, **not to be frozen and protected from light.** The stability study report FFH-0909 comprises a total of 12 batches. Stability was investigated under the following storage conditions: • Long term conditions for 60 months at 5°C ±3°C, 25°C±2°C/60% RH±5% and 30°C±2°C/75% RH±5%, • Accelerated conditions for 6 months at 40°C±2°C / 75% RH±5%.
	Module-IV	Albunorm was registered in the European Union as a bibliographic (well established use) application according to Article 10a of Directive 2001/83/EC. According to this regulation results of preclinical and clinical trials have been replaced by references to published scientific literature. For this reason, no complete Module 4 has been included in the dossier for Albunorm. An overview and summary for preclinical and clinical literature data can be found in Module 2 of the dossier.

	Module-V	By definition, when a medicinal product is given intravenously, its bioavailability is 100%, so for plasma-derived products of human origin, that are given intravenously, clinical studies to investigate the products' bioavailability are not requested. This statement is supported by the European Medicines Agency (EMA) - Guideline on Similar Biological Medicinal Products, CHMP/437/04, 2005: "The standard generic approach (demonstration of bioequivalence with a reference medicinal product by appropriate bioavailability studies) is normally applied to chemically derived medicinal products. Due to the complexity of biological/biotechnology-derived products the generic approach is scientifically not appropriate for these products."
	Remarks	The firm has not performed any non-clinical or clinical studies. It is evident from public assessment reports of different products approved in RRAs like Australia, Germany that these products were authorized on the basis of well-established use and no new non-clinical or clinical studies were performed.
	Decision: Keeping in view the legalized CoPP indicating product availability in the country of origin, Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.	
4.	Name, address of Applicant / Importer	**M/s TIMAX Life Sciences Pvt Ltd,** Address: M-1 FL-37, Block-B, Gulshan-e-Jamal, Karachi
	Details of Drug Sale License of importer	License No: 0323 Address: M-1, FL-37, Block-B, Gulshan-e-Jamal Karachi Address of warehouse-2: R-172, Block-F, Gulshan-e-Jamal Karachi Validity: 05-03-2028
	Name and address of marketing authorization holder (abroad)	M/s Octapharma GmbH Registration Address: Elisabeth-Selbert-Straße 1 1 40764 Langenfeld, Germany
	Name, address of manufacturer(s)	M/s Octapharma Froduktionsgesellschaft Deutschland mbH Wolfgang-Marguerre-Allee 1, 31832 Springe, Germany.
	Name of exporting country	Germany
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Valid original legalized CoPP No. 20090301 dated 03-09-2020 issued by Beziksregierun g Düsseldorf Postfach 300865 40408 Düsseldorf Germany. GMP: Valid legalized GMP Certificate Ref # 41401/H-43 .

	Details of letter of authorization / sole agency agreement	New Legalized Letter of Authorization Number 78/2022 issued dated July 28th 2022 valid till 27-07-2027 & Legalized Sole Agency Agreement (copies are attached)
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 3120 Dated: 27-01-2021
	Details of fee submitted	Deposit Slip # 2035157 of Rs.100030/- (One lac thirty only) Dated 21-01-2021
	The proposed proprietary name / brand name	ALBUNORM 25% 100ML
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Human Albumin Albunorm 25% (Human Albumin 25%) is a solution containing 250g /L of total protein of which at least 96% is human albumin.
	Dosage form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Blood Product
	Finished product specifications	Ph. Eur. Specifications
	Proposed Pack size	100ml glass Vial
	Proposed unit price	Retail price equivalent to Grifols current prices.
	Shelf Life	36 months
	Storage Conditions	2°C -25°C
	The status in reference regulatory authorities	Available in Germany, France, Belgium, Austria, Switzerland.
	For generic drugs (me-too status)	Uman Albumin 25% by M/s Popular International
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	M/s **Octapharma** Froduktionsgesellschaft Deutschland mbH Wolfgang-Marguerre-Allee 1, 31832 Springe, Germany.

	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of fractionation process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance derived from human plasma.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study 60 months final data are available for the long-term conditions at 5°C ±3°C, 25°C±2°C/60% RH±5% and 30°C±2°C/75% RH±5%. 6 months final data are presented for the accelerated condition at 40°C±2°C/75% RH±5%.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, fractionation process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted that the data from the product Fractionation process consistently yields drug product that meets the predetermined acceptance criteria for all quality attributes and the in-process tests are suitable to monitor the fractionation process.
	Container closure system of the drug product	100 ml glass Infusion Vial with sealed cap.
	Stability study data of drug product, shelf life and storage conditions	36 months at +2°C to 25°C, **not to be frozen and protected from light.** The stability study report FFH-1104 comprises a total of 12 batches. Stability was investigated under the following storage conditions: • Long term conditions for 60 months at 5°C ±3°C, 25°C±2°C/60% RH±5% and 30°C±2°C/75% RH±5%, • Accelerated conditions for 6 months at 40°C±2°C / 75% RH±5%.
	Module-IV	Albunorm was registered in the European Union as a bibliographic (well established use) application according to Article 10A of Directive 2001/83/EC. According to this regulation results of preclinical and clinical trials have been replaced by references to published scientific literature. For this reason, no complete Module 4 has been included in the dossier for Albunorm. An overview and summary for

		preclinical and clinical literature data can be found in Module 2 of the dossier.
	Module-V	By definition, when a medicinal product is given intravenously, its bioavailability is 100%, so for plasma-derived products of human origin, that are given intravenously, clinical studies to investigate the products' bioavailability are not requested. This statement is supported by the European Medicines Agency (EMA) - Guideline on Similar Biological Medicinal Products, CHMP/437/04, 2005: "The standard generic approach (demonstration of bioequivalence with a reference medicinal product by appropriate bioavailability studies) is normally applied to chemically derived medicinal products. Due to the complexity of biological/biotechnology-derived products the generic approach is scientifically not appropriate for these products."
	Remarks	Moreover, the firm has not performed any non-clinical or clinical studies. It is evident from public assessment reports of different products approved in RRAs like australia, Germany that these products were authorized on the basis of well-established use and no new non-clinical or clinical studies were performed.
	Decision: Keeping in view the legalized CoPP indicating product availability in the country of origin, Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.	
5.	Name, address of Applicant / Importer	**M/s Hakimsons (Impex) (Pvt.) Ltd.** Hakimsons Building, 19 West Wharf Road, Karachi 74000, Pakistan.
	Details of Drug Sale License of importer	**License No:** 043 **Address:** Hakimsons Building, 19 West Wharf Road, Karachi 74000, Pakistan. **Address of Godown:** NA **Validity:** 15-09-2023. **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	CSL Behring AG Wankdorfstrasse 10 3014 Bern Switzerland
	Name, address of manufacturer(s)	CSL Behring AG Wankdorfstrasse 10 3014 Bern Switzerland
	Name of exporting country	Switzerland

	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP certificate (No.20005252) dated 17.11.2020 issued by Swissmedics for AlbuRx 25 (Albumin CSL 25% Solution for Infusion). The CoPP states that the product is **not on free sale in exporting country**.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from CSL Behring AG. The letter species that the manufacturer appoints M/s Hakimsons (Impex) (Pvt.) Ltd. to register their products in Pakistan. The authorization letter is valid till 30.06.2023
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	08-06-2021
	Details of fee submitted	PKR 100,000/-: 29-04-2021
	The proposed proprietary name / brand name	**AlbuRx™ 25 50ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Human Plasma Protein …….250g/L (of Which ≥ 95% is Human Albumin)
	Pharmaceutical form of applied drug	Human Albumin 25% Solution is filled in type-II vials.
	Pharmacotherapeutic Group of (API)	Blood substitutes and plasma protein fractions (B05AA01)
	Reference to Finished product specifications	Ph. Eur
	Proposed Pack size	**1 vial of 50ml**
	Proposed unit price	66.38 US$- single dose vial
	The status in reference regulatory authorities	Alburx 25% (USFDA Approved)
	For generic drugs (me-too status)	Plasbumin 25 inj. Manufactured by Grifols, USA. Imported by Popular International
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure

		system and stability studies of drug substance.
	Name, address of drug substance manufacturer	CSL Behring AG Wankdorfstrasse 10 3014 Bern Switzerland
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Albumin is isolated from human plasma according to the manufacturing procedure described in section 3.2.S.2.2. The pure albumin is never isolated from the continuous process which leads to human albumin solution. Therefore, no stability summary or conclusions, post – approval stability protocol or stability commitment stability data are available for the drug substance. However, legalized plasma expert report is attached as 1.6.5
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not Required.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	USP Type II glass vials
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40°C ± 2°C for 6 months. The real time stability study data is conducted at 30°C ±2°C the real time stability study data as per ICH guidelines
Remarks of the Evaluator :		
DSL expired. Updated copy of DSL provided. The CoPP states that the product is **not on free sale in exporting country**. However, the firm submitted Certificate of Pharmaceutical product issued by Health Canada indicating product availability in Canada. Additional fee PKR 50,000/- (Slip # 2030578) dated 19-07-2021 is submitted.		
• **Decision: Keeping in view the legalized CoPP indicating product availability in the Reference country (Canada), Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.**		
6.	**Name, address of Applicant / Importer**	**M/s Hakimsons (Impex) (Pvt.) Ltd.** Hakimsons Building, 19 West Wharf Road,

		Karachi 74000, Pakistan.
	Details of Drug Sale License of importer	**License No:** 043 **Address:** Hakimsons Building, 19 West Wharf Road, Karachi 74000, Pakistan. **Address of Godown:** NA **Validity:** 15-09-2023. **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	CSL Behring AG Wankdorfstrasse 10 3014 Bern Switzerland
	Name, address of manufacturer(s)	CSL Behring AG Wankdorfstrasse 10 3014 Bern Switzerland
	Name of exporting country	Switzerland
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP certificate (No.20005253) dated 17.11.2020 issued by Swissmedics for AlbuRx 25 (Albumin CSL 25% Solution for Infusion). The CoPP states that the product is **not on free sale in exporting country**.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from CSL Behring AG. The letter species that the manufacturer appoints M/s Hakimsons (Impex) (Pvt.) Ltd. to register their products in Pakistan. The authorization letter is valid till 30.06.2023
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	08-06-2021
	Details of fee submitted	PKR 100,000/-: 29-04-2021
	The proposed proprietary name / brand name	**AlbuRx™ 25 100ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Human Plasma Protein …….250g/L (of Which ≥ 95% is Human Albumin)
	Pharmaceutical form of applied drug	Human Albumin 25% Solution is filled in type-II vials.
	Pharmacotherapeutic Group of (API)	Blood substitutes and plasma protein fractions (B05AA01)
	Reference to Finished product specifications	Ph. Eur specifications

	Proposed Pack size	**1 vial of 100ml**
	Proposed unit price	132.77 US$- single dose vial
	The status in reference regulatory authorities	Alburx 25% (USFDA Approved)
	For generic drugs (me-too status)	Plasbumin 25 inj. Manufactured by Grifols, USA. Imported by Popular International
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	CSL Behring AG Wankdorfstrasse 10 3014 Bern Switzerland
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Albumin is isolated from human plasma according to the manufacturing procedure described in section 3.2.S.2.2. The pure albumin is never isolated from the continuous process which leads to human albumin solution. Therefore, no stability summary or conclusions, post – approval stability protocol or stability commitment stability data are available for the drug substance. However, legalized plasma expert report is attached as 1.6.5
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Not Required.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	USP Type II glass vials

	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches The accelerated stability study data is conducted at 40ºC ±2ºC for 6 months. The real time stability study data is conducted at 30ºC ±2ºC the real time stability study data as per ICH guidelines
Remarks of the Evaluator :		
DSL expired. Updated copy of DSL provided. The CoPP states that the product is **not on free sale in exporting country**. However, the firm submitted Certificate of Pharmaceutical product issued by Health Canada indicating product availability in Canada. Additional fee PKR 50,000/- (Slip # 2030579) dated 19-07-2021 is submitted.		
Decision: Keeping in view the legalized CoPP indicating product availability in the Reference country (Canada), Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.		

Imported veterinary Biological product from Non Reference countries

7.	**Name and address of Importer**	**M/s VET CURE PHARMA** Situated 191. St. No. 04 Cavalry, Ground Cantt, Lahore
	Detail of DSL	**MS M/S VET CURE PHARMA** Situated 191/04 Cavalry, Ground Cantt, Lahore Valid till: 25-03-2028
	Name and address of Manufacturer	**FARMACOLOGICOS VETERINARIOS S.A.C.** Pan American Highway N°766 Km 198.5, Chincha Alta – Ica – Perú Telephone number: (51) 56 262 267 / Mobile number: 998344760 eFax: (51) 17057225 / email: farvet@farvet.com Web site: www.farvet.com
	Name of exporting country	PERU
	Brand Name +Dosage Form + Strength	OLEOVAC HCI PLUS+®
	Diary No. Date of R& I & fee	Dy. No. 2924 R&I Dated 31-01-2022 Rs. 150,000/-
	Composition	**AMOUNT / TITER PER ML FOR EACH OF THE STRAINS** • Group I, serotype 4 Avian Adenovirus….. ≥ $4x10^{8.0}$ TCID50%: 0.08 ml • Group I, serotype 8 Avian Adenovirus….. ≥ $4x10^{8.0}$ TCID50%: 0.08 ml • Group I, serotype 11 Avian Adenovirus….. ≥ $4x10^{8.0}$ TCID50%: 0.08 ml ***TCID**: Tissue culture infectious dose*
	Pharmacological Group	Veterinary Vaccine
	Type of Form	Form-5A
	Finished Product Specification	Ph. Eur. specifications
	Shelf Life	24 months----(2°C -7°C)
	Document Details	**i. <u>Free Sale Certificate (Original Legalized):</u>** Certificate No.2020-0571 **ii. Original legalized GMP certificate** **iii. Original legalized Product Specific Sole Agency Agreement made on Submitted 10, March 2023 Dy: No: 7105 is submitted by the firm.**
	Pack size & Price	500 ml bottle Vial: Decontrolled
	Reference Regulatory Authority Availability	N/A

	Products already registered in Pakistan	Volvac IBH + NDKV 069674 Vetmune Pharma GP Vac Hydro TC Plus 084594 Grand Pharma
	Remarks of Evaluator	Group I, serotype 11 Avian Adenovirus is not present in both the stated registered products
	Remarks of Dr Qurban Expert member of Registration Board from Animal Husbandry Commission during the Meeting.	Group I, serotype 11 Avian Adenovirus is present in Pakistan.
	Decision: Keeping in view the legalized FSC and GMP indicating product availability in the country of origin, and expert opinion of Dr. Qurban Registration Board approved the product subject to compliance to current import policy for finished drugs.	
8.	**Name and address of Importer**	**M/S VET CURE PHARMA** Situated 191. St. No. 04 Cavalry, Ground Cantt, Lahore
	Detail of DSL	**M/S VET CURE PHARMA** Situated 191/04 Cavalry, Ground Cantt, Lahore Valid till: 30-03-2028 submitted dated : 10-03-2023 Dy: 7105
	Name and address of Manufacturer	**FARMACOLOGICOS VETERINARIOS S.A.C.** Pan American highway N°766 Km 198.5, Chincha Alta – Ica – Perú Telephone number: (51) 56 262 267 / Mobile number: 998344760 eFax: (51) 17057225 / email: farvet@farvet.com Web site: www.farvet.com
	Name of exporting country	PERU
	Brand Name +Dosage Form + Strength	**OLEOVAC HCI-NW PLUS+®**
	Diary No. Date of R& I & fee	Dy. No. 2923 R&I Dated 27-01-2022 Rs. 150,000/-
	Composition	**AMOUNT / TITER PER ML FOR EACH OF THE STRAINS** • Group I, serotype 4 Avian Adenovirus….. ≥ $4x10^{8.0}$ TCID50%: • Group I, serotype 8 Avian Adenovirus….. ≥ $4x10^{8.0}$ TCID50%: • Group I, serotype 11 Avian Adenovirus… ≥ $4x10^{8.0}$ TCID50%: • Newcastle disease virus, LaSota strain …..≥$4x10^{8.0}$ TCID50%: ***TCID**: Tissue culture infectious dose*
	Pharmacological Group	Veterinary Vaccine
	Type of Form	Form-5A
	Finished Product Specification	Ph. Eur. specifications
	Shelf Life	24months----(2-7°C)
	Document Details	**i. <u>Free Sale Certificate (Original Legalized):</u>** Certificate No.2020-0571 **ii. Original legalized GMP certificate** **iii. Original legalized Product Specific Sole Agency Agreement made on Submitted 10, March 2023 Dy: No: 7105 is submitted by the firm.**

	Pack size & Price	500 ml bottle Vial: Decontrolled
	Reference Regulatory Authority Availability	N/A
	Products already registered in Pakistan	Volvac IBH + NDKV 069674 Vetmune Pharma GP Vac Hydro TC Plus 084594 Grand Pharma
	Remarks of Evaluator	Group I, serotype 11 Avian Adenovirus and Newcastle disease virus, LaSota strain is not present in both the stated registered products
	Remarks of Dr Qurban Expert member of Registration Board from Animal Husbandry Commission during the Meeting.	Both Group I, serotype 11 Avian Adenovirus and Newcastle disease virus, LaSota strain are present in Pakistan.
	Decision: Keeping in view the legalized FSC and GMP indicating product availability in the country of origin, and expert opinion of Dr. Qurban Registration Board approved the product subject to compliance to current import policy for finished drugs.	

Deferred case of Nivolunix 40 & 100mg Injection applied by M/s Himmel Pharmaceuticals (Pvt) Ltd Lahore.

The following products of M/s Himmel Pharmaceuticals (pvt) Ltd Lahore was deferred in 324th meeting of Registration Board as per following details.

9.	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals (Pvt.) Ltd, 793-D, Block 'C', Faisal Town, Lahore-54000, Pakistan**
	Details of Drug Sale License of importer	**License No:** 05-352-0065-0016174D **Address:** 793-D, Block 'C', Faisal Town, Lahore-54000, Pakistan **Address of go-down: N/A** **Validity: 06-02-2022** **Status:** License to sell drugs by way of Distributor
	Name and address of marketing authorization holder (abroad)	M/s Beacon Pharmaceuticals Limited **Plant address**: Kathali Bhaluka Mymensingh **Bangladesh.** **Office Address**: 9/B/2 Toyenbee Circular Road Motijheel, Dhaka 1223 Bangladesh
	Name, address of manufacturer(s)	-do-
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized COPP (DA/6-110/2016/3355) issued on 4-June-2020 **by** Directorate General of Drug Administration Ministry of Health & Family welfare Government of the people's republic of Bangladesh. The CoPP specifies free sale status of the product in country of origin along with its availability. The CoPP also confirms the GMP status of the firm. (Periodicity of routine inspection:2years)
	Details of letter of authorization / sole agency agreement	Firm has submitted product specific letter of authorization dated 02-06-2020 from Beacon Pharmaceuticals limited. The letter specifies that the manufacturer appoints M/s Himmel Pharmaceuticals Pvt. Ltd. to register & sell their products in Pakistan.

	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No32920 Dated 10.12.2020, Dy. No.8733 Dated 05.04.2022, Dy. No.13612 Dated 06.06.2022
	Details of fee submitted	Rs. /- 50000 Dated 19.11.2020
	The proposed proprietary name / brand name	Nivolunix 40 Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose contains Nivolumab INN….40mg
	Dosage form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Antineoplastic agents (Anti-cancer), Monoclonal Antibodies
	Reference to Finished product specifications	In house
	Proposed Pack size	Pack Size: 1's
	Proposed unit price	Retail price As per SRO
	Shelf Life	24 months
	Storage Conditions	2 ^{O}C -8^{O}C
	The status in reference regulatory authorities	OPDIVO (NIVOLUMAB 40mg/4mL single dose vial) | BLA #125554 | BRISTOL MYERS SQUIBB in USFDA
	For generic drugs (me-too status)	Not available in Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO. Firm has summarized information related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Geneway Bio-Technology co., Ltd Address: No. 6 Anmin Road, Huangdai Town, Xiangcheng, Suzhou, Jiangsu China

	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at 25±2°C for 10 days, at 5 ±3 °C for 6months & ≤-30 °C for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted specification & in-house analytical method along with Analytical method validation studies for the applied product.
	Container closure system of the drug product	Nivolunix 40mg injection is provided in 5mL clear glass vial (USP type-I glass) 20 mm rubber stopper, type -1 and 20 mm Flip off seal with red color top.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 commercial batches. The accelerated stability study data is conducted at 40° C ± 2° C & 75% ± 5% RH for 6 months. The real time stability study data is conducted at 2 ^{O}C -8^{O}C for 24 months.
	Module-IV	**Pharmacology studies:** The binding of product to human CD279 (programmed cell death 1, PD-1): • Effects on interaction between PD-1 and PD-1 ligands using the PD-1/CHO cell line and biotin-labeled recombinant human PD-L1- Fc and PD-L2-Fc fusion proteins. • Effect on immunoreactivity (on alloantigen-induced T-cell activation, antigen-specific T cell reactivity using Cynomolgus monkeys) • Activity against malignant tumors in mice with malignant melanoma B16F10 cells. • Secondary pharmacodynamics (antibody-dependent cell-mediated cytotoxicity) • Safety pharmacology (Effects on the central nervous system, Effects on the cardiovascular system, Effects on the respiratory system) **Pharmacokinetic studies:** (Analytical procedures-assay, antibody assay, Single-dose administration, Repeated-dose administration) **Toxicology studies:** Single-dose toxicity using cynomolgus monkeys, Repeated-dose toxicity in cynomolgus monkeys, Extended study of pre- and postnatal development in cynomolgus monkeys, Cross-reactivity studies, Four-week repeated intravenous dose toxicity study with ipilimumab coadministration in cynomolgus monkeys) **Note:** The submitted clinical trial data is from bulk manufacture not from the finish product manufacter.

	Module-V	**Phase I study:** • An open-label study to investigate the pharmacokinetics (PK) in 17 patients with advanced solid tumors resistant to conventional therapies. **Phase II study:** An open-label study to investigate the PK and other endpoints in 35 patients. **Phase III study:** A Phase III trial to compare the efficacy & safety of FX02 and Opidivo (Nivolumab) injection in patients with advance NSCLC who had received prior platinum-based chemotherapy. **Note:** The submitted clinical trial data is from bulk manufacture not from the finish product manufacturer.
10.	Name, address of Applicant / Importer	**M/s Himmel Pharmaceuticals (Pvt.) Ltd, 793-D, Block 'C', Faisal Town, Lahore-54000, Pakistan**
	Details of Drug Sale License of importer	License No: 05-352-0065-0016174D Address: 793-D, Block 'C', Faisal Town, Lahore-54000, Pakistan Address of go-down: N/A Validity: 06-02-2022 Status: License to sell drugs by way of Distributor
	Name and address of marketing authorization holder (abroad)	M/s Beacon Pharmaceuticals Limited Plant address: Kathali Bhaluka Mymensingh Bangladesh. Office Address: 9/B/2 Toyenbee Circular Road Motijheel, Dhaka 1223 Bangladesh
	Name, address of manufacturer(s)	-do-
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted original legalized COPP (DA/6-110/2016/3355) issued on 4-June-2020 by Directorate General of Drug Administration Ministry of Health & Family welfare Government of the people's republic of Bangladesh. The CoPP specifies free sale status of the product in country of origin along with its availability. The CoPP also confirms the GMP status of the firm. (Periodicity of routine inspection:2years)
	Details of letter of authorization / sole agency agreement	Firm has submitted product specific letter of authorization dated 02-06-2020 from Beacon Pharmaceuticals limited. The letter specifies that the manufacturer appoints M/s Himmel Pharmaceuticals Pvt. Ltd. to register & sell their products in Pakistan.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales

	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No32921 Dated 10.12.2020, Dy. No.8733 Dated 05.04.2022, Dy. No.13612 Dated 06.06.2022
	Details of fee submitted	Rs. /- 50000 Dated 19.11.2020
	The proposed proprietary name / brand name	**Nivolunix 100 Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each dose contains Nivolumab INN….100mg
	Dosage form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Antineoplastic agents (Anti-cancer), Monoclonal Antibodies
	Reference to Finished product specifications	In house
	Proposed Pack size	Pack Size: 1's
	Proposed unit price	Retail price As per SRO
	Shelf Life	24 months
	Storage Conditions	2^0C -8^0C
	The status in reference regulatory authorities	OPDIVO (NIVOLUMAB 100mg single dose vial) | BLA #125554 | BRISTOL MYERS SQUIBB in USFDA
	For generic drugs (me-too status)	Not available in Pakistan
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO. Firm has summarized information related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Geneway Bio-Technology co., Ltd Address: No. 6 Anmin Road, Huangdai Town, Xiangcheng, Suzhou, Jiangsu China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance at 25±2 °C for 10 days, at 5 ±3 °C for 6months & ≤-30 °C for 12 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development,

		manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted specification & in-house analytical method along with Analytical method validation studies for the applied product.
	Container closure system of the drug product	Nivolunix 40mg injection is provided in 5mL clear glass vial (USP type-I glass) 20 mm rubber stopper, type -1 and 20 mm Flip off seal with red color top.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 commercial batches. The accelerated stability study data is conducted at 40° C ± 2° C & 75% ± 5% RH for 6 months. The real time stability study data is conducted at 2 OC -8OC for 24 months.
	Module-IV	Pharmacology studies: The binding of product to human CD279 (programmed cell death 1, PD-1): • Effects on interaction between PD-1 and PD-1 ligands using the PD-1/CHO cell line and biotin-labeled recombinant human PD-L1- Fc and PD-L2-Fc fusion proteins. • Effect on immunoreactivity (on alloantigen-induced T-cell activation, antigen-specific T cell reactivity using Cynomolgus monkeys) • Activity against malignant tumors in mice with malignant melanoma B16F10 cells. • Secondary pharmacodynamics (antibody-dependent cell-mediated cytotoxicity) • Safety pharmacology (Effects on the central nervous system, Effects on the cardiovascular system, Effects on the respiratory system) Pharmacokinetic studies: (Analytical procedures-assay, antibody assay, Single-dose administration, Repeated-dose administration) Toxicology studies: Single-dose toxicity using cynomolgus monkeys, Repeated-dose toxicity in cynomolgus monkeys, Extended study of pre- and postnatal development in cynomolgus monkeys, Cross-reactivity studies, Four-week repeated intravenous dose toxicity study with ipilimumab coadministration in cynomolgus monkeys) Note: The submitted clinical trial data is from bulk manufacture not from the finish product manufacter.
	Module-V	Phase I study: • An open-label study to investigate the pharmacokinetics (PK) in 17 patients with advanced solid tumors resistant to conventional therapies. Phase II study: An open-label study to investigate the PK and other endpoints in 35 patients. Phase III study: A Phase III trial to compare the efficacy & safety of FX02 and Opidivo (Nivolumab) injection in patients with advance NSCLC who had received prior platinum-based chemotherapy.

		Note: **The submitted clinical trial data is from bulk manufacture not from the finish product manufacturer.**

Bio-similarity studies:

WHO Bio-similarity guidelines	**Data submitted by the firm**
Quality Comparison Physicochemical characterization	**a) Primary Structure:** i. Amino acid sequence by LC-MS & MS/MS ii. N-terminal sequence by LC-MS. iii. C-terminal lysine by LC-MS. iv. N-glycosylation site by Liquid Chromatography with tandem mass spectrometry (LC-MS-MS) **b) Secondary Structure & high order Structure** i. Intact mass by LC-MS ii. Disulfide bond by LC-MS iii. Free thiol (Ellman's) iv. Circular Dichroism (Secondary Structure) by Far spectrogram. v. Thermostability by differential fluorimetry (DSF) **c) Heterogenicity** i. Glycan by LC-MS ii. Heterogenicity of glycosylation by FLD-HPLC iii. Isoelectric point by CIEF iv. Charge variant (CEX-HPLC
Biological Activity	Biological activity by: • PD-I binding activity by ELISA
Impurities	• Purity by SEC-HPLC • Purity by CE-SDS • Protein A by ELISA • DNA residual by qPCR • Host cell protein by ELISA
Stability Studies	Stability studies are provided.
Non-clinical Studies	Primary pharmacodynamics by: • Binding to PD-I • Inhibitory effect against binding of PD-I to PD-L1 or PD-L2 • One month repeated doses toxicity study in monkeys • Six months repeated doses toxicity study in monkeys
Clinical Studies	Comparative clinical study has not been submitted.

Evaluation by BE&R:

Sr. No.	**Decision of 324th meeting**	**Response by the firm**
1.	Regulatory status of products in various countries where the bulk of the product is exported.	The Firm has submitted the registration certificate of the product Nivolunix 40 Injection manufactured by M/s Beacon Medicare Limited Bangladesh.
2.	Publication of clinical trial in any peer reviewed journal.	Not submitted
3.	Data of Periodic Safety Updated report of applied formulation marketed in Bangladesh.	**Not submitted**

Decision: Registration Board deferred the cases for the following clarification /data/information:

- **Regulatory status of products in various countries where the bulk of the product is exported.**
- **Publication of clinical trial in any peer reviewed journal.**
- **Data of Periodic Safety Updated report of applied formulation marketed in Bangladesh.**

• **Differential fee of Rs. 100,000 /- for each product.**		
11.	**Name, address of Applicant / Importer**	M/s Himmel Pharmaceuticals (Pvt.) Ltd. 793-D, Block ‘’C’’, Faisal Town Lahore.
	Details of Drug Sale License of importer	License No: 05-352-0065-016174-D Address: 793-D, Block-C, Faisal Town Lahore Address of Godown: NA Validity: 06.Feb.2024 Status: License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s BEACON Pharmaceuticals Limited Plant address: Kathali ,Bhaluka, Mymensingh Bangladesh Office address: 9/B/2, Toynbee Circular Road, Motijheel Dhaka, Bangladesh
	Name, address of manufacturer(s)	M/s BEACON Pharmaceuticals Limited Plant address: Kathali ,Bhaluka, Mymensingh Bangladesh Office address: 9/B/2, Toynbee Circular Road, Motijheel Dhaka, Bangladesh
	Name of exporting country	Bangladesh
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP:** Original legalized COPP (Certificate# DA/6-110/2016/3353 issued on 04-06-2020 by Government of the people’s republic of Bangladesh, Ministry of Health & Family welfare, Directorate General of Drug Administration, Oushad Bhaban, Mohkhali Dhaka-1212, Bangladesh. **GMP:** Firm has submitted Legalized GMP certificate (Certificate No. DA/6-110/06/10002) issued by M/s Beacon Pharmaceuticals limited. Also Renewal certificate is submitted (Certificate No. DA/6-110/06/4950).
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of distribution certificate from Beacon Pharmaceuticals limited. The letter specifies that the manufacturer appoints M/s Himmel Pharmaceuticals Pvt. Ltd. to register their products in Pakistan. The authorization letter is valid till June, 2025.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No32920 Dated 10.12.2020

		Dy. No.8733 Dated 05.04.2022, Dy. No 1531 Dated 17.01.2023
	Details of fee submitted	PKR: 50,030/- Date: 10-12-2021
	The proposed proprietary name / brand name	Pembroxim Injection 100mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4 ml contains Pembrolizumab INN….100mg
	Pharmaceutical form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Anti-cancer
	Reference to Finished product specifications	In house
	Proposed Pack size	1 s
	Proposed unit price	As per current pricing policy of DRAP
	The status in reference regulatory authorities	Keytruda 100mg
	For generic drugs (me-too status)	NA
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	Geneway Bio-Technology co., Ltd Address: No. 6 Anmin Road, Huangdai Town, Xiangcheng, Suzhou, Jiangsu China
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 12 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 6 months
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials,

		container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Comparative analysis Studies against the reference product Keytruda (Merck sharp & Dohme, B.V Netherlands) has been submitted
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Type 1 Glass Vial
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches. Accelerated stability studies have been conducted at 40ºC±2ºC and 75%±5% RH for 6 months. Real time stability studies conducted at 2 ºC -8 ºC and 65% ± 5% for 24 months

Bio-similarity studies:

WHO Bio-similarity guidelines	**Data submitted by the firm**
Quality Comparison **Physicochemical characterization**	**a) Primary Structure:** i. Amino acid sequence by LC-MS & MS/MS ii. N-terminal sequence by LC-MS. iii. C-terminal lysine by LC-MS. iv. N-glycosylation site by Liquid Chromatography with tandem mass spectrometry (LC-MS-MS) **b) Secondary Structure & high order Structure** i. Intact mass by LC-MS ii. Disulfide bond by LC-MS iii. Free thiol (Ellman's) iv. Circular Dichroism (Secondary Structure) by Far spectrogram. v. Thermostability by differential fluorimetry (DSF) **c) Heterogenicity** i. Glycan by LC-MS ii. Heterogenicity of glycosylation by FLD-HPLC iii. Isoelectric point by CIEF iv. Charge variant (CEX-HPLC
Biological Activity	Biological activity by: • PD-I binding activity by ELISA
Impurities	• Purity by SEC-HPLC • Purity by CE-SDS • Protein A by ELISA • DNA residual by qPCR • Host cell protein by ELISA
Stability Studies	Stability studies are provided.
Non-clinical Studies	Primary pharmacodynamics by: • Binding to PD-I • Inhibitory effect against binding of PD-I to PD-L1 or PD-L2 • One month repeated doses toxicity study in monkeys • Six months repeated doses toxicity study in monkeys
Clinical Studies	Comparative clinical study has not been submitted.

Evaluation by BE&R

Sr. No.	Decision of 324th meeting	Response by the firm
1.	Regulatory status of products in various countries where the bulk of the product is exported.	The Firm has submitted the registration certificate of the product Pembroxim Injection manufactured by M/s Beacon Medicare Limited Bangladesh.
2.	Publication of clinical trial in any peer reviewed journal.	The Firm has submitted following case report published in SciTechnol Journal: *Improved Survival Outcome with Flat Dosing Pembrolizumab (Pembroxim®) in Late-Stage Non-Small Cell Lung Cancer-* However, the study was without conclusive remarks in improving the patient quality of life.
3.	Data of Periodic Safety Updated report of applied formulation marketed in Bangladesh.	The periodic safety report of the product is submitted by the firm with conclusion as under: **"***Though the overall risk-benefit ratio of treatment with Beacon's Pembroxim remains unchanged, changes to the SPC for the product are recommended in order to bring the same in line with the SPC for the innovator. The overall risk-benefit balance for the product remains acceptable*.**"**

Decision: Registration Board deferred the cases for the following clarification /data/information:

- **Regulatory status of products in various countries where the bulk of the product is exported.**
- **Publication of clinical trial in any peer reviewed journal.**
- **Data of Periodic Safety Updated report of applied formulation marketed in Bangladesh.**
- **Differential fee of Rs. 100,000 /- for the applied product.**

Cases of DD-III (Ms. Haleema Sharif)

12.	**Name and address of Importer**	**M/s. Mustafa Brothers 186-D Peoples Colony No. 1, Faisalabad**
	Detail of DSL	M/s. Mustafa Brothers PT-186-D Peoples Colony No. 1, Faisalabad. Valid Up to 21.06.2027
	Name and address of Manufacturer	M/s. Vira vaccine Shaya Co., Sepher Industrial district, Nazarabad, Alborz province, Iran
	Name of exporting country	Iran
	Brand Name +Dosage Form + Strength	Vira- Peste®
	Diary No. Date of R& I & fee	Dy. No. 32428 R&I Dated 29-11-2021 Rs. 75,000/- (Slip No. 557604810169) Firm has submitted fee challan of differential fee of Rupee 75000/- Slip No. (13860179271).
	Composition	Each dose contains:

		Lyophilized dried suspension containing "peste des petitis ruminants (PPR) virus Nigerian 75/I" strain ….$10^{2.5}$ $TCID_{50.}$ Diluent(Solvent): 0.9% sterile isotonic sodium chloride solution (saline solution)
	Pharmacological Group	Viral Vaccine
	Type of Form	Form-5A
	Finished Product Specification	Manufacturer's specifications
	Shelf Life	2 years (2^0C-8^0C)
	Document Details	• Free sale certificate (No.30/96352) dated December, 2022 issued by Ministry Of Agriculture Veterinary Organization is submitted by the firm. • Original Legalized product specific translated distribution agreement is submitted by the firm. • GMP Certificate No.(1400/6378) dated 24/05/2021 Iran veterinary organization Albroz Veterinary Department General valid for one year.
	Pack size	100doses/vial Diluent:100ml
	Reference Regulatory Authority Availability	Not provided
	Products already registered in Pakistan	PESTVAC K by Huzaifa International Live freeze-dried vaccine Each 1ml dose of lyophilized vaccine contains: Freeze dried Modified Peste Des Petits Ruminant virus strain Nig 75/1 not less than $10^{2.5}$ TCID/50 Diluent Diluent for Pestvac K Each 1L contains: NaCl.....8.0g KCl.....0.2g Na2HPO4.....1.15g KH2PO4.....0.2g Distilled water.....upto 1000mL
	Remarks of Evaluator	i. Analytical method for analysis of product is required. ii. Stability data of the product on all parameters as mentioned in finished product specifications is required as submitted data only virus titter and moisture content is determined.
	Decision: Registration Board deferred the case for the following: **i. Submit analytical method for test/analysis of applied product.** **ii. Stability data of the product on all parameters as mentioned in finished product specifications is required as in submitted data only virus titter and moisture content is determined.**	
13.	**Name and address of Importer**	**M/s. Mustafa Brothers** **186-D Peoples Colony No. 1, Faisalabad**
	Detail of DSL	M/s. Mustafa Brothers

		PT-186-D Peoples Colony No. 1, Faisalabad. Valid Up to 21.06.2027
	Name and address of Manufacturer	M/s. Vira vaccine Shaya Co., Sepher Industrial district, Nazarabad, Alborz province, Iran
	Name of exporting country	Iran
	Brand Name +Dosage Form + Strength	Vira- Etyvax®
	Diary No. Date of R& I & fee	Dy. No. 32429 R&I Dated 29-11-2021 Rs. 75,000/- (Slip No. 16918330679) Firm has submitted fee challan of differential fee of Rupee 75000/- Slip No. (16918330679).
	Composition	Each dose contains: Live attenuated Ecthyma virus …. > $10^{4.5}$ $TCID_{50.}$ Diluent(Solvent): Sodium chloride…. 0.9%.
	Pharmacological Group	Biological product
	Type of Form	Form-5A
	Finished Product Specification	Manufacturer's specifications
	Shelf Life	2 years (2^0C-8^0C)
	Document Details	• Free sale certificate (No. 1401/33728) dated January 18, 2023 valid till 06.01.2025 issued by Veterinary organization of the country Albroz General Veterinary Department is submitted by the firm. • Original Legalized product specific translated distribution agreement is submitted by the firm.
	Pack size	50doses/vial, Diluent:50ml
	Reference Regulatory Authority Availability	Approved in USDA (Ovine Ecthyma Vaccine)
	Products already registered in Pakistan	Not available
	Remarks of Evaluator	iii. Analytical method for analysis of product is required. iv. Stability data of the product on all parameters as mentioned in finished product specifications is required as submitted data only virus titter and moisture content is determined.
	Decision: Registration Board deferred the case for the following: **i. Submit analytical method for test/analysis of applied product.** **ii. Stability data of the product on all parameters as mentioned in finished product specifications is required as in submitted data only virus titter and moisture content is determined.**	

E. Miscellaneous/ Deferred Cases

Imported Human Biological i.e. Abrilada 20mg/0.4mL applied by M/s Pfizer Pakistan Limited, Karachi deferred in 324th meeting of Registration Board.

Following product of M/s Pfizer Pakistan Limited Karachi deferred in 324th meeting of Registration Board as per following details:

14.	**Name, address of Applicant / Importer**	**M/s Pfizer Pakistan Limited,** **12 Dockard Road West Wharf Karachi.**
	Details of Drug Sale License of importer	**License No:** 029 **Address:** 12 Dockard Road West Wharf Karachi. **Validity: 25-02-2023** Status: License to sell drugs by way of Whole sale.
	Name and address of marketing authorization holder (abroad)	M/s Pfizer Canada ULC, 17300 Trans-Canada Highway Kirkland, QC Canada, H9J 2M5.
	Name, address of manufacturer(s)	M/s Catalent Indiana, LLC 1300 South Patterson Drive Bloomington, Indiana (IN) 47403, USA
	Name of exporting country	Canada
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	• Firm has submitted original, legalized CoPP (No. 78703) dated 21-12-2021 issued by Health Canada. The CoPP specifies that the product is licensed for sale in country of origin but actually not available.
	Details of letter of authorization / sole agency agreement	Firm has submitted notarized copy of Letter of product specific authorization from Manager Regulatory Affairs Canada of *M/s Pfizer Canada ULC, Canada*. According to the letter, the firm *M/s Pfizer Canada ULC, Canada* authorizes "Pfizer Pakistan Limited" to be Market Authorization Holder in Pakistan and to be responsible for all matters pertaining to the regulation of this product in Pakistan. The letter was issued on 25-02-2022.
	Status of the applicant	□ Manufacturer ☒ Importer □ Is involved in none of the above (contract giver)
	Status of application	□ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import □ Buk import and local repackaging □ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 766 (R&I) Dated 16-05-2022
	Details of fee submitted	PKR 150,000/-: 25-03-2022
	The proposed proprietary name / brand name	Abrilada 20mg/0.4mL

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each PFS (0.4mL) contains: Adalimumab ……20mg
	Dosage form of applied drug	Solution for Injection in Pre-filled Syringe
	Pharmacotherapeutic Group of (API)	TNF Blocker
	Reference to Finished product specifications	As per Innovator.
	Proposed Pack size	1's PFS
	Proposed unit price	Not Provided.
	Shelf Life	36 months
	Storage Conditions	0 0 2 C-8 C
	The status in reference regulatory authorities	HUMIRA® (adalimumab) injection 20 mg/0.4 mL in a singleuse prefilled glass syringe.
	For generic drugs (me-too status)	The product in **40mg/0.8ml PFS** is already approved by the RB & under process for price fixation.
	Module-II (Quality Overall Summary)	Firm has submitted QOS on WHO Template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	M/s Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC. One Burtt Road, Andover, MA 01810, USA
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 7 batches of Drug Substance at accelerated and real time conditions. The real time stability data conducted at -20°C±5°C is for 60 months for 4 batches and for 36 months for 03 batches. The accelerated stability data conducted at 5°C±3°C is

		for 6 months for 4 batches and for 9 months for 03 batches.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted that Validation of test methods performed to ensure the quality, identity, potency, purity, and safety of PF06410293 drug product have been performed. The suitability of methods for their intended use was performed by assessment of all relevant validation elements described in International Conference on Harmonization (ICH) Guidelines on Validation of Analytical Procedures: Text and Methodology Q2 and the current USP <1225> Validation of Compendial Methods.
	Container closure system of the drug product	• 1 mL BD Hypak Type I Borosilicate glass with 29 gauge, ½ inch, thin-walled stainless steel staked needle, and
		thermoplastic elastomer (TPE) elastomeric needle shield that is not manufactured from natural rubber (latex) within a nonproduct contact rigid polypropylene cover. • 1mL West Pharmaceutical chlorobutyl elastomeric closure Plunger stopper
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 process validation batches. The accelerated stability study data is conducted at 30 ± 2^0C /60±5%RH for 6 months. The real time stability study data is conducted at 5 ± 3^0C for 36 months. The batches are not stable at accelerated conditions.
	Module-IV Non-Clinical	Summarized in Biosimilarity data.
	Module-V Clinical	Summarized in Biosimilarity data.

Bio similarity data as per WHO guidelines submitted by the firm is as follows:

WHO Biosimilarity Guidelines	**Data Submitted by the firm**

Quality Comparison • Physicochemical Characterization	• Primary Structure and Posttranslational Modifications a. Establishment and Verification of Adalimumab Amino Acid Sequence b. Characterization of Molecular Mass, Primary Structure and Posttranslational Modifications c. HILIC/MS - N-Linked Glycan Mapping d. N-LINKED GLYCAN STRUCTURE - SIALIC ACID ANALYSIS • Charge Heterogeneity a. Heightened Characterization of Charge Isoforms b. LC/MS Characterization of Charge Isoforms c. Characterization by Carboxypeptidase B Treatment d. Biological Activity of Charge Isoforms • **Disulfide Bonds** a. Characterization of Disulfide Bonds b. Sulfhydryl Analysis • **Higher order structure** a. Secondary Structure Characterization – Far-UV CD Spectroscopy b. Secondary Structure Characterization – FTIR Spectroscopy c. Tertiary Structure by Near-UV CD Spectroscopy d. Tertiary Structure Characterization – Intrinsic Fluorescence Emission Spectroscopy e. Thermal Stability Characterization – DSC f. Higher Order Structure - X-ray crystallography
Biological Activity & Immunochemical properties	• **Functional Characterization of the Fc domain** i. Characterization of Antibody-Dependent Cellular Cytotoxicity (ADCC) Function a. Primary NK Cell ADCC Assay

	b. PBMC ADCC Assay (FcγRIIIa 158 V/F donor genotype) c. PBMC ADCC Assay (Fc RIIIa 158 F/F donor genotype) d. FcγRIIIa Reporter Gene Assay (FcγRIIIa RGA) e. Binding to FcγRIIIa by SPR Analysis ii. Characterization of Complement Dependent Cytotoxicity (CDC) Function a. CDC Assay b. C1q Binding ELISA c. CDC Effector Function Conclusion d. Mixed Lymphocyte Reaction (MLR) Assay e. Additional Fcγ Receptor Binding SPR Assays f. FcRn Binding SPR Assay • **Functional Characterization of the Fab Domain** i. Functional Assays Demonstrating Blockade of sTNF a. Inhibition of Apoptosis Assay b. Inhibition of ELAM-1 Expression Assay c. Binding to sTNF Target Antigen by ELISA ii. Functional Assays Demonstrating mTNF Binding Activity a. Binding to mTNF Target Antigen on NS0 Cells b. Reverse Signaling iii. Lymphotoxin alpha (LT-a) Binding Activity
Impurities	• Product Purity a. HMMS and Monomer – Size Exclusion HPLC b. Fragments and Heavy Chain + Light Chain - Capillary Gel Electrophoresis (Reducing) c. Intact IgG - Capillary Gel Electrophoresis (NonReducing)
Stability Studies	**Forced Degradation** Confirmation of similar degradation profiles forced degradation conditions of Elevated temperature, Light exposure, Forced deamidation and Forced oxidation with peracetic acid.
Non-clinical Comparison	**Primary Pharmacodynamic Studies** Already recorded in Biological Activity **Pharmacokinetic Studies** a. Quantitation of PF-06410293 and Adalimumab-EU in Cynomolgus Monkey Serum. b. Detection of Anti-PF-06410293 and AdalimumabEU Antibodies in Cynomolgus Monkey Serum. c. Repeat-Dose Toxicokinetics
Clinical Comparison	i. A double-blind (Sponsor-open), randomized (1:1:1), parallel-group, 3-arm, single-dose, PK similarity study of PF-06410293 and adalimumab sourced from the US and EU administered SC in the lower abdomen by a PFS to healthy adult. ii. A double-blind (Sponsor-open), randomized (1:1:1), parallel-group, 3-arm, single-dose, definitive PK similarity study of PF-06410293 and adalimumab sourced from the US and EU administered SC in the lower abdomen by a PFS to healthy adult subjects.

	iii. An open-label, randomized (1:1), parallel-group, 2-arm, single-dose PK comparability study to assess the PK of PF-06410293 following SC administration in the lower abdomen or upper anterior thigh (alternative assignment in each device weight group) using a PFS or a PFP in healthy adult subjects iv. A multi-national, 2-arm, randomised (1:1), double-blind, parallel-group study designed to evaluate the safety, efficacy, population PK, and immunogenicity of PF06410293 versus adalimumab-EU administered SC in the abdomen or thigh by a PFS, both in combination with methotrexate (MTX) to treat subjects with moderately to severely active RA who had an inadequate response to MTX therapy.
Remarks: The CoPP submitted by the firm indicates that the product is licensed but not available in country of origin. The firm has submitted that Pfizer is currently preparing to launch **Abrilada** 20mg PFS in Canada & they will submit a marketed CoPP to DRAP as soon as possible following the launch in Canada. The firm has also submitted the **Abrilada** 20mg PFS product has not yet been launched in any country.	
Previous Decision in 324th RB meeting: ***Registration Board deferred the case for submission of valid legalized CoPP / Free Sale Certificate from country of origin or any other reference regulatory authority wherein the product marketed/on free sale.***	
Evaluation by DBE&R: Now the firm has submitted valid legalized COPP (No. 82024) valid for one year from the date of issue i.e. 13.03.2023 indicating that product is freely available in Canada.	
Decision: Keeping in view the legalized CoPP indicating product availability in the country of origin, Registration Board approved the product subject to compliance to the current Import Policy for finished drugs.	

Imported Human Biological i.e. AdimFlu-S (QIV) applied by M/s ASTO Life Sciences Private Limited. Lahore deferred in 316th meeting of Registration Board.

Following product of M/s ASTO Life Sciences Private Limited. Lahore deferred in 316th meeting of Registration Board as per following details:

15.	**Name and address of Importer**	**M/s ASTO Life Sciences Private Limited.** Plaza No. 1, Block Orchard No.1 Paragon City, Barki Road, Dist. Lahore.
	Detail of DSL	Drug Sale License as a distributor No. 05-352-0068-045428D valid upto 21-09-2021
	Name and address of Manufacturer	**Product License Holder & Manufacturer:** M/s Adimmune corporation, No. 3 Section 1, Tanxing Road, Tanzi District,Taichung city 42743 Taiwan.
	Brand Name +Dosage Form + Strength	AdimFlu-S (QIV) Quadrivalent Influenza Vaccine
	Diary No. Date of R& I & fee	Dy. No. 31262 Dated 24-11-2020 (Rs. 100,000/- Dated 24-11-2020)
	Composition	Each 0.5ml PFS contains: Hemagglutinin of Influenza A Virus (H1N1) ..... 15µg HA Hemagglutinin of Influenza A Virus (H3N2) ..... 15µg HA Hemagglutinin of Influenza B Virus (Yamagata lineage) ..... 15µg HA Hemagglutinin of Influenza B Virus (Victoria lineage) 15µg HA
	Pharmacological Group	Human Influenza Vaccine
	Type of Form	Form-5F

	Finished Product Specification	EUR. Ph. JP and CP
	Shelf Life	24 months (2^0C-8^0C)
	Document Details	i. CoPP No. 080558 dated 13-10-2020 (Notarized but not legalized)ii.GMP valid till 5-9-2021(Notarized but not legalized) ii. Copy of Sole Agency Agreement
	Pack size/ Price	1's PFS/ As per SRO.
	International Availability	Vaxigrip Tetra of M/s Sanofi Pastures France
	Products already registered in Pakistan	Vaxigrip Tetra of M/s Sanofi Aventis Pakistan Ltd.
	Initial Remarks of Evaluator (Khurram Khalid)	i. Notarized copy of Sole Agency/ Market Authorization certificate. ii. CoPP and GMP certificates are not legalized. iii. In stability data, following tests have not been performed in long termstability data; a. Fractionation test b. Test for freedom from Ether c. Test for freedom from abnormal toxicity d. Identity test e. Overall albumin content test. While accelerated studies of only one batch has been provided. iv. Clinical Trial Data a. Phase II: A Phase II, One arm, Single dose, Open label, Single center study, in120 subjects b. Phase III: As Phase III, Single Dose, Randomized Double blind, Multiple-centerStudy. in 710 subjects. c. Phase III: Open label, Multiple-center Study, 174 subjects.
	Decision of Registration Board (297th meeting) Registration Board deferred the product for submission of following by the firm: a. Valid legalized Certificate of Pharmaceutical Product (CoPP) OR valid legalized GMP Certificate & valid legalized Free Sale Certificate. b. Original or Notarized copy of sole Agency Authorization. c. Pharmacopoieal monograph of the product. d. Clarification regarding not performing Fractionation test, Test for freedom from Ether, Test for freedom from abnormal toxicity, Identity test, Overall albumin content test in stability data. e. Accelerated stability data of three batches.	

Evaluation by DBE&R for 308th Reg. Board meeting

It is submitted that It is submitted that in context to the decision of Reg. Board the firm replied on 08-06-2021. The case was evaluated and is summarized as under;

Document required as per decision of RB	***Response submitted by the firm***	***Remarks of Evaluator***
Valid legalized Certificate of Pharmaceutic8al Product (CoPP) OR valid legalized GMP Certificate & valid legalized Free Sale Certificate.	Manufacturer, has submitted that CoPP and GMP were notarized and legalized from notary public and ministry of foreign affairs of Taiwan.	The firm has not submitted any document regarding the legalization by the Pakistan embassy.
Original or Notarized copy of Sole Agency Authorization.	Provided	Provided

Pharmacopoieal monograph of the product.	The firm has submitted that they follow Chinese Pharmacopoeia in Taiwan which is the same as European Pharmacopeia. However, pH Value, Test for freedom from ether and Formaldehyde complies with JPXVII Influenza HA vaccine. Furthermore, all other have been referred to European Pharmacopoeia for which the firm has also submitted the monograph. The firm has also submitted the Japanese monograph which is not for the applied product.	No single Pharmacopeia is being followed. The reason for following two different standard pharmacopeias is not mentioned.
Clarification regarding not performing Fractionation test, Test for freedom from Ether, Test for freedom from abnormal toxicity, Identity test, Overall albumin content test in stability data.	These are the parameters that do not decrease and increase over time. All the results complied with specifications; therefore, they were only tested at release.	The firm has provided following tests in stability data; 1. Appearance 2. pH Value 3. Potency test 4. Sterility test 5. Bacterial endotoxin.
Accelerated stability data of three batches.	We only have one batch for accelerated stability data. Generally, we do not have accelerated stability as regular items, which also do not necessary in Taiwan, so we do not have the accelerated stability data for three batches.	Accelerated stability data of three batches is not available.

The firm was asked to provide following documents through letter dated 15th June 2021:

1. The CoPP is not legalized by Embassy of Pakistan.
2. Regarding specifications
   a. A comparative summary of specifications of Chinese and European Pharmacopeia in tabulated form to assess similarity.
   b. Why two different standard pharmacopeias are being followed i.e. Japanese & European Pharmacopeia for different tests.
   c. The provided Japanese Pharmacopeia monograph is not for the applied product.
3. Any documental evidence that accelerated stability data of only one batch is required.

The complete response by the firm is pending and the firm has only responded to query raised at Sr. No.1. The firm has submitted that there is no embassy of Pakistan in Taiwan, hence the documents are only legalized and Notarized by the Notary Public.

Decision of Reg. Board in its 308th Meeting

"Registration Board deferred the products for submission of following by the firm:
a. Tabulated comparison of finished product specifications with pharmacopoeia monograph.
b. Accelerated stability data of three batches for 06 months."

Evaluation by DBE&R for 313th Reg. Board meeting

The firm has submitted the following:

a. Tabulated comparison of finished product specifications with pharmacopoeia monograph indicating that the product complies with Ph. Eur. Specifications.
b. The firm has submitted accelerated stability data of 3 months for 1 batch and 02 months for 02 batches and informed that they don't have 6 months data.

Decision of Reg. Board in its 313th Meeting:

The case was deferred in 313th meeting of Registration Board as per following details:
Registration Board deferred the case in its 313th meeting for following:

i. *Confirmation from Ministry of Commerce regarding Trade of vaccines from Taiwan.*
ii. *Submission of valid CoPP legalized from Embassy of Pakistan by the firm.*
iii. *Submission of 6 months accelerated stability data of 03 batches by the firm.*

Evaluation by DBE&R for 316th Reg. Board meeting

In this context, it is submitted that in response following letter has been received from Ministry of Commerce:

3. According to Policy Guidelines on Taiwan, there are no restrictions on trade with Taiwan subject to the following conditions:

- Trade is conducted strictly on un-official basis and through private sector only.
- No direct contacts to be made with the Taiwan authority agencies.
- No Pakistan government functionary can visit Taiwan.
- No Taiwan authority functionary can visit Pakistan.
- Government/official investment from Taiwan is not allowed into Pakistan.
- Exchange of delegation(s) is not allowed.
- Holding of trade exhibitions, establishment of display is not allowed.
- No publicity is given to Pakistan's trade or commercial contacts with Taiwan.
- Private businessmen can, technically, interact with Taiwan parties.
- No Pakistan government functionary can visit Taiwan.

Moreover, the firm has not yet submitted any response.

Decision of Reg. Board in its 316th Meeting:

Keeping in view response from M/o commerce, Registration Board referred the case to DRAPAuthority for seeking guidance whether to proceed with grant of registration of finished drugproduct from Taiwan or otherwise.

Evaluation by DBE&R for 328th Reg. Board meeting:

A. *The Authority, after detailed deliberations and discussions decided as under:*

1. *Approved following guidelines regarding import of therapeutic goods from Taiwan:*

i. *The consignments of raw materials imported from Taiwan will be cleared by the DRAP Field offices subject to fulfilment of requisite codal formalities.*
ii. *Registration/Enlistment of finished therapeutic goods from Taiwan will be granted, subject to fulfilment of conditions of registration/enlistment, except those requiring mandatory inspections by government functionaries (through physical presence).*

2. *The decision of the Authority will be shared with MOFA / Ministry of Commerce for their input and advice to further refine / modify or change if required under the prevailing policy dealing with Taiwan for private business activity.*

B. *Firm has submitted 6 months accelerated stability data of 03 batches however SRD value (potency) is not within specification limits i.e.12µg HA/0.5ml dose from 2 months to onward in accelerated stability studies.*

C. *Firm has not yet submitted valid CoPP legalized from Embassy of Pakistan for which the firm has already submitted in their reply that Embassy of Pakistan does not exist in Taiwan.*

Decision: Registration Board deferred the case for submission of legalized CPP either attested from the embassy of Pakistan in China or by Ministry of foreign Affairs of Taiwan or any web link to verify the approval of subject product in any reference regulatory authority.
The Board further directed the division of BE&R to present the case in the next RB meeting after confirming/verifying the submitted document from the official website of Ministry of foreign Affairs Taiwan.

Locally Manufactured Human Biological i.e. Heparin Injection applied by M/s Macter International Limited deferred in 323rd meeting of Registration Board.

Following product of M/s Macter International Limited. Karachi was deferred in 323rd meeting of Registration Board as per following details:

16.	**Name of Manufacturer**	**M/s Macter International Limited.** **F- 216, S.I.T.E, Karachi 75700, Pakistan.**
	DML and last GMP details	DML No. 000141 Address: F- 216, S.I.T.E, Karachi 75700, Pakistan. **Evidence of section:** Liquid and Lyophilized recombinant DNA technology products (biological) section dated 19th July, 2012 GMP: Last GMP conducted on 13-08-2020 valid up to 12-08-2022
	Bulk Manufacturer	Hubei Enoray Biopharmaceutical Co.,Ltd. No.108, Yanjiang Road, Xiaochi Town, Huangemei County, Hubei Province, China. (Formulation (**dilution), filling, testing & packing**)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	☐ Finished Pharmaceutical product import ☒ Buk import and local repackaging ☐ Buk import and local repackaging for export purpose only
	Dy. No. and date of submission	Form 5 Dy.No.30665 dated 09-11-2021. Fee Submitted: Rs.30,000/- dated 20-10-2021.
	Details of fee submitted	Rs: 30,000/- dated: 20-10-2022
	Brand Name + Dosage Form + Strength	Inhixa Solution for Injection
	Composition	One ml of solution for injection contains 5000 IU of heparin sodium. While 1 vial (5 ml) contains 25000 IU of heparin sodium.
	Dosage form of applied drug	Injection

	Pharmacotherapeutic Group of (API)	Anticoagulants
	Reference to Finished product specifications	B.P
	Proposed Pack size Proposed unit price	1's, 2's, 5's, 10's & 25's vialAs per DPC/
	Shelf Life	24 Months
	Storage Conditions	(Store below 25^0C)
	The status in reference regulatory authorities	Heparin Sodium Injection, USP FDA Approved
	For generic drugs (me-too status)	Brand Name: Heparin Injection 25000 IU/ 5ml, 1's Pack Importer Name: M/s Leo/ Zam Zam Pharma
	Module-II (Quality Overall Summary	Firm has submitted QOS as per WHO. Firm has summarized information related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubility, physical form, manufacturers description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis an justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches at long term conditions at 25 ℃ RH 60%±10% for 48months. The accelerated stability data is conducted at 40℃ ± 2 ℃ /60% ± 5%RH for 06 months for accelerated conditions.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.

	Analytical method validation/verification of product	Firm has submitted the details of analytical method validation.
	Container closure system of the drug product	USP Type-I glass vial (5mL),13mm slit less butyl grey stopper 133 mm Flip off aluminum caps
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches (two pilot scale & one lab scale) at long term conditions at 25 ℃ RH 60%±10% for 06 months. The accelerated stability data is conducted at 40℃ ± 2 ℃ /75% ± 5%RH for 06 months for accelerated conditions.

Decision of 320th meeting of RB:
"Registration Board referred the case to Licensing Division for confirmation of manufacturing section for production of Heparin Sodium".

The case was processed to Licensing division for the section requirement of local manufacturing non-rDNA Biological Drugs (i.e. Heparin) whether such products can be manufactured in rDNA Biological section as per current rules/regulation/practice of licensing division or not?

The Licensing division has conveyed the following comments:
"The Central Licensing Board approved **Liquid and Lyophilized recombinant DNA Technology** products (Biological) section in its 229th meeting held on 13-06-2021 under Drugs Act 1976 and rule framed thereunder. However, it is pertinent to mention that matter regarding conditions/requirement for manufacturing and registration of drugs does not come under the purview of Licensing Division, DRAP".

Decision: Registration Board deferred the case for following:

- *Submission of section wise products details of M/s Macter International Limited Karachi.*
- *Submission of pharmaceutical equivalence (Quality comparison) of the product.*

Evaluation by DBE&R:
Now the firm has following:
a. Product list of M/s Macter International Limited for biological section:

S.no	Reg.#	Product name	Strength	Dosage	Generic	Drug class
1.	091268	Momentum	25mg/mL	Lyophilized powder for injection	Etanercept	Immunosuppressant (tumor necrosis factor receptor)
2.	092610	Epocan	2000 IU	Solution for Injection	Recombinant Human erythropoietin Alfa	Hematopoietic agent
3.	092611	Epocan	4000 IU	Solution for Injection	Recombinant Human erythropoietin Alfa	Hematopoietic agent
4.	092612	Epocan	10,000 IU	Solution for Injection	Recombinant Human	Hematopoietic agent

					erythropoietin Alfa	
5.	105601	Pegstim	6mg	Solution for Injection	Pegylated filgrastim	Anti-neoplastic & immune modulator

b. Pharmaceutical equivalence report of test product 25000IU(5000IU/ml) with Heparin Sodium Injection of Hikma Pharmaceuticals USA Inc.

Comparison regarding dosage form, API, strength and route of administration:

S.No	Characteristics	Comparison	
		Innovator Product Heparin Sodium Injection	Test Product INHIXA 25000 IU (5000 IU/mL)
1.	API	Heparin Sodium	Heparin Sodium
2.	Dosage Form	Liquid solution for injection	Liquid solution for injection
3.	Strength	5000 IU/mL	5000 IU/mL
4.	Route of Administration	IV/ SC	IV/ SC

Comparison of Tests and Specifications

Sr.No.	Tests & Specifications	Innovator product	Test Product
1.	**Identity by Zone Electrophoresis:** The ration of the distance migrated by the principal band of bands in the gel obtained with sample solution (1) to the distance migrated by the principal band in the gel obtained with standard solution (2) is 0.9 to 1.1.	Complies 0.98	Complies 0.97
2.	**Anti-Factor Xa Activity by Chromogenic assay:** 95 – 105%	101%	98.9%
3.	**Anti-Factor lla Activity by Chromogenic assay:** 4500 – 5550 IU/mL (90% - 111%)	4990IU/ml(99.8%)	4776IU/ml(95.5%)
4.	**Ratio of Anti-Factor Xa to Anti-Factor lla Activity:** 0.9 – 1.1	1.01	1.04
5.	**Related Substances by HPLC:** The area of the peak in the sample due to dermatan sulfate and chondroitin sulfate is note greater than 0.25 times the are of the corresponding peak in the standard solution D. (2.0%) The area of any other peak is not greater than 0.0025 times the area of the peak due to dermatan sulfate and chondroitin sulfate obtained with solution D (disregard limit 0.02%). Disregard any peak that appears during the initial isoratic	Not detected	Not detected
6.	**Primary packaging:**	USP type I clear glass vial, Bromobutyl rubber stopper	USP type I clear glass vial, Bromobutyl rubber stopper

Conclusions

The pharmaceutical equivalence study was carried out and the test product (INHIXA 25000 IU (5000 IU/mL)) was compared with reference product (Heparin Sodium Injection). The two products found to have identical active ingredient, identical strength/ label claim, identical dosage from and identical route of administration. Certain comparative tests were also performed including identification, purity and assay tests. The results of two products for mentioned tests compared and found that these are within the specified limits. On the basis of above satisfactory comparison, both the products are said to be pharmaceutically equivalent.

Decision: Registration Board deferred the product for submission of rational/evidence from RRA by the firm for production of non rDNA product in rDNA manufacturing facility.

Locally Manufactured Human Biological i.e. Enoxaparin Injections applied by M/s Macter International Limited deferred in 323rd meeting of Registration Board.

17.	**Name of manufacturer**	**M/s Macter International Limited.** **F- 216, S.I.T.E, Karachi 75700, Pakistan.**
	DML and last GMP details	DML No. 000141 Address: F- 216, S.I.T.E, Karachi 75700, Pakistan. Evidence of section: Liquid and Lyophilized recombinant DNA technology products (biological) section dated 19th July, 2012 GMP: Last GMP conducted on 13-08-2020 valid up to 12-08-2022 Bulk Manufacturer Hubei Enoray Biopharmaceutical Co.,Ltd. No.108, Yanjiang Road, Xiaochi Town, Huangemei County, Hubei Province, China
	Brand Name + Dosage Form + Strength	**Hepanox 0.2ml vial**
	Composition	Each 0.2 ml vial contains Enoxaparin sodium 20 mg.
	Finished product specifications	Ph. Eur. specifications
	Pharmacological Group	Antithrombotic agent
	Shelf life	24 Months (Store below 25^0C)
	International availability	Levenox the product is available in PFS in the said strength & availability
	Products already registered in Pakistan	Clexane 20mg/0.2ml but the product is available in PFS registered
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5 Dy.No.32430 dated 29-11-2021. Fee Submitted: Rs.30,000/- dated 27-10-2021.
	Demanded Price / Pack size	s & 2's vial/As per SRO'1
	General Documentation	The formulation in 0.2ml vial is not available in reference country
18.	**Name of manufacturer**	**M/s Macter International Limited.** **F- 216, S.I.T.E, Karachi 75700, Pakistan.**

	DML and last GMP details	DML No. 000141 Address: F- 216, S.I.T.E, Karachi 75700, Pakistan. Evidence of section: Liquid and Lyophilized recombinant DNA technology products (biological) section dated 19th July, 2012 GMP: Last GMP conducted on 13-08-2020 valid up to 12-08-2022 Bulk Manufacturer Hubei Enoray Biopharmaceutical Co.,Ltd. No.108, Yanjiang Road, Xiaochi Town, Huangemei County, Hubei Province, China
	Brand Name + Dosage Form + Strength	**Hepanox 0.4ml vial**
	Composition	Each 0.4 ml vial contains Enoxaparin sodium 40 mg.
	Finished product specifications	Ph. Eur.
	Pharmacological Group	Antithrombotic agent
	Shelf life	24 Months (Store below 25^0C)
	International availability	Levenox the product is available in PFS in the said strenght & volume.
	Products already registered in Pakistan	Clexane 20mg/0.2ml but the product is available in PFS
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5 Dy.No.32431 dated 29-11-2021. Fee Submitted: Rs.30,000/- dated 27-10-2021.
	Demanded Price / Pack size	s & 2's vial/As per SRO'1
	General Documentation	The formulation in 0.4ml vial is not available in reference country.
19.	**Name of Manufacturer**	**M/s Macter International Limited.** **F- 216, S.I.T.E, Karachi 75700, Pakistan.**
	DML and last GMP details	DML No. 000141 Address: F- 216, S.I.T.E, Karachi 75700, Pakistan. **Evidence of section:** Liquid and Lyophilized recombinant DNA technology products (biological) section dated 19th July, 2012 GMP: Last GMP conducted on 13-08-2020 valid up to 12-08-2022
	Bulk Manufacturer	Hubei Enoray Biopharmaceutical Co.,Ltd. No.108, Yanjiang Road, Xiaochi Town, Huangemei County, Hubei Province, China
	Brand Name + Dosage Form + Strength	**Hepanox 0.6ml vial**
	Composition	Each 0.6 ml vial contains Enoxaparin sodium 60 mg.
	Finished product specifications	Ph. Eur.

	Pharmacological Group	Antithrombotic agent
	Shelf life	24 Months (Store below 25^0C)
	International availability	Levenox the product is available in PFS in the said strenght & volume.
	Products already registered in Pakistan	Clexane 20mg/0.2ml but the product is available in PFS
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5 Dy.No.32432 dated 29-11-2021. Fee Submitted: Rs.30,000/- dated 27-10-2021.
	Demanded Price / Pack size	s & 2's vial/As per SRO'1
	General Documentation	The formulation in 0.6ml vial is not available in reference country.
20.	**Name of Manufacturer**	**M/s Macter International Limited.** **F- 216, S.I.T.E, Karachi 75700, Pakistan.**
	DML and last GMP details	DML No. 000141 Address: F- 216, S.I.T.E, Karachi 75700, Pakistan. **Evidence of section:** Liquid and Lyophilized recombinant DNA technology products (biological) section dated 19th July, 2012 GMP: Last GMP conducted on 13-08-2020 valid up to 12-08-2022
	Bulk Manufacturer	Hubei Enoray Biopharmaceutical Co.,Ltd. No.108, Yanjiang Road, Xiaochi Town, Huangemei County, Hubei Province, China
	Brand Name + Dosage Form + Strength	**Hepanox 0.8ml vial**
	Composition	Each 0.8 ml vial contains Enoxaparin sodium 80 mg.
	Finished product specifications	Ph. Eur. specifications
	Pharmacological Group	Antithrombotic agent
	Shelf life	24 Months (Store below 25^0C)
	International availability	Levenox the product is available in PFS in the said strength & volume.
	Products already registered in Pakistan	Clexane 80mg/0.8ml but the product is available in PFS registered
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5 Dy.No.32433 dated 29-11-2021. Fee Submitted: Rs.30,000/- dated 27-10-2021.
	Demanded Price / Pack size	s & 2's vial/As per SRO'1
	General Documentation	The formulation in 0.8ml vial is not available in reference country.
21.	**Name of Manufacturer**	**M/s Macter International Limited.** **F- 216, S.I.T.E, Karachi 75700, Pakistan.**

	DML and last GMP details	DML No. 000141 Address: F- 216, S.I.T.E, Karachi 75700, Pakistan. **Evidence of section:** Liquid and Lyophilized recombinant DNA technology products (biological) section dated 19th July, 2012 GMP: Last GMP conducted on 13-08-2020 valid up to 12-08-2022
	Bulk Manufacturer	Hubei Enoray Biopharmaceutical Co.,Ltd. No.108, Yanjiang Road, Xiaochi Town, Huangemei County, Hubei Province, China
	Brand Name + Dosage Form + Strength	**Hepanox 1ml vial**
	Composition	Each 1 ml vial contains Enoxaparin sodium 100 mg.
	Finished product specifications	Ph. Eur. specifications
	Pharmacological Group	Antithrombotic agent
	Shelf life	24 Months (Store below 25^0C)
	International availability	Levenox the product is available in PFS in the said strength & volume.
	Products already registered in Pakistan	Clexane 100mg/ml but the product is available in PFS
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5 Dy.No.32434 dated 29-11-2021. Fee Submitted: Rs.30,000/- dated 27-10-2021.
	Demanded Price / Pack size	s & 2's vial/As per SRO'1
	General Documentation	The formulation in One ml vial is not available in reference country.

Data as per guidelines of 289th meeting of Registration Board;

i) For Bulk Concentrate Import, Local formulation Filling:

	Documents Required	**Documents submitted by the firm**
i.	The firms shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	Copy of GMP No.2020-20 dated 07-09-2020 issued by Hubei Provincial Drug Administration, China. Copy of GMP issued by Mo Industry and trade of the Russian Federation. Manufactuerer and its address: Hubei Enoray Biopharmaceutical Co.,Ltd. No.108, Yanjiang Road, Xiaochi Town, Huangemei County, Hubei Province, China

ii.	The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority.	Not provided.
iii.	The firm shall provide the complete data as adopted for imported Enoxaparin injections in 281st meeting of Registration Board of the finished product of same source (bulk concentrate or ready to fill) manufactured either from country of origin or by any reference regulatory authority as adopted by Registration Board to demonstrate the similar efficacy and safety to innovator product covering following requirements:	
	a) The first criterion for demonstrating sameness of enoxaparin is equivalence of physicochemical properties, such as molecular weight distribution using size exclusion chromatography, chain mapping by cetyltrimethylammonium-coated strong anion exchange chromatography, matrixassisted laser desorption ionization mass spectrometry (MALDIMS), gel permeation chromatograph—electro spray ionization mass	Heparin sodium is dissolved and through salification, esterification, it is converted to heparin benzyl ester, then, Enoxaparin sodium is formed by alkaline degradation. Following a series of purification process (filtration, oxidization, ultrafiltration, membrane filtration, lyophilization, grinding and mixing), the final product Enoxaparin sodium is obtained.
	spectroscopy (GPC-ESI-MS), or reverse phase ion pair—electro spray ionization mass spectroscopy (RPIPESI-MS).	The structure & quality of Enoxaparin sodium has been compared with reference standard (Eu) & reference product**:** **a. Elucidation of Structure and other Characteristics:** i. Molecular weight distribution by LC & eighteen-angle laser scattering instrument, Electronic balance. ii. Quantitative analysis of uronic acid by Microplate reader. iii. Qualitative analysis of amino sugar by Ion chromatograph, ampere pulsed, electronic balance. iv. Qualitative analysis of free anions and combined sulfo groups by Ion chromatograph, Electrical conductivity Dectector. v. Nuclear Magnetic Resonance analysis by NMR analyzer. vi. Infrared analysis by Fourier transform infrared spectrometer. vii.Disaccharide composition analysis by HPLC viii. Reducing end content analysis by HPLC. ix. Oligosaccharide sequence LC-MS
	b) The second criterion for demonstrating the sameness of enoxaparin is equivalence of heparin source material (ie, heparin that is derived from porcine intestinal mucosa and that meets USP monograph standards for heparin sodium USP) and mode of depolymerization (ie, cleavage by alkaline b-elimination of the benzyl ester derivative of heparin). The equivalent heparin source material should have at least a similar distribution of natural disaccharide building block sequences (within the context of its variability). If an equivalent mode of depolymerization is used, the generic drug products should be at least similar.	

	c) The third criterion for demonstrating the sameness of enoxaparin is equivalence in disaccharide building blocks, fragment mapping, and sequence of oligosaccharide species. This can be achieved by exhaustive digestion of enoxaparin with purified heparin digesting enzymes (heparinases I, II, and III) and nitrous acid, among other means, to yield the constituent disaccharide building blocks comprising enoxaparin. These individual disaccharide building blocks can be quantified by capillary electrophoresis (CE), reverse phase highperformance liquid chromatography (RP-HPLC), strong anion exchange HPLC (SAX-HPLC), mass spectroscopy, and nuclear magnetic resonance (NMR) spectroscopy. Chemical approaches such as analysis with modifying reagents (e.g. sodium borohydride, nitrous acid) or modifying enzymes (eg, 2-0-sulfatase, 6-0-sulfatase, and 5glucuronidase) can be included.	analysis by Superhigh pressure liquid chromatograph-mass spectrometer x. Fingerprinting analysis with 2D-LC-Q/Tof-MS **b. Equivalence of heparin source material:** Based on USP monograph, the starting material of Enoxaparin sodium is from porcine intestinal mucosa & these are obtained from marketing authorization. CoA of crude Heparin Sodium has been submitted. Equivalence of Heparin degradation by chemical reaction (Benzethonium heparinate, nHeparin benzyl ester)
	d) The fourth criterion for establishing sameness of enoxaparin is equivalence of in vitro biological and biochemical assay results using activated partial thromboplastin time (aPTT) and Heptest prolongation time. The equivalence in anti-Xa activity, anti-IIa activity, and anti-Xa/anti-IIa ratio between the generic LMWHs should be provided.	Invitro Bioequivalence study of Low molecular weight Heparins for comparison of the product on aPTT & FXa activity with that of reference drug by aPTT assay & Anti-FXa assay. Equivalence in Biological & Biochemical assays: Anti-factor Xa activity & Anti-factor IIa activity by potency test method of USP mpnograph.
	e) The fifth criterion for establishing sameness of enoxaparin is equivalence of ex vivo pharmacodynamic (PD) profile in human volunteers. The comparison of in vivo PD profiles is based on measurements of in vivo anti-Xa and anti-IIa profiles.	Single center, open, randomized, single dose, two cycle, two-sequence & cross pharmacodynamics bioequivalence study aims to pre-estimate the effects of subcutaneous injection of test preparation Enoxaparin Sodium Injection & reference preparation Clexane in Chinese healthy subject under fasting.
iv.	The firm shall provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (If applicable).	NA
v.	The firm shall provide the 6 months accelerated and real time stability studies for drug substance.	24months real time stability study data at 25°C±2°C, 60%RH±5% RH & 6 months accelerated stability study at 40°C±2°C, 75%RH ±5% RH of drug substance from API manufacturer.

vi.	The local manufacturer shall perform all the tests on Enoxaparin Sodium bulk as detailed in Pharmacopoeial monograph of Enoxaparin Sodium.	• Identification by Size-Exclusion Chromatography (GPC) • Anti-Factor Xa Activity Chromogenic assay • Anti-Factor Ila activity Chromogenic assay • Color & clarity of solution • Light Absorption • Sodium by Atomic Absorption Spectrophotometry • Related Substances by HPLC
vii.	The local manufacturer shall manufacture three trial batches of the finished biological product to finalize the formulation and then perform the six months stability data on all the batches along with all the tests as detailed in Pharmacopoeial monograph of Enoxaparin Sodium Injection.	The stability study has been submitted for lowest 20mg, middle 60mg & highest 100mg vial (as per bracketing) 6-months real time stability study data at 25°C±2°C, 60%RH±5% RH & 6 months accelerated stability study at 40°C±2°C, 75%RH ±5% RH.
viii.	The local manufacturer shall perform suitable tests to evaluate the product and process related impurities both in their product and in Innovator product e.g. Total proteins, Individual proteins, Lipids and DNA content etc. The following techniques may be used: a. SDS-PAGE for individual proteins b. GC-MS for lipid impurities c. Threshold ® Total DNA Assay System for DNA content.	Related Substances by HPLC: Purity of LMW heparins by using Anion Exchange Chromatography based test. Sodium by Atomic Absorption Spectrophotometry
ix.	The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	Not submitted
x.	Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event, immediate mandatory reporting procedure shall be followed.	Submitted
xi.	The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.	Not submitted
xii.	If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.	Not submitted

xiii.	All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot	Not submitted
	Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.	

The case was deferred in 320th meeting of Registration Board & the firm has submitted reply which are tabulated below.

Decision of the Board	Response of the firm	Remarks
i. Evidence of availability of formulations in vials in Reference Regulatory Authorities.	With reference to your letter no. F.No.3-88/2015-DDC (BD) Para wise answers are given below, (i.) We would like to inform you that marketed formulation of our innovator brand i.e. Lovenox is available in vial in USA, see link provided below for the presence of Enoxaparin vial in USA; •https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020164s110lbl.pdf In number of countries Enoxaparin formulation is marketed in vial & ampoule i.e. in china and India. Web link is provided below: •http://www.baiyujituan.com/english.php?m=product&a=show&id=29 •https://integratedlaboratories.in/enoxaparin-injection-40mg-inoxa-40/	The submitted links were accessed **the products have not been found in vial in the applied concentration in the USFDA or any other reference regulatory authority.** Only available in cHina & India as per the link submitted by the firm.
ii. Valid legalized Free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority.	• The firm ha ssubmitted copy of CoPP issued by China. The firm has submitted that Finished dosage form of our API supplier HUBEI ENORAY BIOPHARMACEUTICAL is registered in country of origin (China) where market authorization holder is Tianjin Chase Sun Pharmaceutical Co.Ltd. Evidence of availability in Chinese market is mentioned in below; https://www.nmpa.gov.cn/datasearch/search-info.html?nmpa=aWQ9MTkxMzc5Jml0ZW1JZD1mZjgwODA4MTdjODMxMmM0MDE3YzliYmZjOGRlMDM2MA== • The firm has also submitted that HUBEI ENORAY BIOPHARMACEUTICAL Co .Ltd also exports Enoxaparin API to turkey region where it is registered with brand name AXEPARIN. Copy of Registration letter & GMP certificate of Turkish brand Axeparin is enclosed as hard copy. Copy cwerificate of Turkish	

	company purchasing API from our Chinese source is also submitted.	
iii. Agreement with the source manufacturer (bulk concentrate) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.		
iv. Referred the case to Licensing Division for confirmation of manufacturing section for production of Heparin Sodium.	**Comments of Licensing division is given on the previous case.**	
v. An undertaking that the firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.	**Submitted on stamp paper.**	
vi. An undertaking that if any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.	**Submitted on stamp paper.**	
vii. An undertaking that all the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.	**Submitted on stamp paper.**	

Decision in 323rd meeting of Registration Board: Registration Board deferred the case for submission of following:

- *Section wise details of products of M/s Macter International Limited Karachi.*
- *Submission of compatibility, extractables, leachebles and other relevant studies of rubber stopper with the product.*

Evaluation by DBE&R:

Now the firm has following:

a. Product list of M/s Macter International Limited for biological section:

S.no	Reg.#	Product name	Strength	Dosage	Generic	Drug class

1.	091268	Momentum	25mg/mL	Lyophilized powder for injection	Etanercept	Immunosuppressant (tumor necrosis factor receptor)
2.	092610	Epocan	2000 IU	Solution for Injection	Recombinant Human erythropoietin Alfa	Hematopoietic agent
3.	092611	Epocan	4000 IU	Solution for Injection	Recombinant Human erythropoietin Alfa	Hematopoietic agent
4.	092612	Epocan	10,000 IU	Solution for Injection	Recombinant Human erythropoietin Alfa	Hematopoietic agent
5.	105601	Pegstim	6mg	Solution for Injection	Pegylated filgrastim	Anti-neoplastic & immune modulator

b. Firm has not submitted compatibility, extractables, leachebles and other relevant studies of rubber stopper with the product.

Decision: Registration Board deferred the case for the following:

- **For submission of rational/evidence from RRA by the firm for production of non rDNA product in rDNA manufacturing facility.**
- **The board also directed the division of BE&R to recheck/reverify the availaibility of formulation in vial dosageform in USFDA.**

Imported Veterinary Biological applied by M/s. Jovac Global-PAK, Lahore deferred in 326th meeting of Registration Board.

Following product of M/s. Jovac Global-PAK is deferred in 326th meeting of Registration Board as per following details:

22.	**Name and address of Importer**	**M/s. Jovac Global-PAK,** Plot No. 17, Block D, EME, DHA Phase 12, Lahore
	Detail of DSL	M/s. Jovac Global-PAK Address: 4th floor, Plot No.17, Block D, EME DHA, Phase 12 Lahore. Valid up to:15.06.2023
	Name and address of Manufacturer	M/s. Jordan Bio Industries Center (Jovac). Address: Amman, Yajouz road, near Yajouz Agriculture Nursery Amman, Jordan.
	Name of exporting country	Jordan
	Brand Name +Dosage Form + Strength	Jova Zeit 6 Plus vaccine. (Injectable oil emulsion)
	Diary No. Date of R& I & fee	Dy. No. 25502 R&I Dated 14-09-2022 Rs. 150,000/- (Slip No. 9269169953)
	Composition	Each dose contains: Inactivated Adenovirus Serotype 2,4 &8 at least…. $10^{6.5}$ $TCID_{50}$
	Pharmacological Group	Inactivated Vaccine
	Type of Form	Form-5A
	Finished Product Specification	Manufacturer's specifications

	Shelf Life	2 years (2^0C-8^0C)
	Document Details	a. Valid legalized free sale certificate is submitted by the firm however it does not confirm the availability of product in country of origin. b. Valid legalized GMP certificate issued to M/s. Jordan Bio Industries Center (Jovac) valid for three years from the date of inspection i.e. 01/12/2020.
	Pack size	300ml(1000doses)
	Reference Regulatory Authority Availability	N/A
	Products already registered in Pakistan	GPVAC Hydro TC Plus of Grand Pharma Each 0.3ml contains: Inactivated Avian Adenovirus 4…. ≥ $7\log_{10}$ EID_{50}/dose Inactivated Avian Adenovirus-8…. ≥ $7\log_{10}$ EID_{50}/dose
	Remarks of Evaluator	i. Free sale certificate does not confirm the free sale status of product in country of origin. ii. Locally registered product contains Adenovirus serotype 4 & 8 but not serotype 2.
	Decision in 326th RB meeting	Registration Board deferred the case for the following: • For submission of valid legalized Free Sale Certificate indicating product availability in country of origin. • For submission of evidence of locally registered product containing all serotypes.
	Evaluation by DBE&R	Now the firm has submitted following: • Valid legalized Free Sale Certificate (dated 29/03/2023) indicating product availability in country of origin. • The firm is unable to find locally registered product with serotype 2.
	Decision: Registration Board referred the case to Ministry of National Food Security & Research, Islamabad for comments regarding the need of vaccine, prevalence of disease and immunological relevance of the serotype 2 in Pakistan	

Imported Veterinary Biological applied by M/s UM Enterprises, Karachi deferred in 293rd meeting of Registration Board.

Following product of M/s UM Enterprises, Karachi was deferred in 293rd meeting of Registration Board as per following details:

23.	**Name of Importer**	**M/s UM Enterprises, Plot No. 12, Sector 15, Korangi Industrial Area, Karachi.**
	DSL details	DSL No. 2911 dated 11-07-2019 valid till 16-03-2021
	Name of Manufacturer	M/s ZoetisIndustria De ProdutosVeterinarios Ltda., RuaLuiz Fernando Rodriguez, 1701, Vila Boa Vista, Campinas, SP, Brazil
	Brand Name +Dosage Form + Strength	Poulvac Magniplex Live vaccine conjugated to antibodies against the Gumboro Disease

	Composition	Each dose of product contains: Suspension of the Gumboro V877 virus at minimum title on the release date…. 102.0DIE50 Suspension of the Gumboro V877 virus at minimum title on the expiration date…. $10^{1.3}DIE_{50}$ Antibody against the Gumboro Disease…….≥20U
	Finished product specifications	As per Innovator.
	Pharmacological Group	Veterinary Vaccine
	Shelf life	24 months (2^0C -8^0C)
	International availability	Philippines.
	Products already registered in Pakistan	CevacTransmune IBD Vaccine (Reg. No. 039910)
	Type of Form Dy No. & Date of application, Fee submitted	Form-5A Dy. No. 40446 & 14206 Dated 05-12-2018 & 05-08-2019 Rs. 100000/- Dated 05-12-2018
	Demanded Price / Pack size	2000 Doses/ De-controlled
	General documentation	• Legalized GMP Certificate dated 31-08-2017 issued by Ministry of Agriculture, Livestock and Food Supply-MAPA, Brazil. • Legalized FSC No. 1285164 dated 29-06-2017 issued by Ministry of Agriculture, livestock and Food Supply, Brazil.
	Decision of RB in 292nd meeting	*Registration Board deferred the case for submission, of stability studies guidelines for veterinary vaccines of country of origin by the firm.*

The firm has now submitted the stability study guidelines of country which indicates the following:

Test Frequency:

a. Long term stability (granting of definitive shelf life): 0,3,6,9,12,18 and 24 months, then yearly after the second year and until the declared expiration date.

b. Accompanying Stability test: One analysis at time zero must be performed, then every year, until declared expiration date.

The firm has also provided the online link of above guidelines which is not accessible.

Decision of 293rd Registration Board meeting:

Registration Board deferred the case for submission of scientific rationale of using time intervals of 0, 6, 12…. months instead of 0, 3, 6, 9, 12….. months in real time stability data.

Evaluation by DBE&R:

Now the firm has submitted real time stability studies data at 2-8ºC on 0, 3, 6, 9, 12….. 24 months for three batches of Poulvac Magniplex.

Decision: Keeping in view legalized certificate of Licensing and Inspection indicating product availability in country of origin, Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

Imported Veterinary Biological applied by M/s Saadat International, Lahore deferred in 320th meeting of Registration Board.

Following product of M/s Saadat International, Lahore was deferred in 293rd meeting of Registration Board as per following details:

24.	**Name and address of Importer**	**M/s Saadat International, 117 Habitat Flat Shadman II, Jail Road, Lahore.**

	Detail of DSL	**M/s Saadat International:** Address: 117 Habitat Flat Shadman II, Jail Road, District Lahore Valid till: 12-Jun-2022
	Name and address of Manufacturer	**Marketing Authorization Holder:** M/s Boehringer Ingelheim Vetmedica GmbH Binger Strabe 173, 55216 Ingelheim am Rhein, Germany.
		Manufacturer of Drug: M/s Boehringer Ingelheim Animal Health Rue De L aviation, 69800 ST PRIEST -France
	Name of exporting country	France
	Brand Name +Dosage Form + Strength	**Gallimune H9+ND**
	Diary No. Date of R& I & fee	Dy. No. 19297 R&I Dated 09-07-2021 Rs. 150,000/- (Slip No. 07658493298)
	Composition	Each 0.3 ml dose contains: Inactivated Avian Influenza Virus, H9N2 (iraq)strain at least7log2HI.U. Inactivated Newcastle Disease Virus, Ulster 2C strain at least 16HI.Ufr
	Pharmacological Group	Vaccine
	Type of Form	Form-5A
	Finished Product Specification	Manufacturer's Specifications
	Shelf Life	24months----(2-8^{o}C) Stability studies for 27 months at 2-8 ^{o}C
	Document Details	**GMP certificate (Original Legalized):** Certificate No. 20/265668 Issued to: M/s Boehringer Ingelheim Animal Health Rue De L aviation, 69800 ST PRIEST-France (Manufacturer) Issued by: French agency for veterinary medicinal products. Validity: Three years from the date of inspection (conducted on February 17th 2020 to February 20th 2020). **Sole Agency Agreement:** **Boehringer Ingelheim Vetmedica GmbH** (the marketing authorization holder of the product), a company incorporated under the laws of Germany, with its principal office at Binger Strabe 173, 55216 Ingelheim am Rhein, Germany (BIV GmbH) herewith appoints; Saadat International 117 Habitat Flat Shadman II Jail Road Lahore our sole agent in Pakistan for Gallimune H9+ ND, the product is manufactured and supplied to Saadat International by BIV GmbH affiliated company: Boehringer Ingelheim Animal Health France. **COPP (Original Legalized):** Certificate No. 20-268470
	Pack size	300ml bottle
	Reference Regulatory Authority Availability	N/A

	Products already registered in Pakistan	Gallimune 208 ND+Flu H9 M.E. Emelsion for Injection. [Each Dose of Vaccine Contains: - Inactivated Avian Influenza Virus H9N2 Strain Minimum Titer Before Inactivation...108 EID_{50}. Inactivated Newcastle Disease Virus, Ulster 2c Strain Minimum Titer Before Inactivation 1068 EID_{50}].
	Remarks of Evaluator	In response to this division's letter dated 12th January 2022 applicant has submitted following documents: Field trial data. Finished Product Specifications: Manufacturer. Following justification regarding this statement on the COPP that product is not licensed to be placed in the market of country of origin is required. "Gallimune H9+ND is not licensed to be placed in the France market because avian influenza caused by H9N2 subtype is not present in poultry farms of this country. Therefore:
		No Free certificate could be obtained for any H9 vaccine. All the H9 vaccines manufactured in France are for exportation purpose only for the countries that have the H9 as endemic disease, so the authority can only provide certificate of origin and/or Certificate of Pharmaceutical product". Following documents are still required: Finished product specifications in light of 267th RB meeting.
	Previous Decision (M316)	Registration Board deferred the product for submission of evidence of availability of formulation in reference regulatory authorities.
	Evaluation by BE&R Division	*The firm has submitted that Gallimune H9+ND is not registered in reference regulatory authorities (same as all the vaccines contain H9N2 formulations) because avian influenza caused by the H9N2 subtype is not present in poultry farms of these countries.*
	Decision of Registration Board in its 320th meeting	Registration Board deferred the product for submission of evidence of availability of formulation in country of origin or in any other reference regulatory authorities.
	Evaluation of DBE&R	Firm has submitted following: The reason for its non-availability in the country of the origin and countries of the reference regulatory authorities is as under; 1. It is not registered in the country of origin or countries of the reference regulatory authorities because the low pathogenic the avian influenza LPAAI subtype H9N2 is not present in the poultry birds in these countries. 2. The isolates of H9N2 is derived mainly from Middle Eastern lineage not from European lineage which is mainly in the wild birds (no vaccination). 3. The Avian Influenza H9N2 lineage G1-h9.4.2 viruses are widely distributed and endemic poultry in Pakistan, Bangladesh, regions of India, Afghanistan, Nepal, Egypt, Saudi Arabia and Israel. Main Points to support the claim for the safety, quality & efficacy of the drug/vaccine:-

		• However, I would like highlight that the said product is a quality vaccine manufactured by M/S Boehringer Ingelheim, one of the leading animal health companies manufacturing vaccines and Pharmaceutical products at its sites in USA, France and Italy which are fully complying the USDA, EU GMP standards. The said product is manufactured at Boehringer Ingelheim's French site which is fully compliant with the EU and WHO GMP standards. • We have already submitted the GMP certificate and COPP which shows the full compliance status. • Kindly refer to the relevant parts of Quality; safety and efficacy of the Technical Dossier of the vaccine already submitted which shows the full compliance of the EU GMP standards during whole of its manufacturing process. • I would also like to add that one of our already registered vaccine Gallimune 208(Reg. No: 034559) since which has the same composition of Gallimune ND+H9 and has been used by the poultry farmers to control avian influenza H9 with its proven quality, efficacy and safety. • *The Gallimune ND+H9, the vaccine under registration has the same composition except that the subtype (strain) 0f the H9N2 has been upgraded to match the current epidemiological data/prevalence of the disease in our region.* • I would also like to bring to your attention that a number of vaccines with the same composition have already been granted registration which are produced in countries of non reference regulatory authorities such as China, Korea and Egypt.
	Decision: Registration Board referred the case to Ministry of National Food Security & Research, Islamabad for comments regarding the need of vaccine, prevalence of disease and immunological relevance of the applied strains in Pakistan	

Cases of DD-III (Mr. Hafiz Ahsan)

25. M/s Sanofi Aventis Pakistan Limited, Karachi - Extension in labelling exemption for Cerezyme Injection 400 IU (Reg. No. 107918)

M/s Sanofi Aventis Pakistan Limited, Karachi submitted that Cerezyme is indicated for a rare disease called Gaucher disease and required to be imported in a limited quantity. Therefore, it is not possible for manufacturer to follow the Packaging and labeling rules of every country at the time of export plus production, packaging, quality controls of this sterile and temperature sensitive product requires specialized methods and techniques of handling under highly controlled environment. The firm requested to extend the exemption of Urdu Text, Registration number and MRP on packs of Cerezyme (Imiglucerase) for a period of longer than one year. The firm has submitted the following documents:

i. Fee Challan of Rs. 7500/- via e-deposit slip No. 5316605027 and differential fee of Rs. 2500/- via e-deposit slip No. 0923589001 dated 14- 04-2023.
ii. Copy of local SOP for control of Overstamping Operations.
iii. An undertaking that to print the Registration Number and Maximum Retail Price (MRP) on each pack of above product at their Karachi site bearing DML No. 000007, before releasing the goods into the market.
iv. Copy of Registration letter dated 24-05-2021
v. Copy of DML & DSL
vi. Copy of permission of Extension in labeling exemption for Cerezyme (Reg. No. 107918) vide letter No. F.9-2/2022-AD(BD)(PRV) dated 06th April 2023.

In this context, it is submitted that the last request of the firm for exemption of labeling text for Cerezyme Injection 400 IU (Reg. No. 107918) was approved by Registration Board in its 323rd meeting for one year from the date of expiry of previous permission i.e., 23-05-2022.

The firm has submitted import and consumption record of the product in last three years as follows:

Product	No of Units / Packs Imported			No of Units / Packs Sold		
Cerezyme Injection	2021	2022	2023	2021	2022	2023
	50	90	-	-	106	12

Decision: Registration Board decided as follows:

- **Acceded to the request of the firm and extended the permission, for one year from the date of expiry of previous permission i.e. 22-05-2023, to import Cerezyme 400 U (1's, 5's & 25's) (Reg. No. 107918) in Standard Export Packs and to locally print MRP and registration number along with urdu text and other parameters as per Drugs (Labelling & Packing) Rules, 1986 before sale of drug at M/s Sanofi Aventis, Plot 23, sector 22, Korangi Industrial Area, Karachi to comply with the requirements of Drugs (Labelling & Packing) Rules, 1986.**

Imported Human Biological product from Reference countries / WHO PQ:

26.	Name, address of Applicant / Importer	M/s Amson Vaccines & Pharma (Pvt.) Ltd., Plot No. 115, Industrial Triangle, Kahuta Road, Islamabad.
	Details of Drug Sale License of importer	License No: 920-ICT/2013 Address Plot No. 115, Industrial Triangle, Kahuta Road, Islamabad. Validity: 01-08-2022
	Name and address of marketing authorization holder (abroad)	M/s Green Cross Corporation, 40 Sandan-gil, Hwasun-eup, Hwasun-gun, Jeollanam-do, Republic of Korea
	Name, address of manufacturer(s)	M/s Green Cross Corporation, 40 Sandan-gil, Hwasun-eup, Hwasun-gun, Jeollanam-do, Republic of Korea
	Name of exporting country	Republic of Korea
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	• Firm has submitted Legalized CoPP (No. 2021-A1-0638) dated 12-04-2022 issued by Ministry of Food and Drug Safety, Korea. The COPP also specifies the GMP ststua of manufacturer. • Firm has submitted Legalized FSC (No. 2020-A1-0504) dated 24-03-2022 issued by Ministry of Food

		and Drug Safety, Korea. The FSC specifies that the product is permitted to be freely sold in country of origin. • Firm has submitted legalized GMP certificate (No. 2021-F1-0184) dated 18-05-2021 valid till 25-02-2024 issued by Ministry of Food and Drug Safety, Korea.
	Details of letter of authorization / sole agency agreement	Firm has submitted legalized Sole Agency Certificate from General Manager of M/s Green Cross Corporation. According to the letter, the firm M/s Green Cross Corporation exclusively authorizes "M/s Amson Vaccines & Pharma (Pvt.) Ltd. for the purpose of registration, import, promotion and marketing of the product.
	Status of the applicant	☐Manufacturer ☒Importer ☐Is involved in none of the above (contract giver)
	Status of application	☐New Drug Product (NDP) ☒Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒Domestic sale ☐Export sale ☐Domestic and Export sales
	For imported products, specify one the these	☒Finished Pharmaceutical product import ☐Bulk import and local repackaging ☐Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	32870 & 11223 Dated: 15-12-2021 & 10-05-2022
	Details of fee submitted	Rs: 150,000/- Dated: 11-11-2021 Deposit Slip No. 1882973539
	Proposed proprietary name / brand name	BARYCELA Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Powder Vial: Each vial contains: Live attenuated varicella virus (strain: MAV/06, cell line: MRC-5)……..….≥3800PFU Solvent Vial: Each vial contains: Sterile Water for Injection…….0.7ml
	Dosage form of applied drug	Powder & Solvent for Intramuscular Injection
	Pharmacotherapeutic Group of (API)	Varicella Vaccine
	Finished product specifications	WHO specifications
	Proposed Pack size	1's Vial (Powder) + 1's Vial (Solvent) 10's Vials (Powder) + 10's Vials (Solvent)
	Proposed unit price	As per SRO
	Shelf Life	24 months
	Storage Conditions	2°C -8°C
	Reference Regulatory Authorities	WHO Pre-qualified vaccine

	For generic drugs (me-too status)	Varicella vaccine with this strain is not registered.
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to general properties, manufacturers, description of manufacturing process and controls, characterization, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	M/s Green Cross Corp., 586, Gwahaksaneop 2-ro, Ochang-eup, Cheongwon-gu, Cheongju-si, Chungcheongbuk-do, South Korea.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of Varicella vaccine bulk at real time conditions. The real time stability data is conducted at -80 ± 10˚C for 18 months.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method Validation / verification of the product	Firm has submitted the details of analytical method validation.
	Container closure system of the drug product	Powder Vial: • Borosilicate (Type I) Glass Vial • Butyl Rubber Stopper • Aluminum cap Solvent Vial: • Borosilicate (EP Type I) Glass Vial • Chlorobutyl Rubber Stopper • Aluminum cap
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches of Barycela Inj. at accelerated and real time conditions. The real time stability data is conducted at 5°C ± 3°C for 24 months and accelerated stability is conducted at 25°C ±2°C for 06 months. Firm has submitted stability study data of 3 batches of Diluent at real time conditions. The real time stability data is conducted at 5°C ± 3°C for 36 months.
	Module-IV Non-Clinical	Primary Pharmacodynamics

		• Immune response comparison study by animal species (rabbit, rat, and guinea pig) • Efficacy comparison study in rabbits and guinea pigs • Efficacy comparison study with commercial vaccines in rabbits and guinea pigs • Preliminary local tolerance and efficacy study in rabbits Repeat-dose Toxicity • Repeated Subcutaneous Dose Toxicity Study of VZV Vaccine (MG1111) with a Recovery Period in Rabbits. Other Toxicity Study • A Neurovirulence Test of Attenuated Varicella-Zoster Virus (VZV) in Male Cynomolgus Monkeys
	Module-V Clinical	• A Single-center, Dose Block-randomized, Single-blind, Active-controlled, Dose Escalation Phase 1 Clinical Trial to Evaluate the Safety and Efficacy (Immunogenicity) of MG1111 in Healthy Adults • A Phase II/III, Single-blind (Stage 1), Double-blinded (Stage 2), Randomized, Active-controlled, Dose-escalation (Stage 1), Non-inferiority (Stage 2) Study to Evaluate Immunogenicity and Safety of MG1111 in Healthy Children
	Remarks of Evaluator	i. The submitted legalized FSC issued on 24-03-2022 specifies that the product is permitted to be freely sold in country of origin, however, legalized CoPP issued on 12-04-2022 indicates that the product is not actually available in the market in country of origin. ii. RRA status submitted by the firm is of OKA strain while the instant product has a different strain. iii. The instant strain is not registered in Pakistan. iv. pH is not tested in real time stability studies for which the firm has submitted that initially pH was not included in the studies and later Ministry of Food and Drug Safety, Korea (MFDS) advised them to include. The revised stability studies are not yet complete. v. Limits of virus concentration is different in Specifications (3800-38000PFU) and stability data (2530-25298PFU) for which the firm submitted that clinical trial was conducted with target virus concentration of 8000PFU but at the time of review by MFDS, the target virus concentration was 12000PFU, therefore, the final virus concentration limit is also changed from 2530-25298 PFU to 3800-38000PFU.

Decision:

Registration Board deferred the product for submission of following by the firm:

i. Clarification regarding non-availability of product in country of origin as per submitted CoPP.

ii. Evidence of availability of Varicella vaccine with MAV/06 strain in Reference Regulatory Authorities.

iii. Immunological relevance of MAV/06 strain with circulating strains of Pakistan.

iv. Real time stability data including all parameters as per finished product specifications.

The firm has submitted following Documents and clarification:

i. New CoPP submitted by the firm shows the availability of the product in country of origin.

ii. The firm has submitted 28 days stress stability data of finished product with statement that after 02-03-2020.

iii. Regarding Immunological relevance of MAV/06 strain with circulating strains of Pakistan the firm has submitted

"*Report on the Results of Immunogenic Cross-Reactivity Assessment on Attenuated Vaccine Strain and Wild-Type Varicella Viruses in the Serum of Children Administered Varicella Vaccines"*
Conclusion of the study:
"-The serum samples of the MG1111 vaccination group did not show any statistically significant difference in the antibody titers analyzed with the FAMA antigens of 6 VZV strains regardless of clades or attenuation.
- *The serum samples of the Varivax vaccination group showed a statistically significant difference in the antibody titers analyzed with the FAMA antigens of 6 VZV strains. Specifically, when MAV06 and Jena 26 were used as antigens, the antibody titer was statistically significantly lower than the values measured using Varivax_Oka or YC03 as antigens.*
- *When FAMA analysis was performed with the same strain for 6 FAMA antigen strains, there was no difference in antibody titers between the MG1111 and Varivax vaccination groups.*

iv. Evidence of availability of Varicella vaccine with MAV/06 strain in Reference Regulatory Authorities is not provided.

Previous Decision: The Board deferred the case for clarification from EPI regarding immunological relevance and need of applied strains in Pakistan **(M-321).**

Evaluation by BE&R: The firm submitted that the product acquired WHO Pre-qualification status on 14th February, 2023. The product status is checked on 29-05-2023 @ https://extranet.who.int/pqweb/content/barycela-inj .

As per WHO assessment, Barycela (MAV/06 strain) vaccine is comparable to Varivax (Oka Strain) vaccine (International Brand) in immunogenicity and safety profile from clinical point of view, Varivax has the oka strain, the same strain of other varicella vaccine registered in Pakistan (Varilrix, Varivac, Okavax, Vaxapox).

Decision: Keeping in view the WHO PQ status and legalized FSC indicating product availability in the country of origin and GMP status of the firm, Registration Board approved the product subject to compliance of current Import Policy for finished drugs

27.	Name, address of Applicant / Importer	M/s Roche Pakistan Limited, 1st floor, 37-B, Block 6, PECHS, Karachi.
	Details of Drug Sale License of importer	**License No:** 0267 **Address:** Roche Pakistan Limited, 1st floor, 37-B, Block 6, PECHS, Karachi. **Address of Godown:** • R-PI, plot no. 116, sector 15, K.I.A, Karachi • R-PI, plot no. 56, sector 15, K.I.A, Karachi **Validity:** 13-09-2024. **Status:** Drug License by way of wholesale and Drug License by way of retail sale **Renewal:** N/A
	Name and address of marketing authorization holder (abroad)	Roche Registration GmbH, Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Germany.
	Name, address of manufacturer(s)	Genentech Inc., 1 DNA Way, South San Francisco, CA 94080, USA.
	Name of exporting country	Switzerland
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	EMA eCPP Certificate: 09/22/172400 Issue on 04/07/2022.

	Details of letter of authorization / sole agency agreement	• Authorization letter from M/s F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, CH-4070 Basel Switzerland in name of M/s Roche Pakistan Limited, Karachi dated 27-09-2022. • Copy of relationship letter indicating relation of all Roche companies with M/s F. Hoffmann-La Roche Ltd., Basel. Switzerland.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No.29311 dated 17-10-2022
	Details of fee submitted	**Deposit Slip no**. 1770410768 **PKR** 75,000: **Dated** 20-09-2022
	The proposed proprietary name / brand name	**Lunsumio**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**API**: Mosunetuzumab **Strength** : **1 mg** Concentration per vial: 1mg/1ml
	Dosage form of applied drug	Intravenous Use
	Pharmacotherapeutic Group of (API)	Monoclonal Antibodies (ATC code: L01XC)
	Reference to Finished product specifications	Innovator's specifications
	Proposed pack size	1's vial
	Proposed unit price	As per SRO
	Shelf life	24 months
	Storage conditions	2°C - 8°C
	The status in reference regulatory authorities	Lunsumio 1mg concentrate for solution for infusion glass vial (EMA Approved)
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	Genentech, Inc.1 DNA Way South San Francisco, California 94080 USA.

	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	• 48 months real time stability data at -20°C of 03 batches • 06 month accelerated stability data 5°C of 03 batches
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	2 mL, USP/Ph. Eur./JP Type I glass, borosilicate, colorless
	Stability study data of drug product, shelf life and storage conditions	• 24 months real time stability data at 5°C of 03 batches • 06 month accelerated stability data 25°C of 03 batches
	Module-IV Non-Clinical	**4.2.1 Pharmacology** **4.2.1.1 Primary Pharmacodynamics** • 22-0083: In Vitro Biological Characterization of Mosunetuzumab for Human C1q Binding Activity • In Vitro Comparison of BTCT4465A Produced from E. coli and CHO Cells in B-Cell Killing, T-Cell Activation, and Cytokine Production With Human PBMCs • In Vitro Evaluation of BTCT4465A for Human Fc Gamma Receptor Binding Activities • Characterization of Anti-CD20/CD3 TDB Antibody Mechanism of Action and Efficacy • Comparison of Biological Activity (B-Cell Killing, T-Cell Activation, and Cytokine Production) of POC Anti-CD20/CD3 TDB Antibody and BTCT4465A with Human and Cyno Peripheral Blood Mononuclear Cells • In Vitro Pharmacologic Activity of Anti-CD20/CD3 TDB Antibody in the Presence of High Concentration of Rituximab-DANA • In Vitro Pharmacologic Activity of Anti-CD20/CD3 TDB Antibody in the Presence of High Concentration of

		Dexamethasone • In Vitro Evaluation of BTCT4465A (Anti-CD20/CD3 TDB) v0.1 and BTCT4465A v0.2 for Binding Activity to Human and Cynomolgus Monkey B Cells and T Cells • A Single-Dose Efficacy Study of Anti-CD20/CD3 T-Cell-Dependent Bispecific (TDB) Antibody and Non-CD20-Binding TDB Antibody in Human CD20/CD3 Double-Transgenic Mice • Dose Titration of Anti-CD20/CD3 T-Cell--Dependent Bispecific (TDB) Antibody in Depleting Endogenous B Cells in Human CD20/CD3 Double-Transgenic (TG) Mice • A Single Dose, Time-Course Efficacy Study with Anti-CD20/CD3 T-Cell--Dependent Bispecific (TDB) Antibody in huCD20/CD3 Double Transgenic Mice • A Repeat-Dose Efficacy Study of Anti-CD20/CD3 T-Cell-Dependent Bispecific (TDB) Antibody in Humanized NSG Mice **4.2.2 Pharmacokinetics** **4.2.2.1 Analytical Methods and Validation Reports** (if separate reports are available) • The Validation History of an ELISA Method for the Quantitation of BTCT4465A (Mosunetuzumab) in Cynomolgus Monkey Serum • The Validation History of an Immunoassay Method for Detection of Antibodies to BTCT4465A (Anti-CD20/CD3 TDB) in Cynomolgus Monkey Serum **4.2.2.7 Other Pharmacokinetic Studies** • Pharmacokinetics and Pharmacodynamics of E. coli- or CHO-Produced Anti-CD20/CD3 TDB Antibody in huCD20/huCD3 Transgenic Mice • A Single Dose Pharmacokinetic and Pharmacodynamic Study of BTCT4465A Administered by Intravenous Injection to Male Cynomolgus Monkeys • A Single Dose Pharmacokinetic Comparability Study of BTCT4465A via Intravenous Administration to Male • Cynomolgus Monkeys with a 11-Day Observation Period **4.2.3 Toxicology** **4.2.3.1 Single-Dose Toxicity (in order by species, by route)** • A Single Dose Toxicokinetic, Pharmacodynamic, and Toxicology Study of Anti-CD20/CD3 T-cell Dependent Bispecific Antibody via Intravenous Administration in Male Cynomolgus Monkeys

		• A Single Dose Toxicokinetic, Pharmacodynamic, and Toxicology Study of Anti-CD20/CD3 T-cell Directed Bispecific Antibody via Intravenous Administration in Male Cynomolgus Monkeys • A Single Dose Toxicokinetic, Pharmacodynamic, and Toxicology Study of BTCT4465A via Intravenous Infusion or Subcutaneous Administration in Cynomolgus Monkeys with a 7-week Recovery Period **4.2.3.2 Repeat-Dose Toxicity (in order by species, by route, by duration, including supportive toxicokinetics evaluations)** • A Multiple Dose Toxicokinetic, Pharmacodynamic, and Toxicology Study of anti-CD3/CD20 T-cell Dependent Bispecific Antibody Administered by Intravenous Injection to Cynomolgus Monkeys**.** • A Multiple Dose Toxicokinetic, Pharmacodynamic, and Toxicology Study of anti-CD3/CD20 with or without steroid or Rituximab pretreatment via Intravenous or Subcutaneous Administration in Male Cynomolgus Monkeys • Pilot 28-Day Repeat Dose Intravenous Study of Anti-CD20/CD3 T-cell Dependent Bispecific Antibody using Magnetic Resonance Imaging in the Cynomolgus Monkey • BTCT4465A: 25 Day Intravenous (Infusion) Administration Pilot Toxicity Study in the Monkey • BTCT4465A: 26 Week Multiple Dose Intravenous (Infusion) Administration Toxicity and Toxicokinetic Study in the Cynomolgus Monkey **4.2.3.5 Reproductive and Developmental Toxicity (including range-finding studies and supportive toxicokinetics evaluation) (If modified study designs are used, the following subheadings should be modified accordingly.)** **4.2.3.5.2 Embryo-fetal development** • The Weight-of-Evidence Assessment of Developmental Effects for Mosunetuzumab - for nonUS submission. **4.2.3.7 Other Toxicity Studies (if available)** **4.2.3.7.7 Other** • Tissue Cross-reactivity of BTCT4465A with Human and Select Cynomolgus Monkey Tissues • In Vitro Characterization of the Biological Activities of BTCT4465A in Human PBMCs and the Impact of Low Percentage of Anti-CD3 Homodimers on BTCT4465A Activity
	Module-V Clinical	**Study Design: GO29781**

		• An open Label, Multicenter, Phase I/II dose escalation study and expansion study evaluating the Safety, efficacy and tolerability study and Pharmacokinetics of mosunetuzumab as a single agent (and in combination with Tecentriq) in patients with Relapsed or Refractory B Cell Non-Hodgkin's Lymphoma and Chronic Lymphocytic Leukemia. • 447 enrolled into mosunetuzumab IV montherap cohorts (Group A and Group B escalation + expansion).

Remarks of Evaluator:

Sr. No.	Observations	Response by the Firm
1.	Observer blind, Phase-III clinical study data are required since submitted clinical trial is an open label, Phase I/II study design. Justification is required.	The firm has submitted that the application for registration of new drug, Lunsumio (mosunetuzumab) 1mg and 30mg concentrate for solution for infusion, is applied on the basis of phase I/II GO29781 study, and same is the basis of approval for this product in the reference regulatory authorities such as USFDA, EMA and Swissmedic. We would like to add that the phase III (CELESTIMO study) trials for this drug are in process as informed by our principal, F. Hoffmann-La Roche Ltd., Basel, Switzerland.
2.	Relationship of product license holder with Basel, Switzerland.	Product Specific Authorization letter has been issued by M/s. F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, CH-4070 Basel Switzerland & the marketing authorization holder is Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach- Wyhlen, Germany. For this purpose , the firm has submitted a copy of letter indicating relationships among Roch Group of Companies, wherein it has been mentioned M/s F.Hoffmann-La Roche Ltd., Basel Switzerland is the operational headquarter of the Roche Group.

Previous Decision: Registration Board after due discussion decided to defer the case for further deliberation in the next meeting **(M-326)**.

Evaluation by BE&R:

The firm submitted that Lunsumio is a cancer medicine used to treat adults with Follicular lymphoma that does not respond to (refractory) or has come back (relapsed) after at least two previous treatments. ***Follicular lymphoma is a rare disease, and Lunsumio was considered as an 'orphan medicine' (a medicine used in rare diseases) on 16 November 2021 by EMA. Lunsumio is currently approved in US (Dec 2022), EU (June 2022), UK (Oct 2022) and Switzerland (Feb 2023).***

Further submitted that we are enclosing the justification letter received from our principal, F.Hoffman-La Roche Ltd, Basel, Switzerland, to justify the approval of Lunsumio on technical grounds, in the reference regulatory authorities, based on phase I and II clinical trials.

The approval by the SRAs is based on their respective accelerated approval programs where a product is approved after the phase I and II clinical trials. From a public health perspective, Mosunetuzumab represents a chemotherapy-free option with a novel mechanism of action and a favorable benefit-risk profile, and is readily available for treatment. Mosunetuzumab provides meaningful ***Overall Response Rate, Complete Response, Duration of Response,*** while having a ***clinically manageable safety Profile.*** All this is highly welcomed in a patient population that needs new therapies with improved efficacy and safety profile.

Particularly in the US, ***the FDA has introduced expedited programs which are intended to facilitate and expedite development and review of new drugs to address unmet need in the treatment of a serious or Iife threatening condition.*** These programs include fast back designation, breakthrough therapy designation, accelerated approval, and priority review designation. These programs are intended to help ensure that

therapies for serious conditions are approved and available to patients as soon as it can be concluded that the therapies' benefits justify their risks. According to part 312, subpart E (21 CFR part 312): *"The regulations call for earlier attention to drugs that how promise in treating such conditions, including early consultation with FDA for sponsors of such products and efficient trial design, potentially* ***relying on well-controlled phase 2 studies*** *for evidence of effectiveness. "*		
Evaluation by BE&R: The case was presented in 327th meeting of Registration Board wherein the Board decided as under: ***"Keeping in view EMA eCPP and product approval in USFDA, EMA and Swissmedic, Registration Board approved the product subject to compliance to the current Import Policy for finished drugs."*** However, during compilation of minutes of 327th Board meeting, the case could not be incorporated in the final minutes, hence it is again placed for consideration and endorsement by the Board.		
Decision: The Board deliberated the case in the light of decision of 327th meeting of Registration Board and decided to process the issuance of the Registration letter to the firm before formal approval of minutes of this meeting.		
28.	Name, address of Applicant / Importer	M/s Roche Pakistan Limited, 1st floor, 37-B, Block 6, PECHS, Karachi.
	Details of Drug Sale License of importer	**License No:** 0267 **Address:** Roche Pakistan Limited, 1st floor, 37-B, Block 6, PECHS, Karachi. **Address of Godown:** • R-PI, plot no. 116, sector 15, K.I.A, Karachi • R-PI, plot no. 56, sector 15, K.I.A, Karachi **Validity:** 13-09-2024. **Status:** Drug License by way of wholesale and Drug License by way of retail sale **Renewal:** N/A
	Name and address of marketing authorization holder (abroad)	Roche Registration GmbH, Emil-Barell-Strasse 1, 79639 Grenzach-Wyhlen, Germany
	Name, address of manufacturer(s)	Genentech Inc., 1 DNA Way, South San Francisco, CA 94080, USA.
	Name of exporting country	Switzerland
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	EMA eCPP Certificate No: 05/22/172402 Issue on 04-07-2022
	Details of letter of authorization / sole agency agreement	• Authorization letter from M/s F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, CH-4070 Basel Switzerland in name of M/s Roche Pakistan Limited, Karachi dated 27-09-2022. • Copy of relationship letter indicating relation of all Roche companies with M/s F. Hoffmann-La Roche Ltd., Basel. Switzerland.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☒ New Drug Product (NDP) ☐ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale

		☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 29311 ; Dated 17-10-2022
	Details of fee submitted	**Deposit Slip no**. 43585097156 **PKR** 75,000: **Dated** 20-09-2022
	The proposed proprietary name / brand name	**Lunsumio**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**API**: Mosunetuzumab **Strength**: **30 mg** Concentration per vial: 30mg/30ml
	Dosage form of applied drug	Intravenous Use
	Pharmacotherapeutic Group of (API)	Monoclonal Antibodies (ATC code: L01XC)
	Reference to Finished product specifications	Innovator's specifications
	Proposed pack size	1's vial
	Proposed unit price	As per SRO
	Shelf life	24 months
	Storage conditions	2°C - 8°C
	The status in reference regulatory authorities	Lunsumio 30mg concentrate for solution for infusion glass vial (EMA Approved).
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per ICH guidelines. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	Genentech, Inc.1 DNA Way South San Francisco, California 94080 USA.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	• 48 months' real time stability data at -20°C of 03 batches • 06 month accelerated stability data 5°C of 03 batches
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of

		excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	50 mL, USP/Ph. Eur./JP Type I glass, borosilicate, colorless
	Stability study data of drug product, shelf life and storage conditions	• 24 months' real time stability data at 5°C of 03 batches • 06 month accelerated stability data 25°C of 03 batches
	Module-IV Non-Clinical	**4.2.1 Pharmacology** **4.2.1.2 Primary Pharmacodynamics** • 22-0083: In Vitro Biological Characterization of Mosunetuzumab for Human C1q Binding Activity • In Vitro Comparison of BTCT4465A Produced from E. coli and CHO Cells in B-Cell Killing, T-Cell Activation, and Cytokine Production With Human PBMCs • In Vitro Evaluation of BTCT4465A for Human Fc Gamma Receptor Binding Activities • Characterization of Anti-CD20/CD3 TDB Antibody Mechanism of Action and Efficacy • Comparison of Biological Activity (B-Cell Killing, T-Cell Activation, and Cytokine Production) of POC Anti-CD20/CD3 TDB Antibody and BTCT4465A with Human and Cyno Peripheral Blood Mononuclear Cells • In Vitro Pharmacologic Activity of Anti-CD20/CD3 TDB Antibody in the Presence of High Concentration of Rituximab-DANA • In Vitro Pharmacologic Activity of Anti-CD20/CD3 TDB Antibody in the Presence of High Concentration of Dexamethasone • In Vitro Evaluation of BTCT4465A (Anti-CD20/CD3 TDB) v0.1 and BTCT4465A v0.2 for Binding Activity to Human and Cynomolgus Monkey B Cells and T Cells • A Single-Dose Efficacy Study of Anti-CD20/CD3 T-Cell-Dependent Bispecific (TDB) Antibody and Non-CD20-Binding TDB Antibody in Human CD20/CD3 Double-Transgenic Mice • Dose Titration of Anti-CD20/CD3 T-Cell--Dependent Bispecific (TDB) Antibody in Depleting Endogenous B Cells in Human CD20/CD3 Double-Transgenic (TG) Mice

		• A Single Dose, Time-Course Efficacy Study with Anti-CD20/CD3 T-Cell--Dependent Bispecific (TDB) Antibody in huCD20/CD3 Double Transgenic Mice • A Repeat-Dose Efficacy Study of Anti-CD20/CD3 T-Cell-Dependent Bispecific (TDB) Antibody in Humanized NSG Mice **4.2.2 Pharmacokinetics** **4.2.2.1 Analytical Methods and Validation Reports** (if separate reports are available) • The Validation History of an ELISA Method for the Quantitation of BTCT4465A (Mosunetuzumab) in Cynomolgus Monkey Serum • The Validation History of an Immunoassay Method for Detection of Antibodies to BTCT4465A (Anti-CD20/CD3 TDB) in Cynomolgus Monkey Serum **4.2.2.8 Other Pharmacokinetic Studies** • Pharmacokinetics and Pharmacodynamics of E. coli- or CHO-Produced Anti-CD20/CD3 TDB Antibody in huCD20/huCD3 Transgenic Mice • A Single Dose Pharmacokinetic and Pharmacodynamic Study of BTCT4465A Administered by Intravenous Injection to Male Cynomolgus Monkeys • A Single Dose Pharmacokinetic Comparability Study of BTCT4465A via Intravenous Administration to Male Cynomolgus Monkeys with a 11-Day Observation Period **4.2.3 Toxicology** **4.2.3.1 Single-Dose Toxicity (in order by species, by route)** • A Single Dose Toxicokinetic, Pharmacodynamic, and Toxicology Study of Anti-CD20/CD3 T-cell Dependent Bispecific Antibody via Intravenous Administration in Male Cynomolgus Monkeys • A Single Dose Toxicokinetic, Pharmacodynamic, and Toxicology Study of Anti-CD20/CD3 T-cell Directed Bispecific Antibody via Intravenous Administration in Male Cynomolgus Monkeys • A Single Dose Toxicokinetic, Pharmacodynamic, and Toxicology Study of BTCT4465A via Intravenous Infusion or Subcutaneous Administration in Cynomolgus Monkeys with a 7-week Recovery Period **4.2.3.2 Repeat-Dose Toxicity (in order by species, by route, by duration, including supportive toxicokinetics evaluations)** • A Multiple Dose Toxicokinetic, Pharmacodynamic, and Toxicology Study of anti-CD3/CD20 T-cell Dependent Bispecific

		Antibody Administered by Intravenous Injection to Cynomolgus Monkeys**.** • A Multiple Dose Toxicokinetic, Pharmacodynamic, and Toxicology Study of anti-CD3/CD20 with or without steroid or Rituximab pretreatment via Intravenous or Subcutaneous Administration in Male Cynomolgus Monkeys • Pilot 28-Day Repeat Dose Intravenous Study of Anti-CD20/CD3 T-cell Dependent Bispecific Antibody using Magnetic Resonance Imaging in the Cynomolgus Monkey • BTCT4465A: 25 Day Intravenous (Infusion) Administration Pilot Toxicity Study in the Monkey • BTCT4465A: 26 Week Multiple Dose Intravenous (Infusion) Administration Toxicity and Toxicokinetic Study in the Cynomolgus Monkey **4.2.3.5 Reproductive and Developmental Toxicity (including range-finding studies and supportive toxicokinetics evaluation) (If modified study designs are used, the following subheadings should be modified accordingly.)** **4.2.3.5.2 Embryo-fetal development** • The Weight-of-Evidence Assessment of Developmental Effects for Mosunetuzumab - for nonUS submission. **4.2.3.7 Other Toxicity Studies (if available)** **4.2.3.7.7 Other** • Tissue Cross-reactivity of BTCT4465A with Human and Select Cynomolgus Monkey Tissues • In Vitro Characterization of the Biological Activities of BTCT4465A in Human PBMCs and the Impact of Low Percentage of Anti-CD3 Homodimers on BTCT4465A Activity
	Module-V Clinical	**Study Design: GO29781** • An Open Label, Multicenter, Phase I/II dose escalation study and expansion study evaluating the Safety, efficacy and tolerability study and Pharmacokinetics of mosunetuzumab as a single agent (and in combination with Tecentriq) in patients with Relapsed or Refractory B Cell Non-Hodgkin's Lymphoma and Chronic Lymphocytic Leukemia. • 447 enrolled into mosunetuzumab IV monotherapy cohorts (Group A and Group B escalation + expansion).

Remarks of Evaluator:

Sr. No.	Observations	Response by the Firm

3.	Observer blind, Phase-III clinical study data are required since submitted clinical trial is an open label, Phase I/II study design. Justification is required.	The firm has submitted that the application for registration of new drug, Lunsumio (mosunetuzumab) 1mg and 30mg concentrate for solution for infusion, is applied on the basis of phase I/II GO29781 study, and same is the basis of approval for this product in the reference regulatory authorities such as USFDA, EMA and Swissmedic. We would like to add that the phase III (CELESTIMO study) trials for this drug are in process as informed by our principal, F. Hoffmann-La Roche Ltd., Basel, Switzerland.
4.	Relationship of product license holder with Basel, Switzerland.	Product Specific Authorization letter has been issued by M/s. F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, CH-4070 Basel Switzerland & the marketing authorization holder is Roche Registration GmbH Emil-Barell-Strasse 1, 79639 Grenzach- Wyhlen, Germany. For this purpose , the firm has submitted a copy of letter indicating relationships among Roch Group of Companies, wherein it has been mentioned M/s F.Hoffmann-La Roche Ltd., Basel Switzerland is the operational headquarter of the Roche Group.

Previous Decision: Registration Board after due discussion decided to defer the case for further deliberation in the next meeting **(M-326)**.

Evaluation by BE&R:

The firm submitted that Lunsumio is a cancer medicine used to treat adults with Follicular lymphoma that does not respond to (refractory) or has come back (relapsed) after at least two previous treatments. ***Follicular lymphoma is a rare disease, and Lunsumio was considered as an 'orphan medicine' (a medicine used in rare diseases) on 16 November 2021 by EMA. Lunsumio is currently approved in US (Dec 2022), EU (June 2022), UK (Oct 2022) and Switzerland (Feb 2023).***

Further submitted that we are enclosing the justification letter received from our principal, F.Hoffman-La Roche Ltd, Basel, Switzerland, to justify the approval of Lunsumio on technical grounds, in the reference regulatory authorities, based on phase I and II clinical trials.

The approval by the SRAs is based on their respective accelerated approval programs where a product is approved after the phase I and II clinical trials. From a public health perspective, Mosunetuzumab represents a chemotherapy-free option with a novel mechanism of action and a favorable benefit-risk profile, and is readily available for treatment. Mosunetuzumab provides meaningful ***Overall Response Rate, Complete Response, Duration of Response,*** while having a ***clinically manageable safety Profile.*** All this is highly welcomed in a patient population that needs new therapies with improved efficacy and safety profile.

Particularly in the US, ***the FDA has introduced expedited programs which are intended to facilitate and expedite development and review of new drugs to address unmet need in the treatment of a serious or Iife threatening condition.*** These programs include fast back designation, breakthrough therapy designation, accelerated approval, and priority review designation. These programs are intended to help ensure that therapies for serious conditions are approved and available to patients as soon as it can be concluded that the therapies' benefits justify their risks. According to part 312, subpart E (21 CFR part 312):

> *"The regulations call for earlier attention to drugs that how promise in treating such conditions, including early consultation with FDA for sponsors of such products and efficient trial design, potentially* ***relying on well-controlled phase 2 studies*** *for evidence of effectiveness. "*

Evaluation by BE&R: The case was presented in 327th meeting of Registration Board wherein the Board decided as under:

"Keeping in view EMA eCPP and product approval in USFDA, EMA and Swissmedic, Registration Board approved the product subject to compliance to the current Import Policy for finished drugs."

However, during compilation of minutes of 327th Board meeting, the case could not be incorporated in the final minutes, hence it is again placed for consideration and endorsement by the Board.

Decision: The Board deliberated the case in the light of decision of 327th meeting of Registration Board and decided to process the issuance of Registration letter to the firm before formal approval of minutes of this meeting.

Imported Human Biological product from non-Reference countries:

29.	Name, address of Applicant / Importer	M/s AMGOMED, Office # 4, First Floor Ghausia Plaza, Jinnah Avenue Blue arejn a Islamabad Pakistan
	Details of Drug Sale License of importer	License No: DSL-002-ICT/2013 Address: Amgomed office # 4, First floor Ghausia Plaza, Jinnah Avenue Blue area Islamabad Address of Godown: Office number 5, First floor Rose-I plaza, I-8 Markaz Islamabad. Validity: 30-01-2024 Status: Drug License by way of Wholesale
	Name and address of marketing authorization holder (abroad)	M/s Gennova Biopharmaceuticals Limited, Block No.1, Plot No. P-1 and P-2, ITBT Park, Phase II, MIDC, Hinjawadi, Pune 411057 Maharashtra state, India.
	Name, address of manufacturer(s)	M/s Gennova Biopharmaceuticals Limited, Block No.1, Plot No. P-1 and P-2, ITBT Park, Phase II, MIDC, Hinjawadi, Pune 411057 Maharashtra state, India.
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**CoPP**: Firm has submitted original CoPP certificate (CoPP/CERT/PD/110860/2022/11/39406/ 191298) dated 02-07-2015 issued by Food & Drug Administration, M.S. Bandra-Kurla Complex, Bandra (E), Mumbai – 400 051, Maharashtra, India. The applied product is available for free sale in the market of exporting country. The facilities and operations conform to WHO-GMP. The CoPP is valid till 14-07-2022.
	Details of letter of authorization / sole agency agreement	The firm submitted notarized letter of authorization whereby M/s Gennova Biopharmaceuticals Limited, India authorized M/s Amgomed to apply for registration, for marketing, distribution and sale of below mentioned product; Hamsyl 3750 IU / 5ml Injection Each 5 ml vial contains: Pegasparagase (Pegylated L-Asparaginase) HIS 3750 IU The authorization letter is valid till 06-05-2022.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	For imported products, specify one the these	☒ Finished Pharmaceutical product import ☐ Bulk import and local repackaging

		☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No. 26085 Dated: 30-07-2018
	Details of fee submitted	PKR 100,000 (Slip number : 0778294)
	Proposed proprietary name / brand name	Hamsyl 3750 IU / 5ml Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 ml vial contains: Pegaspargase (Pegylated L-Asparginase)……..3750 IU
	Pharmaceutical form of applied drug	Solution for IV / IM Administration
	Pharmacotherapeutic Group of (API)	Antineoplastic agents ATC-code: L01XX24
	Finished product specifications	In-house
	Proposed Pack size	1's vial
	Proposed unit price	As per SRO
	Shelf Life	24 months
	Storage Conditions	Store at 2 °C to 8 °C
	The status in reference regulatory authorities	Oncaspar Injection 3,750 IU / 5ml vial of M/s Sigma Tau (USFDA approved).
	For generic drugs (me-too status)	Pegaspargase (Peg-L-Asparaginase of LDS (Reg#105067)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Name, address of drug substance manufacturer	DMF Holder Address: M/s Chanzhou Qianhong Bio-Pharma Co, Ltd., No.192, Huanghe West Road, Xinbei District, Changzhou, Jiangsu, China. Name and Address of the manufacturer: M/s Chanzhou Qianhong Bio-Pharma Co, Ltd., No.192, Huanghe West Road, Xinbei District, Changzhou, Jiangsu, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	Gennova Biopharmaceuticals limited do not intend to store the API manufactured. It is immediately transfer for fill finish activities. Hence formal stability study for Pegaspargase Bulk is not intended as there is no change in the composition of Bulk and Finished product. Its only containerization process. Hence, we have carried out hold time study for bulk and finished product stability study is reflective for API stability

		as well.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted data of Pharmaceutical Equivalence: Hamsyl 3750 IU /5ml Injection and reference product Oncaspar by Sigma Tau Corporation, USA.
	Analytical method validation / verification of product	The firm has submitted relevant data including analytical method validation for the drug product including the impurities.
	Container closure system of the drug product	Pegaspargase Injection is filled in USP Type I Glass vial. One such labelled vial is placed in Plastic Tray and which is packed in Monocarton along with leaflet. Primary packaging materials conform to specifications.
	Stability study data of drug product, shelf life and storage conditions	Real time stability (Long term) studies have been conducted at 5°C ± 3°C for 24 months of 3 batches. Accelerated stability studies is conducted at 25 °C ± 2 °C / 60% ± 5% RH for 6 months of 3 batches. 431401H01 431402H02 431403H03
	Non-Clinical (Module IV)	**Single dose toxicity** Acute Intravenous toxicity study in Swiss Albino mice Acute Intravenous toxicity study in Sprague Dawley rat **Multiple Dose** Subchronic intravenous toxicity study in the Swiss Albino Mouse Subchronic intra venous toxicity study in the Sprague Dawley Rat
	Module V	• A prospective, open label, randomized, active control, parallel design, comparative pharmacokinetics study of intramuscular pegaspargase (Hamsyl) of M/s Gennova Biopharmaceuticals Ltd versus intramuscular Oncaspar in pediatric patients with **relapsed cases** of Acute Lymphoblastic Leukemia (ALL). **Twenty-four** (24) Pediatric patients diagnosed with Acute Lymphoblastic Leukemia (ALL) in relapsed stage enrolled in 1:1 ratio in two arms randomly. • To demonstrate the pharmacokinetic comparability of Hamsyl® (Pegaspargase) compared to Oncaspar® (Pegaspargase) given intramuscularly during induction in patients with ALL therapy. • To compare the immunogenicity and toxicity of Hamsyl® (Pegaspargase) compared to Oncaspar® (Pegaspargase).
Remarks of Evaluator: The submitted original CoPP is not legalized however, the firm has submitted undertaking that we will submit legalized original copy of CoPP after attestation. Meanwhile, we request you to please include our product in DRB meeting.		
Evaluation by BE&R:		

Sr. No.	Decision of 324th meeting	Response by the firm
1.	Submission of Phase I, II, III clinical study data for the proposed indication since already submitted study is a pharmacokinetic comparison of applied product with reference product.	Hamsyl is a pegylated version of native-asparaginase. Hamsyl was approved as an 'Orphan drug' in India in the second line of treatment of relapsed Acute Lymphoblastic Leukemia (ALL). This approval was based on a bioequivalency study (PK) against the reference product (Oncaspar) in patients with ALL in India. The serum asparaginase activity (> 100 IU/L) has been considered as a surrogate marker for efficacy1 and has been used for the approval of asparaginase formulations worldwide. For instance, *Erwinia asparaginase* US-FDA approval was based on the nadir serum asparaginase activity >100 IU/L. Hamsyl was found to be 'Bioequivalent' to Oncaspar. Importantly, both drugs maintained a nadir serum L-asparaginase activity> 100 IU/L. The secondary endpoints of the study included comparison of the L• asparaginase antibodies response profile and changes in L-asparagine and glutamine amino acids levels. No statistically significant differences were observed in the secondary endpoints. Based on these results, Hamsyl was approved and Phase III study was waived off. Hamsyl has been available in India for therapeutic use since 2014. Various independent investigators have published their experience of treatment with Hamsyl as retrospective studies with no new significant concerns.
2.	Details of pharmaceutical comparison with reference product Oncaspar Injection 3750 IU / 5ml.	The firm has submitted comparability evaluation report of Oncaspar (ON3066X2) and Hamsyl injection (3750 IU/vial) for the identified critical quality attributes.
3.	Legalization of CoPP	**CoPP**: Firm has submitted original Legalized CoPP certificate (CoPP/CERT/PD/1108776/2022/11/41643/ 204858) dated 02-07-2015 issued by Food & Drug Administration, M.S. Bandra-Kurla Complex, Bandra (E), Mumbai – 400 051, Maharashtra, India. The applied product is available for free sale in the market of exporting country. The facilities and operations conform to WHO-GMP. The CoPP is valid till 09-07-2025.

Decision: Registration Board decided to refer the case to Pharmacy Services Division for opinion on firm's justification for exemption of Phase III clinical study data.

30.	Name, address of Applicant / Marketing Authorization Holder / Importer	M/s Genetics Pharmaceuticals Pvt. Ltd., 522 Sundar Industrial Estate, Raiwind Road, District Lahore.

	Name, address of Manufacturing site.	M/s Lanzhou Biotechnique Development Co., Limited. Address: 888 Yanchang Road, Lanzhou, Gansu, People's Republic of China.
	Details of Drug Sale License of Importer	**License No.:** 05-352-0065-03297D **Address of go-down:** 522 Sundar Industrial Estate, Lahore Pakistan **Validity:** 12-Dec-2023
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Name of exporting country	China
	Details of Certificates Submitted (Free sale certificate, CoPP, GMP Certificate)	**CoPP:** The firm has submitted valid legalized CoPP (No. Gansu 20220041) issued on 29-09-2022. The CoPP confirms free sale status of the product in the country of origin. GMP Certificate is Valid till: 25-07-2023 DML Validity: 10-06-2023
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 26484 ; Dated: 08-10-2020
	Details of fee submitted	PKR 100,000/, deposit slip no. 2004107, dated 09-09-2020
	Proposed proprietary name / brand name	BTXA 50 Units Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Botulinum Toxin Type A…….50 Units
	Pharmaceutical form of applied drug	IM Injection
	Pharmacotherapeutic Group of (API)	Other muscle relaxants, peripherally acting agents (ATC group: M03AX01)
	Finished product specifications	Chinese Pharmacopoeia
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	Shelf life	36 months
	The status in reference regulatory authorities	**Reference Regulatory Authority:** EMA Botox 50U **of Allergan Pharmaceuticals**
	For generic drugs (me-too status)	**MAH in Pakistan:** Sante (Pvt) Ltd. **Brand name:** BTXA **Strength:** 50 IU **Composition:** Botulinum Toxin Type A **Dosage form:** Intramuscular
	GMP status of the Finished product manufacturer	GMP Certificate is Valid till: 25-07-2023 DML Validity: 10-06-2023
	Name and address of API manufacturer.	**API:** Botulinum Toxin Type A **Name**: M/s Lanzhou Biotechnique Development Co., Limited.,

		Address: 888 Yanchang Road, Lanzhou, Gansu, People's Republic of China.
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted detail of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance (Botulinum Toxin type A).
	Stability studies of Drug Substance	Stability study conditions: This study was conducted to investigate the stability of bulk at 2 ~ 8°C on Day 0, 15, 25, 30, 35, 40 and 50. Three batches of bulk were under studied. Tests performed include toxicity, purity and A260/A280. According to the result showed in section 3.2.S.7.3, the toxicity of bulk - active ingredient of BTXA was stable for at least 45 days at 2 ~ 8°C. The shelf life of bulk is then considered for 45 days at 2 ~ 8°C. Batches: (B-20141007, B-20141001, and B-20141002)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Analytical method validation/verification of product	Method validation studies have submitted including sterility, moisture, identity, potency, endotoxin and pH.
	Description of Pack (Container closure system)	The primary packaging material in contact with product of BTXA is 2mL glass vial and butyl rubber stopper. The packaging materials, which are not in contact with the product, are Aluminum-plastic combined cap, inner label, inner plastic box, package insert and paper box.
	Stability Storage Condition	Three consecutive batches of finished product of botulinum toxin type A 50U were selected for the tests. All finished products are kept in the final packaging material. Numbers of batches under examination are: 50U: 20101202, 20110305, 20110503 **Long term test conditions:** Temperature: 2°C－8°C Testing frequency: 3, 6, 12, 18, 24, 36 months **Accelerated test conditions:** Temperature: 25°C ± 2°C Humidity: 60%RH ± 5%RH

		Testing frequency: Initial, 3, 6 months **High temperature test conditions:** Temperature: 35°C ± 2°C Testing frequency: 15 days **Test conditions after reconstitution:** Temperature: 2°C ─ 8°C Testing frequency: Initial and 4 hours after product reconstitution with normal saline
Non-Clinical and Clinical data		
Module IV		The firm has submitted the Non-Clinical Studies of BTXA (Botulinum Toxin Type A). -Toxicity test on Animal model (monkey) experiments indicated that the LD_{50} of monkey was close to 50 LD_{50} (mouse)/Kg. -Toxicity Test: 0.2 LD_{50} (mouse) Kg was effective for making an artificial antagonistic extraocular muscle in proper order and time. An amount of toxin 10 LD_{50} (mouse) Kg, was given to monkeys, they were still healthy and did not occur any systemic symptom of botulism. So, it could be concluded that the products were good in quality, if a suitable amount were applied under control, they should be very effective preparation for treating some diseases of muscular spasm in human.
Module V		Clinical study including bio-similarity, toxicity and safety in human use, bioavailability study, results of clinical trials and literature references has been submitted. A Double-blind, Randomized, Crossover Study of Prosigne (BTXA) Versus Botox in Patients with Blepharospasm and Hemifacial Spasm. **BTXA which has been produced since 1988 by Lanzhou Biological Products Institute, was approved in 1996 for commercial use in China, It was registered in Brazil in 2003, and is provided through the Brazilian High-Cost Drugs Dispensing Program. Treatment of CD burdens the public health system with considerable expenses, and therefore the comparison of the efficacy and safety of the drugs available is of utmost importance.** Phase I, II and III Clinical Study of Treatment of Strabismus, Entropion, Blepharospasm and Hemi-facial Spasm with BTXA (Botulinum Toxin Type A) for Injection has been performed. **<u>Phase I Study:</u>** Phase I Clinical Study for Treatment of Strabismus, Entropion, Blepharospasm and Hemi-facial Spasm with BTXA (Botulinum Toxin Type A) for Injection **<u>i. Strabismus:</u>** **Efficacy result** This evaluation of efficacy was performed in 10 study subjects, who were injected the study drug, within the guideline set in the protocol, and were observed to elicit correction of eye ball positions. According to efficacy assessment criteria, the total efficacy is 100%. **Safety result** No general side effect was observed.

	Ophthalmic side effects were spontaneously normalized after 1 week. ii**. Entropion:** **Efficacy result** This evaluation of efficacy was performed in 2 study subjects, who were injected the study drug, within the guideline set in the protocol, and were observed to elicit correction of eye lid positions. According to efficacy assessment criteria, the total efficacy is 100%. **Safety result** No any local or general side effect was observed. iii. **Blepharospasm and Hemi-facial Spasm:** **Efficacy result** This evaluation of efficacy was performed in 21 study subjects, who were injected the study drug, within the guideline set in the protocol, and were observed to elicit relief of spasm. According to efficacy assessment criteria, the total efficacy is 100%. **Safety result** No serious general side effect was observed. Mild side effects occur at eyes and faces in 4 cases but spontaneously normalized within 1 to 3 weeks. **Phase II Study:** The Study of evaluation of the efficacy and safety of BTXA (Botulinum Toxin Type A) injection therapy in patients with strabismus, entropion, blepharospasm and hemifacial spasm. i. **Strabismus:** **Efficacy result** This evaluation of efficacy was performed in 27 study subjects, who were injected the study drug, within the guideline set in the protocol, and were observed to elicit correction of eye ball positions. According to efficacy assessment criteria, the total efficacy is 100%. **Safety result** No general side effect was observed. Ophthalmic side effects were spontaneously normalized after 4-8 weeks. ii. **Entropion:** **Efficacy result**: This evaluation of efficacy was performed in 30 study subjects, who were injected the study drug, within the guideline set in the protocol, and were observed to elicit correction of eye lid positions. According to efficacy assessment criteria, the total efficacy is 100%. **Safety result** No general side effect was observed. Ophthalmic side effects were spontaneously normalized after 1-3 weeks. iii. **Blepharospasm and Hemi-facial Spasm:** **Efficacy result** This evaluation of efficacy was performed in 112 study subjects, who were injected the study drug, within the guideline set in the protocol, and were observed to elicit relief of spasm. According to efficacy assessment criteria, the total efficacy is 100%. **Safety result** No serious general side effect was observed. Mild side effects occur at eyes and faces in 4 cases but spontaneously normalized within 2 to 8 weeks. **Phase III Study:** Clinical Study of Treatment of Blepharospasm, Hemi-facial Spasm and Strabismus with BTXA (Botulinum

	Toxin Type A) for Injection. **i. Strabismus:** **Efficacy result** This evaluation of efficacy was performed in 35 study subjects, who were injected the study drug, within the guideline set in the protocol, and were observed to elicit correction of eye ball positions. According to efficacy assessment criteria, the total efficacy is 97.14**%.** **Safety result** No general side effect was observed. Ophthalmic side effects were spontaneously normalized within 2-4 weeks. **ii. Blepharospasm and Hemi-facial Spasm:** **Efficacy result** This evaluation of efficacy was performed in **465 study subjects,** who were injected the study drug, within the guideline set in the protocol, and were observed to elicit relief of spasm. According to efficacy assessment criteria, the total efficacy is 100%. **Safety result** No serious general side effect was observed. Mild side effects occur at eyes and faces in 314 cases but spontaneously normalized within 2 or 3 weeks.

Remarks of Evaluator:

The firm has submitted termination of distribution agreement with Sante Distribution (Pvt) Limited as Follows:
"We, Lanzhou Biotechnique Development Co., Ltd, the manufacturer of BTXA (Botulinum Toxin Type A for Injection), hereby declare to terminate any distribution agreements signed with Sante Distribution (Pvt) Limited. Sante Distribution (Pvt) Limited is no longer authorized to import, sell, market and follow up registration of BTXA (Botulinum Toxin Type A for Injection) in Pakistan."
The evaluation of deficiencies is as under:

Sr. No.	Deficiencies / Short-comings	Reply to Deficiencies / Short-comings
i.	Justify how applied product is similar to innovator product (Botox) which is Onabotulinum approved by USFDA.	• BTXA contains Clostridium Botulinum Toxin Type A. • Clostridium Botulinum Toxin Type A is manufactured by Lanzhou Institute of Technology, China. (3rd in the world after UK & USA manufacturing Therapeutic Botulinum Toxin A i.e. Onabotulinum Toxin A. • Clostridium Toxin Type A (Onabotulinum Toxin A) manufactured by Lanzhou China has similar nomenclature as of Botox manufactured by Allergen Inc, Ireland. • Different comparison of Lanzhou's Clostridium Toxin Type A and Allergen's "Botox" with respect to Similarity, Efficacy and Safety is Available Internationally *(References Attached).*
ii.	Valid Legalized CoPP or Valid legalized FSC + GMP Certificate	**CoPP:** The firm has submitted valid legalized CoPP (No. Gansu 20220041) issued on 29-09-2022. The CoPP confirms free sale status of the product in the country of origin. GMP Certificate is Valid till: 25-07-2023 DML Validity: 10-06-2023
iii.	Valid Drug Sale License (DSL)	**License No.:** 05-352-0065-03297D **Address of go-down:** 522 Sundar Industrial Estate, Lahore Pakistan **Validity:** 12-Dec-2023

iv.	Incorrect information against point "Proposed label (outer(secondary) & inner (Primary) & color scheme in accordance with Drug (Labelling & Packing Rules, 1986 along with specimens" as per Section 1.5.7 of Form 5-F.	Labelling and Packing of BTXA 50IU in accordance with Drug (Labelling & Packing Rules, 1986 along with specimens" as per Section 1.5.7 of Form 5-F.

Evaluation by BE&R:

Sr. No.	Decision of 324th meeting	Response by the firm
1.	Approval status of applied product in reference regulatory authorities adopted by Registration Board in its 275th meeting.	The firm has submitted approval of formulation in MHRA. **Botox 50 Allergen units – powder for solution for Injection.**
2.	Whether applied drug falls in Biological or Medical Device Division in the light of DRAP Act, 2012.	BTXA is therapeutically classified as a neuromuscular paralyzing agent. BTXA falls under the **Biological Section** in the light of DRAP Act.
3.	Indications proposed for the applied product.	BTXA is indicated in the treatment of symptom of disease such as: • Blepharospasm, hemifacial spasm in adults, strabismus which cannot be corrected through operation in the patients 12 years of age and above and strabismus caused by endocrine myopathy. • Pediatric Cerebral Palsy • Chronic migraine (injections may help reduce headache frequency). • Bladder dysfunction (BTXA injections can also help reduce urinary incontinence caused by an overactive bladder). • Eye twitching (BTXA injections may help relieve contracture or twitching of muscles around the eye). • Pediatric upper limb spasticity. • Adult spasticity. • Also indicated in spasmodic torticollis, cervical dystonia, spasticity, cerebral paralysis, muscular rehabilitation, hyperkinetic facial lines, and hyperhidrosis in adults. • In the Treatment of Cervical Dystonia (painful condition, in which neck muscles contract involuntarily causing head to twist or turn into an uncomfortable position), typically may include injection of BTXA into the sternocleidomastoid, levator scapulae, scalene, splenius capitis, and trapezius muscle.

Decision: The Board after thorough deliberation decided to defer the case for approval of applied product from same manufacturer in stringent regulatory authorities adopted by Registration Board in its 275th meeting and also for further deliberation.

31.	Name, address of Applicant / Marketing Authorization Holder / Importer	M/s Genetics Pharmaceuticals Pvt. Ltd., 522 Sundar Industrial Estate, Raiwind Road, District Lahore.
	Name, address of Manufacturing site.	M/s Lanzhou Biotechnique Development Co., Limited. Address: 888 Yanchang Road, Lanzhou, Gansu, People's Republic of China

	Details of Drug Sale License of Importer	**License No.:** 05-352-0065-03297D **Address of go-down:** 522, Sundar Industrial Estate, District Lahore. **Validity:** 12-Dec-2023
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Name of exporting country	China
	Details of Certificates Submitted (Free sale certificate, COPP, GMP Certificate)	**CoPP:** The firm has submitted valid legalized CoPP (No. Gansu 20220041) issued on 29-09-2022. The CoPP confirms free sale status of the product in the country of origin. GMP Certificate is Valid till: 25-07-2023 DML Validity: 10-06-2023
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☒ Domestic sale ☐ Export sale ☐ Domestic and Export sales
	Dy. No. and date of submission	Dy No. 26485 ; Dated: 08-10-2020
	Details of fee submitted	PKR 100,000/, deposit slip no. 2004109, dated 09-09-2020
	The proposed proprietary name / brand name	BTXA 100 Units Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Botulinum Toxin Type A…….100 Units
	Pharmaceutical form of applied drug	IM Injection
	Pharmacotherapeutic Group of (API)	Other muscle relaxants, peripherally acting agents (ATC group: M03AX01)
	Reference to Finished product specifications	Chinese Pharmacopoeia
	Proposed Pack size	1×1's
	Proposed unit price	As per SRO
	Shelf life	36 months
	The status in reference regulatory authorities	**Reference Regulatory Authority:** EMA Botox 100U of M/s Allergan Pharmaceuticals Ireland
	For generic drugs (me-too status)	**MAH in Pakistan:** Barret Hodgson, Pakistan **Brand name:** Botox **Strength: 100** U **Composition:** Botulinum Toxin Type A **Dosage form:** Intramuscular
	GMP status of the Finished product manufacturer	GMP Certificate is Valid till: 25-07-2023 DML Validity: 10-06-2023
	Name and address of API manufacturer.	**API:** Botulinum Toxin Type A **Name**: Lanzhou Biotechnique Development Co., Limited. **Address:** 888 Yanchang Road, Lanzhou, Gansu, People's Republic of China.
	Module-II (Quality Overall Summary)	The firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure,

		general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted.
	Module III (Drug Substance)	The firm has submitted details of nomenclature, structure, general properties, solubility's, physical form, manufacturers, description of manufacturing process and controls, tests for impurity D, G & related substances (impurity A & unspecified), specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance (Botulinum Toxin type A).
	Stability studies of Drug Substance	Stability study conditions: This study was conducted to investigate the stability of bulk at 2 ~ 8°C on Day 0, 15, 25, 30, 35, 40 and 50. Three batches of bulk were under studied. Tests performed include toxicity, purity and A260/A280. According to the result showed in section 3.2.S.7.3, the toxicity of bulk - active ingredient of BTXA was stable for at least 45 days at 2 ~ 8°C. The shelf life of bulk is then considered for 45 days at 2 ~ 8°C. Batches: (B-20141007, B-20141001, and B-20141002)
	Module-III (Drug Product):	The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product.
	Analytical method validation/verification of product	Method validation studies have submitted including sterility, moisture, identity, potency, endotoxin and pH.
	Description of Pack (Container closure system)	The primary packaging material in contact with product of BTXA is 2mL glass vial and butyl rubber stopper. The packaging materials, which are not in contact with the product, are Aluminum-plastic combined cap, inner label, inner plastic box, package insert and paper box.
	Stability Storage Condition	Three consecutive batches of finished product of botulinum toxin type A 50U were selected for the tests. All finished products are kept in the final packaging material. Numbers of batches under examination are: 100U: 20110102, 20110103, 20110104 **Long term test conditions:** Temperature: 2°C－8°C Testing frequency: 3, 6, 12, 18, 24, 36 months **Accelerated test conditions:** Temperature: 25°C ± 2°C Humidity: 60%RH ± 5%RH Testing frequency: Initial, 3, 6 months **High temperature test conditions:** Temperature: 35°C ± 2°C Testing frequency: 15 days **Test conditions after reconstitution:**

		Temperature: 2°C – 8°C Testing frequency: Initial and 4 hours after product reconstitution with normal saline
Non-Clinical and Clinical Data:		
Module IV		The firm has submitted the Non-Clinical Studies of BTXA (Botulinum Toxin Type A). -Toxicity test on Animal model (monkey) experiments indicated that the LD50 of monkey was close to 50 LD50 (mouse)/Kg. -Toxicity Test: 0.2 LD50 (mouse) Kg was effective for making an artificial antagonistic extraocular muscle in proper order and time. An amount of toxin 10 LD50 (mouse) Kg, was given to monkeys, they were still healthy and did not occur any systemic symptom of botulism. So, it could be concluded that the products were good in quality, if a suitable amount were applied under control, they should be very effective preparation for treating some diseases of muscular spasm in human.
Module V		Clinical study including biosimilarity, toxicity and safety in human use, bioavailability study, results of clinical trials and literature references has submitted in CTD Dossier. A Double-blind, Randomized, Crossover Study of Prosigne (BTXA) Versus Botox in Patients with Blepharospasm and Hemifacial Spasm. BTXA which has been produced since 1988 by Lanzhou Biological Products Institute, was approved in 1996 for commercial use in China, It was registered in Brazil in 2003, and is provided through the Brazilian High-Cost Drugs Dispensing Program. Treatment of CD burdens the public health system with considerable expenses, and therefore the comparison of the efficacy and safety of the drugs available is of utmost importance. Phase I, II and III Clinical Study of Treatment of Strabismus, Entropion, Blepharospasm and Hemi-facial Spasm with BTXA (Botulinum Toxin Type A) for Injection has performed. **Phase I Study:** Phase I Clinical Study for Treatment of Strabismus, Entropion, Blepharospasm and Hemi-facial spasm with BTXA (Botulinum Toxin Type A) for Injection i**. Strabismus:** **Efficacy result** This evaluation of efficacy was performed in 10 study subjects, who were injected the study drug, within the guideline set in the protocol, and were observed to elicit correction of eye ball positions. According to efficacy assessment criteria, the total efficacy is 100%. **Safety result** No general side effect was observed. Ophthalmic side effects were spontaneously normalized after 1 week. ii**. Entropion:** **Efficacy result** This evaluation of efficacy was performed in 2 study subjects, who were injected the study drug, within the guideline set in the protocol, and were observed to elicit correction of eye lid positions. According to efficacy

	assessment criteria, the total efficacy is 100%. **Safety result** No any local or general side effect was observed. iii. **Blepharospasm and Hemi-facial Spasm:** **Efficacy result** This evaluation of efficacy was performed in 21 study subjects, who were injected the study drug, within the guideline set in the protocol, and were observed to elicit relief of spasm. According to efficacy assessment criteria, the total efficacy is 100%. **Safety result** No serious general side effect was observed. Mild side effects occur at eyes and faces in 4 cases but spontaneously normalized within 1 to 3 weeks. **Phase II Study:** The Study of evaluation of the efficacy and safety of BTXA (Botulinum Toxin Type A) injection therapy in patients with strabismus, entropion, blepharospasm and hemifacial spasm. i. **Strabismus:** **Efficacy result** This evaluation of efficacy was performed in 27 study subjects, who were injected the study drug, within the guideline set in the protocol, and were observed to elicit correction of eye ball positions. According to efficacy assessment criteria, the total efficacy is 100%. **Safety result** No general side effect was observed. Ophthalmic side effects were spontaneously normalized after 4-8 weeks. ii. **Entropion:** **Efficacy result**: This evaluation of efficacy was performed in 30 study subjects, who were injected the study drug, within the guideline set in the protocol, and were observed to elicit correction of eye lid positions. According to efficacy assessment criteria, the total efficacy is 100%. **Safety result** No general side effect was observed. Ophthalmic side effects were spontaneously normalized after 1-3 weeks. iii. **Blepharospasm and Hemi-facial Spasm:** **Efficacy result** This evaluation of efficacy was performed in 112 study subjects, who were injected the study drug, within the guideline set in the protocol, and were observed to elicit relief of spasm. According to efficacy assessment criteria, the total efficacy is 100%. **Safety result** No serious general side effect was observed. Mild side effects occur at eyes and faces in 4 cases but spontaneously normalized within 2 to 8 weeks. **Phase III Study:** Treatment of Blepharospasm, Hemi-facial Spasm and Strabismus with BTXA (Botulinum Toxin Type A) for Injection. **i. Strabismus:** **Efficacy result** This evaluation of efficacy was performed in 35 study subjects, who were injected the study drug, within the guideline set in the protocol, and were observed to elicit correction of eye ball positions. According to efficacy assessment criteria, the total efficacy is 97.14**%.** **Safety result** No general side effect was observed. Ophthalmic side effects were spontaneously normalized

	within 2-4 weeks. **ii. Blepharospasm and Hemi-facial Spasm:** **Efficacy result** This evaluation of efficacy was performed in 465 study subjects, who were injected the study drug, within the guideline set in the protocol, and were observed to elicit relief of spasm. According to efficacy assessment criteria, the total efficacy is 100%. **Safety result:** No serious general side effect was observed. Mild side effects occur at eyes and faces in 314 cases but spontaneously normalized within 2 or 3 weeks.

Remarks of Evaluator:

The firm has submitted termination of distribution agreement with Sante Distribution (Pvt) Limited as Follows:
"We, Lanzhou Biotechnique Development Co., Ltd, the manufacturer of BTXA (Botulinum Toxin Type A for Injection), hereby declare to terminate any distribution agreements signed with Sante Distribution (Pvt) Limited. Sante Distribution (Pvt) Limited is no longer authorized to import, sell, market and follow up registration of BTXA (Botulinum Toxin Type A for Injection) in Pakistan."

The evaluation of deficiencies is as under:

Sr. No.	Deficiencies / Short-comings	Reply to Deficiencies / Short-comings
i.	Justify how applied product is similar to innovator product (Botox) which is Onabotulinum approved by USFDA.	• BTXA contains Clostridium Botulinum Toxin Type A. • Clostridium Botulinum Toxin Type A is manufactured by Lanzhou Institute of Technology, China. (3rd in the world after UK & USA manufacturing Therapeutic Botulinum Toxin A i.e. Onabotulinum Toxin A. • Clostridium Toxin Type A (Onabotulinum Toxin A) manufactured by Lanzhou China has similar nomenclature as of Botox manufactured by Allergen Inc, Ireland. • Different comparison of Lanzhou's Clostridium Toxin Type A and Allergen's "Botox" with respect to Similarity, Efficacy and Safety is Available Internationally *(References Attached).*
ii.	Valid Legalized CoPP or Valid legalized FSC + GMP Certificate	**CoPP:** The firm has submitted valid legalized CoPP (No. Gansu 20220041) issued on 29-09-2022. The CoPP confirms free sale status of the product in the country of origin. GMP Certificate is Valid till: 25-07-2023 DML Validity: 10-06-2023
iii.	Valid Drug Sale License (DSL)	**License No.:** 05-352-0065-03297D **Address of go-down:** 522 Sundar Industrial Estate, Lahore Pakistan **Validity:** 12-Dec-2023
iv.	Incorrect information against point "Proposed label (outer(secondary) & inner (Primary) & color scheme in accordance with Drug (Labelling & Packing Rules, 1986 along with specimens" as per Section 1.5.7 of Form 5-F.	Labelling and Packing of BTXA 50IU in accordance with Drug (Labelling & Packing Rules, 1986 along with specimens" as per Section 1.5.7 of Form 5-F.

Evaluation by BE&R:

Sr. No.	Decision of 324th meeting	Response by the firm
1.	Approval status of applied product in reference regulatory authorities adopted by Registration Board in its 275th meeting.	The firm has submitted approval of formulation in MHRA. **Botox 50 Allergen units – powder for solution for Injection.**
2.	Whether applied drug falls in Biological or Medical Device Division in the light of DRAP Act, 2012.	BTXA is therapeutically classified as a neuromuscular paralyzing agent. BTXA falls under the **Biological Section** in the light of DRAP Act.
3.	Indications proposed for the applied product.	BTXA is indicated in the treatment of symptom of disease such as: • Blepharospasm, hemifacial spasm in adults, strabismus which cannot be corrected through operation in the patients 12 years of age and above and strabismus caused by endocrine myopathy. • Pediatric Cerebral Palsy • Chronic migraine (injections may help reduce headache frequency). • Bladder dysfunction (BTXA injections can also help reduce urinary incontinence caused by an overactive bladder). • Eye twitching (BTXA injections may help relieve contracture or twitching of muscles around the eye). • Pediatric upper limb spasticity. • Adult spasticity. • Also indicated in spasmodic torticollis, cervical dystonia, spasticity, cerebral paralysis, muscular rehabilitation, hyperkinetic facial lines, and hyperhidrosis in adults. • In the Treatment of Cervical Dystonia (painful condition, in which neck muscles contract involuntarily causing head to twist or turn into an uncomfortable position), typically may include injection of BTXA into the sternocleidomastoid, levator scapulae, scalene, splenius capitis, and trapezius muscle.

Decision: The Board after thorough deliberation decided to defer the case for approval of applied product from same manufacturer in stringent regulatory authorities adopted by Registration Board in its 275th meeting and also for further deliberation.

Cases of Local manufacturing of Human Biological Product

Application of Contract manufacturing by M/s The Searle company limited, Karachi.

DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm have achieved the benchmark of more than **100,000 USD** during the **fiscal Year 2021-2022** and submitted their applications for priority consideration in lieu of export facilitation for Registration Board, please.

32.	Name, address of Applicant / Importer	M/s The Searle Company Limited. F - 319, S.I.T.E, Karachi, Pakistan.

	Status of the applicant	Contract Giver: The Searle Company Limited ☐ Manufacturer ☐ Importer ☐ Bulk Import and Local Repack ☐ Manufacturer ☒ Is involved in none of the above Contract Acceptor: Nextar Pharmaceuticals Pvt. Ltd. ☒ Manufacturer ☐ Importer ☐ Bulk Import and Local Repack ☐ Is involved in none of the above
	Name, address of manufacturer(s)	M/s Nextar Pharma (Pvt) Ltd Plot No. E-58. North Western, Industrial Zone, Port Qasim Karachi.
	GMP of manufacturer & Evidence of Section	The firm M/s Nextar pharma is granted GMP certificate based on inspection conducted on 21-05-2021. The firm has provided **Pre-filled syringe** section issued by licensing vide letter No. F.2-4/2004-Lic dated 29-05-2013.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	Not Applicable Bulk Concentrate Import, Local Formulation Filling (Local Manufacturing)
	Dy. No. and Date of submission	Dy. No. 8780 (R&I) Dated 30-03-2023
	Details of fee submitted	PKR.75,000/- Dated 10-03-2023.
	The proposed proprietary name / brand name	**Adalib Solution for injection 40mg/0.8ml (Pre-filled Syringe)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 0.8ml Pre-filled Syringe contains: Adalimumab……..…40mg
	Pharmaceutical form of applied drug	Solution for Subcutaneous Injection
	Pharmacotherapeutic Group of (API)	Tumor Necrosis Factor alpha (TNF-α) inhibitor ATC Code: L04AB04
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	1's PFS
	Proposed unit price	As per DPC
	Shelf Life	24 Months
	Storage Condition	2°C - 8°C
	The status in reference regulatory authorities	Humira Solution for Injection 40mg/0.8mL (USFDA APPROVED)

	For generic drugs (me-too status)	Pamera 40 Pre-filled syringe of M/s Altimi Biosciences (Reg# 115104)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Name: Hisun Biopharmaceutical Co., Ltd. Address: 8 Haizheng Road, Xukou Town, Fuyang District, Hangzhou City, Zhejiang Province, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis an justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Data as per guidelines of 297th meeting of Registration Board; **i) For Bulk Concentrate Import, Local formulation Filling:**	
	The firm shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	Firm has submitted original legalized GMP Certificate No. (ZJ20190146) issued by National Medical products administration. The certificate is valid till 29.11.2024.
	The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority.	Firm has submitted original legalized CoPP certificate (No.20220061) valid till 12.04.2024 issued by Zhejiang Medical Products Administration for Adalimumab Solution for Injection 40mg/0.8ml. The CoPP specifies that the product is licensed to be placed for use in the exporting country as well as the product is actually in the market of exporting country. The CoPP confirms the GMP status of the manufacturing site through periodic inspection.
	The firm shall provide the lot release certificate of the finished product manufactured by same	Not Applicable

	bulk concentrate/ ready to fill from country of export (If applicable).	
	The firm shall provide the 6 months accelerated and real time stability studies for drug substance.	Firm has submitted stability study data of concentrated bulk drug substance at accelerated and real time conditions. The accelerated stability data is conducted at 5°C ± 3°C for 6 months, and the real time stability data is conducted Under ≤-70°C for 24 months. Batch No: 0201617004 Batch No: 0201617005 Batch No: 0201617006
	The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	**Submitted**
	Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event, immediate mandatory reporting procedure shall be followed.	Firm have submitted undertaking & SOP as detailed in 278th meeting of Registration Board by the local manufacturer.
	The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.	Firm have submitted undertakings as detailed in 297th meeting of Registration Board by the local manufacturer.
	If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.	Firm have submitted undertakings as detailed in 297th meeting of Registration Board by the local manufacturer.
	All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.	Firm have submitted undertaking as detailed in 297th meeting of Registration Board by the local manufacturer.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted bio-similarity studies with innovator product.
	Analytical method validation/verification of product	Firm has submitted details of analytical method validation.
	Container closure system of the drug product	Packed and sealed in pre-fillable 1ml syringe USP Type-I, in UV Laminated board unit carton along with leaflet and plastic plunger.
	Documents for the procurement of API with approval from DRAP	The firm has submitted copy of invoice specifying the import of 36 g of Adalimumab cleared by AD (I&E) DRAP Karachi.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 03 batches. The accelerated stability study data is conducted at 25°C ± 2°C, 60% ± 5% RH for 6 months. The real

		time stability study data is conducted at 5°C±3°C for 6 months. Batch No. / Batch Size / Manufacturing date TADM-001 / 250 PFS / 20-04-2022 TADM-002 / 250 PFS / 20-04-2022 TADM-003 / 250 PFS / 20-04-2022
	Module IV	Detailed in Biosimilarity data mentioned below
	Module V	Detailed in Biosimilarity data mentioned below
	The firm has submitted Bio-similarity data as per following details:	

WHO Biosimilarity	**Data Submitted**
Quality Comparison 1. Physicochemical Characterization	Adalimumab from Hisun Biopharmaceutical Co., Ltd. has been compared with Humira Reference Listed Drug (RLD) The quality attributes of Adalimumab were studied in terms of structural, physicochemical and functional properties.

Primary Structure	**Comparison with RLD**
N-terminal Amino Acid Sequence (Edman)	Consistent with Humira® and theoretical value
C-terminal Amino Acid Sequence (LC-MS/MS)	Consistent with Humira® and theoretical value
Molecular Weight (LC-MS)	Consistent with Humira® and theoretical value
Post-Translational Modifications (LC-MS/MS)	Comparable to Humira®
Reduced Peptide Mapping (LC-MS/MS)	Comparable to Humira®
Non-reduced Peptide Mapping (LC-MS/MS)	Comparable to Humira®
Peptide Coverage (LC-MS/MS)	Comparable to Humira®
Isoelectric point (icIEF)	8.6
Higher-order Structure	**Higher order structure:**
Circular Dichroism	Comparable to Humira®
FT-IR Spectroscopy	Comparable to Humira®
Thermal Stability (DSC)	Comparable to Humira®
Disulfide Bonds (LC-MS/MS	Consistent with Humira® and theoretical value
Free Sulfhydryl Content (Ellman)	HS016: 0.03-0.04 mol/mol Humira®: 0.01-0.03 mol/mol
Glycosylation	**Glycosylation:**

	Glycosylation Site	HS016: Heavy Chain Asn301 Humira®: Heavy Chain Asn301
	Identification of N-Glycan (LC-MS) (HPLC)	Similar to Humira®
	Total Afucosylation (HPLC,%)	HS016:14.39-17.80 Humira®:11.14-12.12 HS016 slight trend toward higher level
	Afucosylation (HPLC,%)	HS016:2.39-2.92 Humira®:1.45-1.86 HS016 slight trend toward higher level
	High Mannose (HPLC,%)	HS016:11.83-15.41 Humira®:9.26-10.08 HS016 slight trend toward higher level
	Galactosylation (HPLC,%)	HS016:11.83-15.41 Humira®:9.26-10.08 HS016 slight trend toward higher level
	Sialylation (HPLC,%)	HS016:13.66-16.04 Humira®:15.05-16.53 HS016 slight trend toward lower level.
Biological Activity	The results of biological activity show that the ADCC activity and CDC activity of HS016 are comparable to that of Humira®, and FcγRIIIa affinities (158V, 158F) and C1q affinity of HS016 are highly similar to that of Humira® (see 8.13, 8.14 and 8.15 for details). It is concluded that the slight differences in N-glycan ratios have no effect on the ADCC activity and CDC activity of HS016. In addition, ADCC activity and CDC activity are not the critical MOA for the proposed indication of HS016, so the risk of affecting clinical efficacy is low.	
	Biological Activity	**Comparison with Reference**
	sTNFα Binding Activity (ELISA, %)	HS016:89-109 Humira®:83-104
	Cell Death Inhibition Activity (L929) (x10^5 AU/mg)	HS016:2.59-3.24 Humira®:2.38-3.36
	Apoptosis Inhibition Activity (U937) (%)	HS016:82.5-111.9 Humira®:88.0-123.0
	Inhibition Activity of TNFα-induced IL-8 (%)	HS016:88.0-114.3 Humira®:85.2-118.5
	tmTNFα Binding Activity (ELISA, %)	HS016:96.3-105.2 Humira®:83.6-100.7
	ADCC (%)	HS016:85.9-116.5 Humira®:79.6-109.7
	CDC (%)	HS016:78.8-110.9 Humira®:85.0-109.7
	Binding Specificity of TNFα	Similar to Humira®
	TNFα Binding Site	Similar to Humira®
	Biological activity and safety of HS016, and is considered as no clinically meaningful differences, and the data submitted support a demonstration that HS016 is highly similar to Humira®.	

Immunochemical properties

TNFα and TNFβ are members of the TNF family. The study determines the binding specificity of human TNFα.

FcγRIIIa is CD16a, which is a kind of transmembrane protein and widely expressed in the activated monocytes, macrophage, NK cells and T cells. FcγRIIIa is a Fc receptor with high affinity to IgG and mainly binds to Fc region of IgG1, IgG3 and IgG4. The 158 locus of FcγRIIIa is polymorphic (F/F, V/V and F/V).

Immunochemical Properties	**Comparison with Reference**
sTNFα Affinity (SPR, pM)	HS016:30.61-50.62 Humira®:36.38-47.23
FcRn Affinity (BLI, nM)	HS016:39-78 Humira®:58-110
FcγRI Affinity (BLI, nM)	HS016:3.4-3.7 Humira®:3.9-5.0
FcγRIIa (H131) Affinity (BLI, nM)	HS016: 6.2-8.0 Humira®5.9-12.0
FcγRIIa (R131) Affinity (BLI, nM)	HS016:5.7-7.9 Humira®:6.3-7.6
FcγRIIIa (158V) Affinity (BLI, nM)	HS016:0.56-1.30 Humira®:0.60-1.10
FcγRIIIa (158F) Affinity (BLI, nM)	HS016:6.4-8.5 Humira®:6.7-11.0
C1q Binding Activity (ELISA, %)	HS016:101-129 Humira®:78-102

The similarity results of immunochemical properties and their correlation with clinical outcomes suggested that HS016 (Adalimumab of Hisun) and Humira have similar immunochemical properties.

Impurities

Product-related Impurities	**Comparison with Reference**
SEC-HPLC	
Purity (%)	HS016:99.5-100.0 Humira®:99.4-99.7
Aggregation (%)	HS016:0.0-0.5 Humira®:0.3-0.5
rCE-SDS	
LC+HC (%)	HS016:98.1-98.8 Humira®: 96.6-98.8
NGHC (%)	HS016:0.9-1.5 Humira®:1.0-1.5
nrCE-SDS	
Purity (%)	HS016:92.6-95.1 Humira®:93.0-97.7
LMW (%)	HS016:4.9-7.4 Humira®:2.3-7.0
RP-HPLC	
Bebofre Major Peak (%)	HS016:1.57-2.03 Humira®:1.76-2.34
Major Peak (%)	HS016:87.88-89.69 Humira®:87.68-89.56
After Major Peak (%)	HS016:9.32-10.04 Humira®:8.49-9.86
Charged Variants (IEC-HPLC)	HS016:78.5-82.8 Humira®:76.8-81.2
Main Peak (%)	HS016:15.0-19.2 Humira®:15.6-18.9
Acidic Peak (%)	HS016: (1.7-2.5) Humira®:2.7-4.3

	Basic Peak (%) Lysine Variants (IEC-HPLC, %) **<u>Process-related Impurities</u>** Host-cell-derived Protein (%) Residual Protein A (%) Residual DNA (pg/40mg)	 HS016:85.5-89.3 Humira®:83.0-85.6 HS016:0.0000364-0.00012 Humira®:0.000100-0.000437 HS016:less than LOQ Humira®:less than LOQ HS016:less than LOQ Humira®:less than LOQ
	The non-reducing CE-SDS chromatogram of HS016 is consistent with that of Humira®. The non-reducing CE-SDS purity and low molecular weight impurities content of HS016 are consistent with that of Humira®. According to the quality range method (Mean±3SD), all HS016 batches have the same quality range in major peak purity, impurities content before major peak and impurities content after major peak as Humira® batches. It is concluded that the major peak purity, impurities content before major peak and impurities content after major peak of HS016 are highly similar to that of Humira®.	
Stability Studies	The firm has submitted stability studies.	
Non-clinical Comparison I. *In-vitro* Studies II. *In-vivo* Studies a) Biological / Pharmacodynamic activity b) Non- clinical Studies	Pharmacology Pharmacokinetics Acute toxicity Repeated-dose toxicity	The Non clinical studies results showed that the affinity with TNF-α, binding specificity with human TNF-α, Inhibition of TNF-α binding to its receptor and Neutralization of TNF- α mediated cytotoxicity, and Preventing Tg 197 mice from inflammation developing model of HS016 were similar to Humira. The PK results showed that compared with HS016 intermediate dose group by single subcutaneous injection, the difference in AUC(0-1008h), CL, Vss, Cmax, $t_{1/2}$ and MRT, was no statistically significant (P>0.05). It was concluded that HS016 appeared similar pharmacokinetic behavior to Humira® in cynomolgus monkeys. The SD rat acute toxicity studies results showed the maximal tolerance dose (MTD) of SD rat should be not less than 1000mg/kg when administered HS016 by subcutaneous injection. Administered 178~400mg/kg HS016 by subcutaneous injection in cynomolgus monkeys, the NOAEL was 267mg/kg. The main toxic reactions were heart rate decreasing, WBC fluctuation and atrophy of thymus. The target organs of the toxic reaction were mainly hematological system (peripheral blood) and immune system (thymus), which was consistent with that reported on Humira in related literature. The repeated-dose toxicity studies results showed that the toxic action and toxic characters of HS016 were similar to the same dose Humira®. HS016 has the similar toxicokinetics characteristics to Humira®. No obvious irritation was observed when administered 10.0~200.0mg/kg HS016 by subcutaneous injection in cynomolgus monkeys. The immunogenicity and toxic action of immune system from HS016 and Humira on cynomolgus monkeys were observed, mainly the generation of specific antibody, increasing of IgG and

		the atrophy of thymus and spleen white pulp, the toxicity was reversible. It was suggested that close attention should be paid in clinical trial.
Clinical Studies	A randomized, double-blind, parallel-controlled **phase I** clinical trial report on pharmacokinetic and safety similarity of single subcutaneous injection of recombinant anti-TNF-α fully human monoclonal antibody injection and Humira® in healthy male subjects. A total of **795 subjects** were screened in this trial, and 661 subjects failed the screening. Among them, 660 subjects failed the screening for not meeting the inclusion and exclusion criteria, and one subject for other reasons (not showing up for screening due to temporary engagement). The subjects 01-177 and 01-192, although not meeting the inclusion and exclusion criteria, were actually administered with drug, so a total of 136 subjects were randomized, with 68 subjects each in HS016 group and Humira® group. All randomized subjects completed the trial. All randomized subjects entered the full analysis set, the pharmacokinetic analysis set, and the safety analysis set. Subjects entered the full analysis set according to randomized group. Since subject 01-046 was randomly assigned to HS016 group but misused Humira®, and subject 01-042 was randomly assigned to Humira® group but misused HS016, they entered the pharmacokinetic analysis set and the safety analysis set according to actually administered drug group. In the single-dose PK contrast test of HS016 and Humira® in healthy male subjects, bioequivalence and pharmacokinetic profile in AUC0-t, AUC0-∞ and Cmax were similar, and safety and immunogenicity were similar in overall. A multicenter, randomized, double-blinded, parallel, active control **Phase III** clinical study to evaluate the efficacy and safety of domestic recombinant anti-tumor necrosis factor-α fully human monoclonal antibody injection (HS016) vs originator drug Humira® subcutaneous injection in active ankylosing spondylitis. A total of 1068 subjects were screened in this study, of which 419 subjects failed, and 649 subjects were randomized. A total of **648 subjects** (99.85%) were treated, of which 416 were in HS016 group and 232 in Humira® group. 570 subjects (87.83%) completed the study, of which 362 (87.02%) were in HS016 group and 208 (89.27%) in Humira® group. 79 subjects prematurely discontinued (including the subject untreated), of which 54 (12.98%) were in HS016 group and 25 (10.73%) in Humira® group. The primary reason for discontinuation was occurrence of adverse event. 30 subjects (7.21%) in HS016 group and 13 subjects (5.58%) in Humira® group discontinued due to adverse event. The efficacy, safety, PK and immunogenicity results supported high comparability between HS016 and originator control drug Humira® for clinical profile, efficacy, safety and immunogenicity in active ankylosing spondylitis.
Remarks	The firm has submitted Declaration letter regarding English name of Manufacturer on GMP certificate: "*We M/s Hisun Biopharmaceutical Co., Ltd located at 8 Haizheng Road, Xukou Town, Fuyang District, Hangzhou City, Zhejiang Province, China hereby declare that the English name "Haizheng Biopharmaceutical Co., Ltd on GMP certification is based on pronunciation of Chinese name. Both Hisun and Haizheng have the same effect in this certification.*"
Decision: Keeping in view the Biosimilarity data submitted by the firm in light of guidelines of 297th meeting, Registration Board approved the registration of Adalib Solution for injection 40mg/0.8ml (Pre-filled Syringe).		

Application of Ready to Fill Bulk Import, Local filling by M/s Macter International Limited, Karachi.

DRAP Authority in its 133rd meeting held on 13th April 2022, decided to grant registration on priority basis i.e one molecule for each 100,000 USD worth of export of medicines (to a maximum of 15 such molecules) during a fiscal year. In compliance to the aforementioned decision of the authority, the following firm have achieved the benchmark of more than **100,000 USD** during the **fiscal Year 2021-2022** and submitted their applications for priority consideration in lieu of export facilitation for Registration Board, please.

33.	Name, address of Applicant / Importer	M/s Macter International Limited. F- 216, S.I.T.E, Karachi 75700, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Bulk Import and Local Repack ☐ Is involved in none of the above
	Name, address of manufacturer(s)	M/s Macter International Limited. F- 216, S.I.T.E, Karachi 75700, Pakistan.
	GMP of manufacturer & Evidence of Section	DML No. 000141 Address: F- 216, S.I.T.E, Karachi 75700, Pakistan. Evidence of section: Liquid and Lyophilized recombinant DNA technology products (biological) section dated 19th July, 2012 GMP: Last GMP conducted on 13-08-2020 valid up to 12-08-2022
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	Not Applicable API Import, Local Formulation Filling (Local Manufacturing)
	Dy. No. and Date of submission	Dy.No. 4861 (R&I) dated 20-02-2022
	Details of fee submitted	PKR.30,000/- (Slip # 10008463700018)
	The proposed proprietary name / brand name	**Seglutide 2mg/1.5ml vial**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains 1.34 mg of semaglutide. (i.e. 2 mg / 1.5 ml per vial)
	Pharmaceutical form of applied drug	Solution for Subcutaneous Injection
	Pharmacotherapeutic Group of (API)	Glucagon-like peptide-1 (GLP-1) analogues ATC Code: A10BJ06
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	1's vial
	Proposed unit price	As per DPC
	Shelf Life	24 Months
	Storage Condition	Store in a refrigerator (2 °C – 8 °C)
	The status in reference regulatory authorities	OZEMPIC (semaglutide) solution for injection 2 mg/1.5 ml

		(USFDA APPROVED)
	For generic drugs (me-too status)	Ozempic by M/S Novo Nordisk Pharma (Private) Limited Karachi (Registration number : 107915)
	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Livzon New North River Pharmaceutical Co., Ltd. Renmin One Road, Qingyuan City, Guangdong Province, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis an justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Data as per guidelines of 278th meeting of Registration Board; **ii) For Bulk Concentrate Import, Local formulation Filling:**	
	The firm shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	GMP Issue Date : June-02-2022 GMP Valid Date : June-01-2024 Firm has submitted the GMP issued by People's Republic of China, Qingyoun City Qingcheng District ShijiaoTow .
	The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority.	Firm has submitted that Issuance of FSC / COPP is not required by country of origin as it is an API, hence COPP/FSC not applicable. Semaglutide has been exported by DS Manufacturer to different countries such as Pakistan, Bangladesh, Vietnam, South Korea, Slovenia etc.
	The firm shall provide the lot release certificate of the finished product manufactured by same bulk	Not Applicable

	concentrate/ ready to fill from country of export (If applicable).	
	The firm shall provide the 6 months accelerated and real time stability studies for drug substance.	Firm has submitted stability study data of concentrated bulk drug substance at accelerated and real time conditions. The accelerated stability data is conducted at 5°C ± 3°C for 6 months, and the real time stability data is conducted Under -20°C ± 5°C for 24 months. Batch No: SM-2101002 Batch No: SM-2101003 Batch No: SM-2103004
	The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	**Submitted**
	Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event, immediate mandatory reporting procedure shall be followed.	Firm have submitted undertaking & SOP as detailed in 278th meeting of Registration Board by the local manufacturer.
	The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.	Firm have submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.
	If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.	Firm have submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.
	All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.	Firm have submitted undertaking as detailed in 278th meeting of Registration Board by the local manufacturer.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence and sameness evaluation studies with innovator product.
	Analytical method validation/verification of product	Firm has submitted details of analytical method validation.
	Container closure system of the drug product	3 ml USP type 1 clear glass vials accompanied with 13 mm slit less siliconized butyl grey rubber stoppers and aluminum flip off seal.
	Documents for the procurement of API with approval from DRAP	The firm has submitted copy of GD, form 6 & invoice specifying the import of 10gram of semaglutide.
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 03 batches. The accelerated stability study data is conducted at 25±2°C, 60%±5% RH for 6 months. The real time

<table>
<tr><td></td><td></td><td>stability study data is conducted at 5°C±3°C for 6 months.

<table><tr><td>Batch No.</td><td>Batch Size</td><td>Manufacturing date</td></tr><tr><td>SEMA-01A</td><td>200 vials</td><td>15-04-2022</td></tr><tr><td>SEMA-02A</td><td>200 vials</td><td>19-04-2022</td></tr><tr><td>SEMA-03A</td><td>200 vials</td><td>21-04-2022</td></tr></table></td></tr>
<tr><td></td><td>Module IV</td><td>Detailed in sameness evaluation mentioned below</td></tr>
<tr><td></td><td>Module V</td><td>Detailed in sameness evaluation mentioned below</td></tr>
<tr><td></td><td colspan="2">The firm has submitted Detailed in sameness evaluation mentioned below data as per following details:</td></tr>
<tr><td colspan="2">Biosimilarity parameters</td><td>Sameness evaluation Data Submitted by M/s Macter International Limited.</td></tr>
<tr><td colspan="2">Quality Comparison
2. Physicochemical Characterization</td><td>Seglutide Injection has been compared with Ozempic inj Reference Listed Drug (RLD)
The quality attributes characterize biological products in terms of structural, physicochemical and functional properties.
A. Primary sequence and physicochemical properties
B. Secondary structure
C. Oligomer/aggregation states
D. Biological activities (by in vitro or animal studies)
Sameness studies
1. Structural comparison
Following robust characterization of drug substance and drug product proves the sameness of Seglutide with RLD.
<u>Primary Structure</u>:
• Complete peptide sequence analysis by mass spectrometry
• Peptide mapping
• Peptide coverage map
• N terminal sequence analysis
• Molecular weight by high resolution mass spectrometry
<u>Secondary Structure</u>:
• IR Spectrum
• UV absorption
See Annex 6.7
2. Quality:
• Chiral analysis
• Elemental analysis
• Capillary isoelectric focusing
• Physiochemical properties
• Hygroscopicity
• <u>Comparative testing of Seglutide with RLD</u>
• Identification by RP HPLC
• Related Substances by RP HPLC
• Identification and molecular weight determination bybTris Tricine SDS – Page
• Protein content & Binding assay by ELISA
• Determination of HMW proteins by Size Exclusion Chromatography
• Determination of Specific activity</td></tr>
</table>

Biological Activity	Biological bioactivity
	A. <u>Animal studies (Mutagenicity testing):</u>
	Development of structural alerts for the In vivo micronucleus assay in rodents.
	
	Comparative studies done by Macter:
	• Drug Substance:
	  • Physical appearance
	  • Water Content
	  • Assay
	  • RP HPLC
	  • Specific bioactivity
	  • Identification
	  • RP-HPLC
	  • Peptide mapping
	  • Tris Tricine SDS PAGE
	  • Purity
	  • High molecular weigh proteins
	  • Related Substances
	  • Residual Solvents
	  • N,N – Dimethyl formamide
	  • Tetrahydrofuran
	  • Dichloromethane
	  • Ethanol
	  • N,N disopropylethylamine
	  • Safety
	  • BET
	  • Microbial Limits
	  • Aerobic count
	  • Yeast & mould count
	  • Escherichia Coli

Immunochemical properties	

Impurities	<u>Impurity Profile</u>
	• Peptide-related impurities
	  • Hydrophilic and hydrophobic impurities
	• High molecular weight protein impurities
	• Process related impurities
	  • HCP & HCDNA
	• Intermediate residue and reaction by products
	• Inorganic and ion impurities
	• Residual solvents
	• Elemental impurities
	• Genotoxic impurity
	• Residual host cell DNA
	• Nitrosamine impurities
	  • By process
	  • By contamination
	  • By degradation
	  • By packing material
	  • Antibiotic residues
	  • Degradation impurities
	  • Isomeric
	  • Dipeptide+oxidative impurities
	  • Isomer & hydrolytic impurities.
	  • High Temperature and high humidity degradation.

Stability Studies	The firm has submitted stability studies.
Non-Clinical studies	Not submitted
Clinical Studies	Not submitted

Evaluation by BE&R:

Sr. No.	Deficiencies	Response by the firm
1.	The submitted commercial invoice for the import of Semaglutide is not cleared by assistant director (I & E) of respective field office.	System generated Form 6 and Good Declaration Certificate attached.
2.	Provide result of all quality parameter in comparative analysis of developed formulation with innovator product as the submitted report comprises of reduced testing.	The firm has submitted comparative analysis of test product with innovator Ozempic (Batch# MP5A069) has been carried out on following parameters and all satisfactory results indicate that our product resemble to Innovator product. The parameters include Dosage form, Strength, Route of administration, Physical Appearance, pH, Particulate Matter, Identification by HPLC, Molecular Wight (SDS PAGE), Assay by RP HPLC, Specific Activity by Biological Assay, Protein content by ELISA, Phenol Content, Impurities (Hydrophilic Impurities, Hydrophobic Impurities, Total impurities), Aggregates (high molecular weight proteins), Sterility test, Endotoxin test.
3.	Justify container closure system of USP type I clear glass vial while innovator product Ozempic is packaged in multi dose cartridge single patient pen injector.	Product contact parts in both cases are same i.e. Class 1 clear glass in cartridge used in RLS and same class 1 glass vial is used in Seglutide. Stability studies indicate no interaction of primary packing with product.
4.	Submit legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate /ready to fill bulk of biological drug to Pakistani manufacturer for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	Direct link of GMP inspection report of national regulatory authority of exporting country is provided of the drug substance manufacturer.
5.	Submit legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to concerned authority.	Issuance of FSC / COPP is not required by country of origin as it is an API, hence COPP/FSC not applicable. Semaglutide has been exported by DS Manufacturer to different countries such as Pakistan, Bangladesh, Vietnam, South Korea, Slovenia etc.
6.	Submit the complete Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill) manufactured either from country of origin or by any reference regulatory authority as adopted by Registration Board to demonstrate the bio-similarity	Following criteria of sameness evaluation has been used. Detailed report is attached. A. Primary sequence and physicochemical properties B. Secondary structure C. Oligomer/aggregation states D. Biological activities (by in vitro or animal studies <u>Semaglutide is not a protein by the definition of USFDA. It is a peptide.</u>

		Bio-similarity applies to large complex biomolecules owing to the size and complexity of molecules which has primary, secondary/ tertiary and quaternary structures which cannot be fully elucidated by analytical means that's why clinical evidences are required to prove the efficacy and safety. Biosimilarity applies mostly to protein based therapeutics. 21 CFR 600.3(h)(6) defines a protein is any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size. (Annex 5. page 2, para 2) <u>Semaglutide is peptide which is included in complex APIs & complex product</u> Semaglutide which is comprised of 31 amino acids (less than 40) is not a protein is categorized as complex API and due to complex active and drug product containing small peptide is defined ad complex product. (Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA, Guidance for Industry issued in October 2022). (see Annex 7, page 3 para 2). <u>Waiver of *In-vivo* bioequivalence by **USFDA** product specific guideline</u> Product Specific Guideline on Semaglutide (annex 6.1) has described the conditions to qualify for submitting an waiver of in vivo bioequivalence (BE) study on the basis that BE is self-evident under 21 CFR 320.22(b (annex 6.2)), a generic Semaglutide subcutaneous solution for injection product should qualitatively (Q1) and quantitatively (Q2) be the same as the Reference Listed Drug (RLD).
7.	Provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export	Not applicable.
8.	Submit justification for not performing all test mentioned on Certificate of analysis	Complete analysis has been performed on following parameters. **Comparative COA is attached**
9.	Provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	Agreement with DS manufacturer has been attached

Decision: Registration Board after thorough deliberation decided to deffer for the documents/information as under:

• **The firm shall submit evidence (legalized FSC/CoPP/Registration certificate) of finished product manufactured by same concentrate/ready to fill bulk. either from country of origin or by any reference regulatory authority as adopted by Registration Board**		
34.	Name, address of Applicant / Importer	M/s Macter International Limited. F- 216, S.I.T.E, Karachi 75700, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Bulk Import and Local Repack ☐ Is involved in none of the above
	Name, address of manufacturer(s)	M/s Macter International Limited. F- 216, S.I.T.E, Karachi 75700, Pakistan.
	GMP of manufacturer & Evidence of Section	DML No. 000141 Address: F- 216, S.I.T.E, Karachi 75700, Pakistan. Evidence of section: Liquid and Lyophilized recombinant DNA technology products (biological) section dated 19th July, 2012 GMP: Last GMP conducted on 13-08-2020 valid up to 12-08-2022
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒ Domestic and Export sales
	For imported products, specify one the these	Not Applicable API Import, Local Formulation Filling (Local Manufacturing)
	Dy. No. and Date of submission	Dy.No. 4862 (R&I) dated 20-02-2022
	Details of fee submitted	PKR.30,000/- (Slip # 10008463700018)
	The proposed proprietary name / brand name	**Seglutide 4mg/3ml vial**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains 1.34 mg of semaglutide. (i.e. 4 mg / 3 ml per vial)
	Pharmaceutical form of applied drug	Solution for Subcutaneous Injection
	Pharmacotherapeutic Group of (API)	Glucagon-like peptide-1 (GLP-1) analogues ATC Code: A10BJ06
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	1's vial
	Proposed unit price	As per DPC
	Shelf Life	24 Months
	Storage Condition	Store in a refrigerator (2°C – 8°C)
	The status in reference regulatory authorities	OZEMPIC (semaglutide) solution for injection 4 mg/3ml (USFDA Approved)
	For generic drugs (me-too status)	Ozempic by M/S Novo Nordisk Pharma (Private) Limited Karachi (Registration number : 107914)

	Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD. Firm has summarized information related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, Characterization (Elucidation of Structure and Other Characteristics), impurities, specifications, analytical procedures, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product.
	Name, address of drug substance manufacturer	Livzon New North River Pharmaceutical Co., Ltd. Renmin One Road, Qingyuan City, Guangdong Province, China.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis an justification of specification, reference standard, container closure system and stability studies of drug substance.
	Module-III Drug Product:	Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability.
	Data as per guidelines of 278th meeting of Registration Board; **iii) For Bulk Concentrate Import, Local formulation Filling:**	
	The firm shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	GMP Issue Date : June-02-2022 GMP Valid Date : June-01-2024 Firm has submitted the GMP issued by People's Republic of China, Qingyoun City Qingcheng District ShijiaoTow .
	The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority.	Firm has submitted that Issuance of FSC / COPP is not required by country of origin as it is an API, hence COPP/FSC not applicable. Semaglutide has been exported by DS Manufacturer to different countries such as Pakistan, Bangladesh, Vietnam, South Korea, Slovenia etc.
	The firm shall provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (If applicable).	Not Applicable
	The firm shall provide the 6 months accelerated and real time stability studies for drug substance.	Firm has submitted stability study data of concentrated bulk drug substance at accelerated and

<table>
<tr><td></td><td></td><td>real time conditions. The accelerated stability data is conducted at 5°C ± 3°C for 6 months, and the real time stability data is conducted Under -20°C ± 5°C for 24 months.
Batch No: SM-2101002
Batch No: SM-2101003
Batch No: SM-2103004</td></tr>
<tr><td></td><td>The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.</td><td>Submitted</td></tr>
<tr><td></td><td>Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event, immediate mandatory reporting procedure shall be followed.</td><td>Firm have submitted undertaking & SOP as detailed in 278th meeting of Registration Board by the local manufacturer.</td></tr>
<tr><td></td><td>The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule.</td><td>Firm have submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.</td></tr>
<tr><td></td><td>If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.</td><td>Firm has submitted undertakings as detailed in 278th meeting of Registration Board by the local manufacturer.</td></tr>
<tr><td></td><td>All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.</td><td>Firm have submitted undertaking as detailed in 278th meeting of Registration Board by the local manufacturer.</td></tr>
<tr><td></td><td>Pharmaceutical Equivalence and Comparative Dissolution Profile</td><td>Firm has submitted Pharmaceutical Equivalence and sameness evaluation studies with innovator product.</td></tr>
<tr><td></td><td>Analytical method validation/verification of product</td><td>Firm has submitted details of analytical method validation.</td></tr>
<tr><td></td><td>Container closure system of the drug product</td><td>3 ml USP type 1 clear glass vials accompanied with 13 mm slit less siliconized butyl grey rubber stoppers and aluminum flip off seal.</td></tr>
<tr><td></td><td>Documents for the procurement of API with approval from DRAP</td><td>The firm has submitted copy of GD, form 6 & invoice specifying the import of 10gram of semaglutide.</td></tr>
<tr><td></td><td>Stability study data of drug product, shelf life and storage conditions</td><td>Firm has submitted stability study data of 03 batches. The accelerated stability study data is conducted at 25±2°C, 60%±5% RH for 6 months. The real time stability study data is conducted at 5°C±3°C for 6 months.
<table><tr><td>Batch No.</td><td>Batch Size</td><td>Manufacturing date</td></tr></table></td></tr>
</table>

		SEMA-01B | 200 vials | 26-04-2022 SEMA-02B | 200 vials | 27-04-2022 SEMA-03B | 200 vials | 28-04-2022
	Module IV	Detailed in sameness evaluation mentioned below
	Module V	Detailed in sameness evaluation mentioned below
	The firm has submitted Detailed in sameness evaluation mentioned below data as per following details:	

WHO Biosimilarity Guidelines	**sameness evaluation** **Data Submitted by M/s Macter International Limited.**
Quality Comparison 3. Physicochemical Characterization	Seglutide Injection has been compared with Ozempic inj Reference Listed Drug (RLD) The quality attributes characterize biological products in terms of structural, physicochemical and functional properties. E. Primary sequence and physicochemical properties F. Secondary structure G. Oligomer/aggregation states H. Biological activities (by in vitro or animal studies) **Sameness studies** **3. Structural comparison** Following robust characterization of drug substance and drug product proves the sameness of Seglutide with RLD. Primary Structure: • Complete peptide sequence analysis by mass spectrometry • Peptide mapping • Peptide coverage map • N terminal sequence analysis • Molecular weight by high resolution mass spectrometry Secondary Structure: • IR Spectrum • UV absorption See Annex 6.7 **4. Quality**: • Chiral analysis • Elemental analysis • Capillary isoelectric focusing • Physiochemical properties • Hygroscopicity • Comparative testing of Seglutide with RLD • Identification by RP HPLC • Related Substances by RP HPLC • Identification and molecular weight determination bybTris Tricine SDS – Page • Protein content & Binding assay by ELISA • Determination of HMW proteins by Size Exclusion Chromatography • Determination of Specific activity
Biological Activity	Biological bioactivity B. Animal studies (Mutagenicity testing): Development of structural alerts for the In vivo micronucleus assay in rodents. Comparative studies done by Macter: • Drug Substance: • Physical appearance • Water Content

	• Assay
	  • RP HPLC
	  • Specific bioactivity
	• Identification
	  • RP-HPLC
	  • Peptide mapping
	  • Tris Tricine SDS PAGE
	• Purity
	  • High molecular weigh proteins
	  • Related Substances
	• Residual Solvents
	  • N,N – Dimethyl formamide
	  • Tetrahydrofuran
	  • Dichloromethane
	  • Ethanol
	  • N,N disopropylethylamine
	• Safety
	  • BET
	• Microbial Limits
	  • Aerobic count
	  • Yeast & mould count
	  • Escherichia Coli

Immunochemical properties	Not submitted.

Impurities	Impurity Profile
	• Peptide-related impurities
	  • Hydrophilic and hydrophobic impurities
	• High molecular weight protein impurities
	• Process related impurities
	  • HCP & HCDNA
	• Intermediate residue and reaction by products
	• Inorganic and ion impurities
	• Residual solvents
	• Elemental impurities
	• Genotoxic impurity
	• Residual host cell DNA
	• Nitrosamine impurities
	  • By process
	  • By contamination
	  • By degradation
	  • By packing material
	  • Antibiotic residues
	  • Degradation impurities
	  • Isomeric
	  • Dipeptide+oxidative impurities
	  • Isomer & hydrolytic impurities.
	  • High Temperature and high humidity degradation.

Stability Studies	The firm has submitted stability studies.
Non-clinical Studies	Not submitted
Clinical Studies	Not Submitted

Evaluation by BE&R:

Sr. No.	Deficiencies	Response by the firm

1.	The submitted commercial invoice for the import of Semaglutide is not cleared by assistant director (I & E) of respective field office.	System generated Form 6 and Good Declaration Certificate attached.
2.	Provide result of all quality parameter in comparative analysis of developed formulation with innovator product as the submitted report comprises of reduced testing.	The firm has submitted comparative analysis of test product with innovator Ozempic (Batch# MP5A069) has been carried out on following parameters and all satisfactory results indicate that our product resemble to Innovator product. The parameters include Dosage form, Strength, Route of administration, Physical Appearance, pH, Particulate Matter, Identification by HPLC, Molecular Wight (SDS PAGE), Assay by RP HPLC, Specific Activity by Biological Assay, Protein content by ELISA, Phenol Content, Impurities (Hydrophilic Impurities, Hydrophobic Impurities, Total impurities), Aggregates (high molecular weight proteins), Sterility test, Endotoxin test.
3.	Justify container closure system of USP type I clear glass vial while innovator product Ozempic is packaged in multi dose cartridge single patient pen injector.	Product contact parts in both cases are same i.e. Class 1 clear glass in cartridge used in RLS and same class 1 glass vial is used in Seglutide. Stability studies indicate no interaction of primary packing with product.
4.	Submit legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate /ready to fill bulk of biological drug to Pakistani manufacturer for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin.	Direct link of GMP inspection report of national regulatory authority of exporting country is provided of the drug substance manufacturer.
5.	Submit legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to concerned authority.	Issuance of FSC / COPP is not required by country of origin as it is an API, hence COPP/FSC not applicable. Semaglutide has been exported by DS Manufacturer to different countries such as Pakistan, Bangladesh, Vietnam, South Korea, Slovenia etc.
6.	Submit the complete Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill) manufactured either from country of origin or by any reference regulatory authority as adopted by Registration Board to demonstrate the bio-similarity	Following criteria of sameness evaluation has been used. Detailed report is attached. E. Primary sequence and physicochemical properties F. Secondary structure G. Oligomer/aggregation states H. Biological activities (by in vitro or animal studies <u>Semaglutide is not a protein by the definition of USFDA. It is a peptide.</u> Bio-similarity applies to large complex biomolecules owing to the size and complexity of molecules which has primary, secondary/ tertiary and quaternary structures which cannot be fully elucidated by analytical means that's why clinical

		evidences are required to prove the efficacy and safety. Biosimilarity applies mostly to protein based therapeutics. 21 CFR 600.3(h)(6) defines a protein is any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size. (Annex 5. page 2, para 2) <u>Semaglutide is peptide which is included in complex APIs & complex product</u> Semaglutide which is comprised of 31 amino acids (less than 40) is not a protein is categorized as complex API and due to complex active and drug product containing small peptide is defined ad complex product. (Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA, Guidance for Industry issued in October 2022). (see Annex 7, page 3 para 2). <u>Waiver of *In-vivo* bioequivalence by **USFDA** product specific guideline</u> Product Specific Guideline on Semaglutide (annex 6.1) has described the conditions to qualify for submitting an waiver of in vivo bioequivalence (BE) study on the basis that BE is self-evident under 21 CFR 320.22(b (annex 6.2)), a generic Semaglutide subcutaneous solution for injection product should qualitatively (Q1) and quantitatively (Q2) be the same as the Reference Listed Drug (RLD).
7.	Provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export	Not applicable.
8.	Submit justification for not performing all test mentioned on Certificate of analysis	Complete analysis has been performed on following parameters. **Comparative COA is attached**
9.	Provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents.	Agreement with DS manufacturer has been attached

Decision: Registration Board after thorough deliberation decided to deffer for the documents/information as under:

- **The firm shall submit evidence (legalized FSC/CoPP/Registration certificate) of finished product manufactured by same concentrate/ready to fill bulk. either from country of origin or by any reference regulatory authority as adopted by Registration Board**

Imported Veterinary Biologicals from Non-Reference Countries:

35.	**Name, address of applicant / Importer**	M/s Huzaifa International, Commercial area, Aziz Bhatti Town, Sargodha.

DSL details	License to sell drugs as a distributor, DSL No. 08-384-0120-022405D,valid till . 20th November 2023
Name of Manufacturer	M/s Komipharm International Co., Ltd. Address:17, Gyeongje-Ro, Siheung-Si, Gyeonggi-Do, South Korea [Before Address System CHange: 1236-6, Chongwang-Dong, Shihung-Si, Kyonggi-Do, South Korea]
Brand Name +Dosage Form + Strength	**PRO-VAC™ IBD Plus**
Composition	Each dose contains Infectious Bursal Disease Virus (K7 strain)……. Min. $10^{2.5}EID_{50}$
Finished product specifications	Ph. Eur. specifications
Pharmacological Group	Poultry Vaccine
Shelf life	15 months (When stored at 2°C - 8°C)
Products already registered in Pakistan	Not confirmed
Type of Form Dy No & Date of application, Fee submitted	Form 5-A DyNo.4914 dated 05-08-2015 Rs.100,000/-; 05-08-2015
Demanded Price / Pack size	Decontrolled/ 1000 doses vial
General documentation	***Original Legalized Free Sale Certificate (FSC):*** **Issued by:** Animal and Plant Quarantine Agency of the Ministry for Agriculture Food and Rural Affairs of the Republic of Korea **Issued on:** 30-09-2014 **valid upto** 30-09-2019 ***Original Legalized GMP Certificate:*** • **Issued by:** As mentioned above • **Issued on:**19-06-2018.

The case was deferred in 264th meeting of Registration Board & the board decided as under;

Deferred for evaluation by Dr. Qurban Ali, Member Registration Board.

Now the expert opinion of Dr. Qurban Ali, member Registration Board has been received on **17-08-2022** to the Director Biological Drugs via email which is reproduced as under;

Infectious bursal disease (IBD), also known as Gumboro disease is a highly contagious, immunosuppressive disease of young chickens and is responsible for major economic losses in the poultry industry worldwide. IBD virus (IBDV) is a double-stranded RNA virus, having two serotypes (1 and 2) with only serotype 1 causing the disease in young chickens. The virus infects the bursa of Fabricius causing immunosuppression that enhances the susceptibility of chicken to other infections and interferes with vaccination against other diseases.

The IBDV is highly resistant virus and tends to persist in the farm environment despite strict hygiene measures. Therefore immunization is considered the most important measure to control IBD; where protective immunity in birds depends on inducement of both humoral and cell-mediated immune responses; however, rampant usage of live vaccines worldwide has resulted in the evolution of new strains antigenic variants and very virulent strains (vvIBDV) resulting into significant losses and high mortality in chicken, and virus continuously evolving in the field with changes in antigenicity and virulence necessitating the development and use of newer vaccines with improved efficacy.

Most commercially available conventional live IBDV vaccines are based on classical virulent strains. Those classified as mild, intermediate and ''intermediate plus (or hot) vaccines. IBD-K7 was isolated in 2007 from Seonghwan, Chungnam, Korea, which was later fully characterized, sequenced, patented and deposited in 2013 with the accession number KCTC 12376BP to the Gene Bank of Korea Biotechnology Institute (Yeoseong-gu, Daejeon, Korea) as an international depositing institution. The virus was taken as vaccine candidate and translated into live intermediate IBD Vaccine fulfilling all requirements of production and

testing. Studies found IBD K7 as a novel recombinant virus compared to existing viruses with some of the virogenic viral antigen properties, besides showing better immunogenicity than the mid-dose vaccine D-78 and no significant difference from the mid-dose plus vaccine of Winterfield strain. The product is lyophilized, dispensed with adjuvant, stabilizers, preservatives and diluent for use. The product can be administered as injection (i/m or s/c) or use in drinking water/ spray vaccination from at day one; where virus strain used has low virulence and higher immunogenicity than intermediate IBD vaccines.

*From afore going, vaccine **from IBD K7 strain is recommended for registration** to enhance repertoire of veterinarians for control of a difficult disease of IBD.*

Remarks of Evaluator: Free Sale certificate is expired on 30-09-2019 which was valid at the time of submission.

Previous Decision: Registration Board referred the case to Animal Husbandry Commissioner for comments regarding immunological relevance and need of applied strain in Pakistan **(M-320)**.

Evaluation by BE&R: Ministry of National Food Security and Research has conveyed vide letter F.No.3-1/84-D&V dated 19th April, 2023 that this Ministry recommends import of **Pro-Vac IBD Plus (K7 Strain $10^{2.5}$ EID_{50})** from Komipharm International Co., Ltd South Korea to cater the national needs subject to fulfillment of all codal formalities.

Decision: On the recommendations of Ministry of National Food Security and Research vide its letter F.No.3-1/84-D&V dated 19th April, 2023, the Registration Board after discussion approved the registration of Pro-Vac IBD Plus (K7 Strain $10^{2.5}$ EID_{50}) from Komipharm International Co., Ltd South Korea .

Transfer of Registration from M/s Eli Lilly Pakistan (Pvt) Limited Karachi to M/s Golden Harvest, Karachi

M/s Golden harvest, Karachi applied for registration of following veterinary biologicals in their name from M/s Eli Lilly Pakistan (Pvt.) Ltd., Karachi:

36.	**Name, address of applicant / Importer**	**M/s Golden Harvest,** Address: Plot No. 49-C, 24th Commercial Street Phase-II Extt: DHA, Karachi.
	DSL details	License to sell drug as distributor No. 054 valid till 26-02-2023
	Name of Manufacturer	**Lohmann Animal Health** Heinz-Lohmann-StraBe 4, 27472 Cuxhaven, Germany
	Name of exporting country	Germany.
	Brand Name +Dosage Form + Strength	Avipro Salmonella DUO
	Diary No. Date of R& I & fee	Dy. No. 2542 (R&I); Dated 21-01-2021 Rs.100,000 (Slip No.0711592)
	Composition	Composition per dose: 1 dose contains Each dose contains: Live Salmonella Enteritidis bacteria, strain Sm24/Rif12/Ssq, At least 1 x 10^8.0 CFU* Live Salmonella Typhimurium bacteria, strain Nal2/Rif9/Rtt, At least 1 x 10^8.0 CFU* *CFU = Colony Forming Units
	Pharmacological Group	Live Freeze dried bacterial veterinary vaccine
	Type of Form	Form-5A
	Finished Product Specification	Ph. Eur. Specification
	Shelf Life	18 months (2°C-8°C)
	Pack size and demanded price	10 × 2000 dose vial / Decontrolled
	International availability	Germany, EU, UK.

Products already registered in Pakistan	Avipro Salmonella DUO is already registered in Pakistan as an innovative product with Reg no**. 083177**.
Stability data of finished product	The firm has submitted stability study data of 26 months conducted at 2°C to 8°C for three consecutive batches as below: 200308-1C 200312-2C 200401-3C
Document Details	• Legalized Free Sale Certificate No. 048/LAH/2020.issued by State Office for Consumer Protection and Food Safety, Germany (Niedersächsisches Landesamt für Verbraucherschutz und Lebensmittelsicherheit) Dated: 10/08/2020 • Legalized GMP Certificate No.075/LAH/2018 Dated: 23 Feb 2018.

Remarks of Evaluator
Valid copy of Drug sale license is required to be submitted.

Sr. No.	**Decision of 317th meeting of RB**	**Response by the firm**
1.	Original termination letter from manufacturer abroad for previous importer.	Original Letter of Termination dated 11/03/22 submitted by Firm
2.	Valid legalized approval of 21 months shelf life issued by regulatory authority of country of origin.	The firm has submitted revised Form 5A with correct shelf life for 18 months' shelf life which can be verified from online database of Germany.
3.	Real time stability data for both products including all the parameters as mentioned in finished product specifications. Only test for bacterial counts and residual moisture (%) have been provided. While as per CoA four tests are performed, i.e. identification of active substance, viable testing, purity test and residual moisture.	The firm has submitted an Explanation Letter regarding the vaccine AviPro Salmonella DUO: According to our previous explanation in the stability justification letter on March 12, 2022, the provisions that are taken in the account regarding veterinary vaccines in the European Union (EU), Germany, are the ones defined in monograph no. 62 of the European Pharmacopoeia (EP), section 2-2-3-Stability. *"For a live freeze-dried bacterial veterinary vaccine like the one we are dealing with, the bacterial counts and residual moisture testing are the parameters to be studied, and both have been tested in the provided stability trial.* *Monitoring all the parameters defined in batch release (CoA) is not a common practice as per se it has not added value. Only monitoring the parameters that may change and therefore influence on the quality and shelf-life of a veterinary vaccine are the ones to be controlled."* Having said that, regarding the 4 parameters mentioned by the Board: identification of active substance viable testing

			purity test residual moisture Viable testing (which are the bacterial count test) and residual parameters were assayed in the stability trial. In relation to the identification of the active substance, this a bivalent live bacterial vaccine composed by *Salmonella* Enteritidis and *Salmonella* Tiphymurium. *The full identification profile was done at batch release.* The characteristics to identify these 2 *Salmonella* serotypes do not change over time. Chemically-defined substances may change over time, but, for bacteria, if grown during shelf-life (confirmed by the viable bacterial count), they do not change its identity and therefore it does not need to be reconfirmed. In relation to purity, this test was also carried out at batch release. Once purity is confirmed, the vaccine is already manufactured, so filled in, freeze-dried and sealed. The vial is no longer manipulated and therefore it cannot be (re-contaminated). This is why purity is another parameter that does not need to be reconfirmed. To summarize, we would like to highlight that the 4 parameters the 2 critical ones (already mentioned in the EP) were carried out in the trial, and the 2 other ones were duly checked at batch release, are not susceptible to change over time and cannot influence shelf-life."
	Previous Decision: Registration Board decided to provide the opportunity of personal hearing to M/s Eli Lilly Pakistan (Pvt) Limited Karachi under section 42 of the Drugs Act, 1976 of schedule VI of DRAP Act 2012 for cancellation of Registration of Avipro Salmonella DUO of M/s Eli Lilly Pakistan (Pvt) Limited Karachi and as per NOC of M/s Eli Lilly Pakistan (Pvt) Limited Karachi, the case shall also be considered for grant of registration of said product to M/s Golden Harvest, Karachi after personal hearing **(M-326)**.		
	Decision: Mr. Muhammad Zubair Sr. Manager RA appeared before the Board on behalf of M/s Eli Lilly Pakistan Pvt. Ltd, Karachi for personal hearing. After being heard the authorized person of M/s Eli Lilly Pakistan Pvt. Ltd, Karachi, the Registration Board acceded to the request of the firm for cancellation of registration of Avipro Salmonella DUO of M/s Eli Lilly Pakistan Pvt. Ltd, Karachi and grant the registration of the same product in the name of M/s Golden Harvest, Karachi.		

Transfer of Registration from M/s Eros Pharmaceutical Pvt Limited, Karachi to M/s JOVAC Global Pak, Lahore

M/s JOVAC Global Pak, Lahore applied for registration of following veterinary biological in their name from M/s Eros Pharmaceutical Pvt Limited, Karachi:

37.	**Name, address of applicant / Importer**	**M/s JOVAC Global Pak,** Address: 4th Floor, Plot No. 17, Block-D, EME DHA, Phase 12, Lahore.
	DSL details	License to sell drug as distributor No. 05-352-0066-072607D valid till 15-06-2023.
	Name of Manufacturer	M/s. Jordan Bio Industries Center (Jovac). Address: Amman, Yajouz road, near Yajouz Agriculture Nursery Amman, Jordan.
	Name of exporting country	Jordan

	Brand Name +Dosage Form + Strength	Gallovac 9R vaccine with Diluent Live attenuated freeze dried pellet for injection
	Diary No. Date of R& I & fee	Dy. No. 13028 (R&I); Dated 28-05-2022 Rs.150,000 (Slip No.5532950674)
	Composition	Each dose of vaccine contains: Viable organisms of *Salmonella gallinarum* strain 9R……..at least 2.0×10^7
	Pharmacological Group	Live Freeze dried veterinary vaccine
	Type of Form	Form-5A
	Finished Product Specification	Innovator's Specification
	Shelf Life	18 months (2°C-8°C)
	Pack size and demanded price	1000 doses / 1's vial ; Decontrolled
	Products already registered in Pakistan	Gallovac 9R vaccine with Diluent of M/s Eros pharma (Reg # 091373).
	Stability data of finished product	The firm has submitted stability study data of 24 months conducted at 2°C to 8°C for three consecutive batches as below: 9R0217-01 9R0218-01 9R0219-01
	Document Details	c. Valid legalized free sale certificate issued by the Ministry of Agriculture and Animal Health Directorate confirm free sale status of the product. The certificate is valid till 22-04-2025. d. Valid legalized GMP certificate issued to M/s. Jordan Bio Industries Center (Jovac) valid for three years from the date of inspection i.e. 01/12/2020.
	The firm has submitted following: Copy of Registration letter and last renewal status Termination/change of Distribution letter from manufacturer NOC from the existing registration holder (M/s Eros Pharmaceutical Pvt. Ltd, Karachi).	
	Decision: Registration Board was apprised that NAB Karachi has sent freezing order for M/s Eros Medicose, Dadu. Therefore, the Board decided todefer the cade and consider the same again after clarification from NAB Karachi whether both business entities i.e Erose Modicose, Dadub and Erose Pharmacuticals, Pvt. Ltd. Karachi are the same or otherwise.	

Imported Veterinary Biologicals from Reference countries:

38.	**Name, address of applicant / Importer**	**M/s Inouko Animal Health (Private) Limited.,** Address: 3rd Floor, Plaza No. 3 D-Block, DHA Phase 5 Cantt, District Lahore.
	DSL details	License to sell drug as distributor No. 05-352-0058-043305D valid till 18-07-2023.
	Name of Manufacturer	M/s. Biomune Company, 8906, Rosehill Road Lenexa KS 66215, US
	Name of exporting country	United States
	Brand Name +Dosage Form + Strength	Ultifend IBD ND
	Diary No. Date of R& I & fee	Dy. No. 3017 (R&I); Dated 27-02-2020 Rs.100,000 (Slip No.2044728) dated 27-02-2020
	Composition	Each dose of vaccine contains: Bursal disease-Marek's Disease-Newcastle Disease virus …… min 2818 pfu's through expiration
	Pharmacological Group	Live freeze dried veterinary vaccine
	Type of Form	Form-5A
	Finished Product Specification	Innovator's specification
	Shelf Life	24 months in liquid nitrogen gas

	Pack size and demanded price	4000 doses in glass ampoule ; Decontrolled
	International availability	Approved in United states, Peru, Venezuela, Mexico
	Stability data of finished product	The firm has submitted stability study data of 27 months for three commercial scale batches that were stored under stringent conditions (Liquid nitrogen): 376-001 376-002 376-003
	Document Details	The firm has submitted original legalized **certificate of licensing and inspection** (License No. 368) issued by U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Center for Veterinary Biologics dated 20-03-2018. The certificate confirm that the biological veterinary product is freely marketed in the country of origin and authorize the manufacturer to manufacture, package and sell immunological veterinary medicinal products. Product specific sole agency agreement with Ceva Sante Animale S.A., 10 avenue de la Ballastiere, 33500 Libourne, France.
	Remarks	The firm has submitted declaration that Ceva headquarter located in France is parent company of all Ceva subsidiaries, offices, manufacturing sites and secondary packaging sites. Biomune Company, 8906 Rosehill Road, Kansas 66215. US is the Ceva Manufacturing site located in US.
	Decision: Keeping in view the legalized CLI indicating product availability in the country of origin, Registration Board approved the product subject to compliance to the current import policy for finished drugs.	

39. Inspection report of M/s Brand Station, 69 Wocland Villas, Near Raiwind Road, Lahore

Following product of M/s Brand Station, Lahore was approved in 321st meeting of Registration Board with following details:

Manufacturer	**Brand name and composition**	**Document details**	**Decision of RB**
M/s. Yebio Bioengineering Co., Ltd Adress: No.260 Heyuan Road Hongdao, Qingdao, China	Yevac ND vaccine 500ml Each dose (0.5ml) contains: Newcastle Disease Virus Strain Lasota $\geq 10^{8.1}$ EID_{50} before inactivation.	24 months (2°C -8°C) 500 ml Decontrolled Original legalized FSC Original legalized GMP	Keeping in view legalized GMP and Free Sale Certificate indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs & submission of valid Sole agency agreement/authorization letter.

Accordingly, inspection of the manufacturing site i.e., M/s Yebio Bioengineering Co. Ltd. Address: No. 260 Heyuan Road, Hongdao, Qingdao, China was carried out on 12.12.2022 & 21.12.2022, by Zafar Mahmood Minhas (Director, National Control Laboratory for Biologicals), and Saadia Mahwish (Federal

Inspector of Drugs, DRAP, Islamabad) for the product YEVAC ND Vaccine 500ml. The panel of inspection concluded as below:

The proceedings of the virtual inspection were adversely influenced by a slew of factors summarized below:

1. Lack of provision for appropriate tools like cameras, borescopes, fiberoscopes etc. by the manufacturer to carry out virtual inspection.
2. Lack of provision of internet inside the production facility due to which production area could not be inspected.
3. The videos of production area provided by the manufacturer were devoid of description, voiceovers, step by step explanation of manufacturing process as well as the visuals of machinery in operation.
4. Lack of readily available documents for review in English language with notarization or Embassy verification.
5. Inadequacy of provided documents & videos as discussed in detail above.
6. Non availability of key documents in English language like veterinary Chinese Pharmacopoeia & Chinese GMP guidelines from an independent source.
7. Non-compliance of sterile area monitoring practices & their frequencies in accordance with Internationally accepted Guidelines.
8. Lack of clarification regarding the equivalence of Chinese GMP standards with International Guidelines & of Chinese Veterinary Pharmacopoeia with official books (BP, USP etc.) as mentioned in the Drugs Act, 1976 & DRAP Act, 2012.

Considering the facts mentioned above, the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, the panel reached the conclusion that since manufacturing/ production facility of the firm could not be viewed combined with deficiencies in the provided documents, it is not possible to ascertain basic vaccine manufacturing system or its compliance with GMP. It is therefore, strongly recommended that on-site inspection of the firm should be carried out before grant of registration of applied product i.e. Yevac ND vaccine and the firm should be compelled/ obligated to maintain & keep an English translation of relevant documents readily available for review on request.
Decision: The case has already been taken up by the Registration Board in its 327th meeting.

Agenda Item No.VII. Division of Quality Assurance & Laboratory Testing

S. No.	Case title
AGENDA ITEM NO. 01 - PERSONAL HEARING CASES	
01	MANUFACTURE & SALE OF ADULTERATED & SUB-STANDARD STERILE WATER FOR INJECTION REG. NO. 030217, BATCH NO. 799 MANUFACTURED BY M/S. ZAFA PHARMACEUTICAL LABORATORIES (PVT.) LTD., KARACHI
02	MANUFACTURE & SALE OF SUB-STANDARD STERILE WATER FOR INJECTION BATCH NO. W-20017 & W-20024, MANUFACTURED BY M/S. MEDIATE PHARMACEUTICAL (PVT.) LTD., KARACHI.
AGENDA ITEM NO. 02- OOS INVESTIGATION	
03	MANUFACTURE & SALE OF SUB-STANDARD STERILE WATER FOR INJECTION REG. NO. 030217, BATCH NO. 826 MANUFACTURED BY M/S. ZAFA PHARMACEUTICAL LABORATORIES (PVT.) LTD., KARACHI.
04	MANUFACTURE & SALE OF SUB-STANDARD DRUG (TEMPRIN SUSPENSION) BATCH NO. TM070 MANUFACTURED BY M/S. KOHS PHARMACEUTICALS (PVT) LTD., P/8 S.I.T.E HYDERABAD.
05	MANUFACTURE & SALE OF SUB-STANDARD OPHTH-CARB STERILE INTRAOCULAR SOLUTION BATCH NO. OP154 MANUFACTURED BY M/S OPHTH PHARMA (PVT) LTD., KARACHI
06	MANUFACTURE & SALE OF SUBSTANDARD LETIRIX SYRUP, BATCH NO. L2033, MANUFACTURED BY M/S. ALLIANCE PHARMACEUTICALS (PVT) LIMITED, PESHAWAR.
07	MANUFACTURING AND SALE OF SUB-STANDARD ALCAZAR INJECTION, BATCH NO.37, MANUFACTURED BY M/S PHARMEDIC LABORTORIES,16-KM MULTAN ROAD, LAHORE.

AGENDA ITEM NO. 01 - PERSONAL HEARING CASES

CASE NO. 01: MANUFACTURE & SALE OF ADULTERATED & SUB-STANDARD STERILE WATER FOR INJECTION REG. NO. 030217, BATCH NO. 799 MANUFACTURED BY M/S. ZAFA PHARMACEUTICAL LABORATORIES (PVT.) LTD., KARACHI.

The Federal Inspector of Drug-III / Assistant Director-XII, DRAP, Karachi inspected the premises of M/s. National Institute of Child Health (NICH) Rafeeqi Shaheed Road Karachi. on 28-05-2021 wherein the sample of drug along with other drugs were taken for the purpose of test/analysis on prescribed Form-3.

The Federal Government Analyst, Central Drugs Laboratory, Karachi declared the above said sample as "Adulterated and Sub-Standard" quality vide their test report No.KQ.134/2021 (Initial) dated 11th June 2021 and test report No. KQ.134/2021 (Final) dated 30th, July 2021.

S. No.	Name of Drug	Reg; No	Batch No.	Mfg. Date	Exp. Date	Mfg.by	Result of CDL	Basis of Result
01	Zafixime 500mg Injection	027228	440	01-2021	01-2023	M/s. Zafa Pharmaceutical Laboratories (Pvt) Limited, Karachi.	Standard	-
-	Sterile Water for Injection 5ml Ampoule	030217	799	12-2020	12-2025	---do---	Adulterated & Substandard	**Containing white fibers visible to**

								the naked eye.

In the light of above test reports of Federal Government Analyst, Central Drug Laboratory, Karachi an explanation letter of even number dated 11th June 2021 and 02nd, August 2021 issued by FID to M/s. Zafa Pharmaceutical Laboratories (Pvt) Limited, Plot No. B-10, Block-B, S.I.T.E. North Karachi, for explaining their position in the matter of manufacturing/selling of above mentioned Adulterated and Sub-Standard drug.

M/s. Zafa Pharmaceutical Laboratories (Pvt) Limited, Plot No. L-1/B, block 22, Federal "B", Area Karachi, 75950 vide their letter No. Nil dated 23th August,2021 requesting for retesting of Drug Zafixime 500mg Injection Batch No. 440, from NIH Islamabad. under section 22(5) of the drug Act 1976 for testing.

FID submitted the request of firm for retesting dated 25-08-2021.

M/s. Zafa Pharmaceutical Laboratories (Pvt) Limited, again requested for Appellate testing dated 07-10-2021.

Proceedings and Decision of 313th Meeting of Registration Board.

The Board after thorough deliberations and considering the facts of the case decided to ask/request Federal Government Analyst, Karachi to provide OOS investigation and complete testing record on which the product is declared as of Adulterated and Substandard quality.
The decision of Board has been communicated dated 16-12-2022 after approval of minutes.

M/s. Zafa Laboratories replied dated 11-01-2022, the conclusion of firm is reproduced as:

> *"In light of above investigation, product Water for Injection 5ml, Batch no. 799 was found as per specification. Therefore, OOS is not required against complaint."*

Response received from Central Drugs Laboratory, Karachi received through WhatsApp dated 14-03-2022 wherein the remarks of OOS Investigation Form are reproduced as:

> "Containing white fibers (WFI) visible to the naked eyes. The sample is of adulterated and substandard quality.

Technical Evaluation of the case:

- Water for injection was declared adulterated and substandard, containing white fibers visible to the naked eyes.
- Defects may not be equally distributed over the batch that's why it is not necessary for a Board or retention portion to be defective. Allowing retesting may result in false negative results and pose the risk to patient which can be avoided otherwise.
- Moreover, the remarks of CDL may be considered for further investigation of quality defect considering the statistical validity of sample size.

Proceedings and Decision of 316th Meeting of Registration Board.
The Board after thorough deliberations and considering the facts of the case decided:

i. To issue show cause notice for suspension/cancellation/ prosecution in Drug Court of the subject cited drug to M/s. Zafa Pharmaceutical Laboratories (Pvt.) Ltd., Karachi and called them for personal hearing before Registration Board.

Mr. Adnan Rizvi, Member of Board has recorded his note of dissent i.e. the sample should be sent to NIH for appellate testing.

Decision of 316th meeting of Registration Board has been communicated vide letter No. F.03-11/2022-QC (316-RB) dated 27-05-2022.

Firm has replied vide letter Nil dated 02-06-2022 wherein they again requested to send sample for appellate testing to NIH for physical testing.

Firm has been called for personal hearing.

Procedings and Decision of 320th Meeting of Registration Board.

M/s. Zafa Pharmaceutical Laboratories (Pvt) Limited, Karachi submitted vide Ref No. Nil dated 29-08-2022 that the concerned technical person was not available to attend the hearing due to unavoidable circumstances (rain and flood). They further requested for personal hearing in next meeting.

Decision: *"The Board after considering the facts of the case, request of the firm to grant another opportunity of personal hearing and after thorough deliberations acceded the request and provide them another opportunity of personal hearing."*

In view of decision of 320th meeting, they have been called for personal hearing.

Procedings and Decision of 321st Meeting of Registration Board.

Mr. Aquil Ahmed Rizvi, QA Manager and Mr. Ikram Habib, Manager Regulatory appeared before the Board. They inform that they have tested the retained sample of product and found it satisfactory and request to send the Board's portion for Appellate testing.

Registration Board after detailed discussion and considering the facts of the case decided:

"Sample of Sterile Water for Injection Batch No. 799 manufactured by M/s. Zafa Pharmaceutical Laboratories (Pvt) Limited, Plot No. B-10, Block-B, S.I.T.E. North Karachi will be sent to appellate lab for testing of visible particulate matter, on which the sample was declared as Adulterated and Substandard by CDL, Karachi."

Sample has been sent to NIH, Islamabad for appellate testing. The sample of sterile water for injection was declared as substandard by NIH. A show cause notice was served to Ms. Zafa Pharmaceutical Laboratories (Pvt) Limited, Karachi dated 10-03-2023. They have submitted their reply and request for personal hearing. ***It is also worth to mention here that another batch of same product i.e. water for injection Reg. no. 030217 batch No. 826 has again been declared substandard on the basis of sterility and bacterial endotoxin tests (Placed as next agenda item).***

Firm has been called for personal hearing vide office letter F.No. 3-26/2023-QC (329-RB) dated 30-05-2023.

Procedings and Decision of 329th Meeting of Registration Board.

No one appeared before the Board, however, M/s. Zafa Pharmaceutical Laboratories (Pvt) Limited, Karachi submitted their reply vide letter no nil dated 31-05-2023 that their authorized representative was unable to appear in the meeting due to personal leaves. They further requested to adjourn the case for next meeting.

Registration Board after considering the facts of the case along with another similar case of substandard sterile water for injection batch no. 826 of M/s. Zafa Pharmaceutical Laboratories (Pvt) Limited, Karachi (case no. 03). Further, two samples (Batch no. 739 and 751) took by Provincial inspector of drugs were also declared as adulterated and substandard. These batches were failed on Sterility test. Board after detailed discussion decided to club case no 1 and 3 and issue show cause notice with personal hearing under section 42 of Drug Act 1976 read with rule 24(17) of Drug (Licensing, Registering & Advertising) rules 1976, to the firm.

Case No. 02: MANUFACTURE & SALE OF SUB-STANDARD STERILE WATER FOR INJECTION BATCH NO. W-20017 & W-20024, MANUFACTURED BY M/S. MEDIATE PHARMACEUTICAL (PVT.) LTD., KARACHI.

The Federal Inspector of Drug, DRAP, Karachi visited the premises of M/s Mediate Pharmaceutical (Pvt.) Ltd., Karachi on 14-04-2021 wherein following samples along with other drugs were taken for the purpose of test/analysis on prescribed Form-3. Details are:

Name of Product	**Manufactured by**	**Reg. no.**	**Batch no.**	**Mfg. Date**	**Exp. Date**	**CDL remarks**
Hitaxime 1gm Injection (vial) Cefotaxime	Mediate Pharmaceutical (Pvt.) Ltd., Karachi	044109	V-20059	11-2020	11-2022	Standard.
Sterile water for injection (ampoule)	Mediate Pharmaceutical (Pvt.) Ltd., Karachi	053244	W-20017	07-2020	07-2023	Substandard on the basis of Bacterial endotoxin.
Hilixophin 500mg Injection (vial) Ceftriaxone	Mediate Pharmaceutical (Pvt.) Ltd., Karachi	044105	V-20085	12-2020	12-2022	Standard.
Sterile water for injection (ampoule)	Mediate Pharmaceutical (Pvt.) Ltd., Karachi	053244	W-20024	12-2020	12-2023	Substandard on the basis of Bacterial endotoxin.

02. Results of CDL on the basis of which sample under reference has been declared as Substandard are reproduced as under:-

i. Reports No. KQ.91/2021:

(STERILE WATER FOR INJECTION)

S.No.	**Test**	**Acceptance Criteria**	**Result**	**Reference**
1.	Description	Clear sterile water, free from visible particles, preserved in single dose glass or plastic container.	Complies.	USP 43
2.	Bacterial Sterility	Must be sterile.	Complies.	USP 43
3.	**Bacterial Endotoxin**	**Less than 0.25 EU per ml.**	**Does not comply.**	**USP 43**

(HITAXIME 1GM INJECTION)

S.No.	**Test**	**Acceptance Criteria**	**Result**	**Reference**
1.	Description	Offwhite powder in clear glass vial	Complies.	Mfg. Specs.
2	Identification	The identification test must identify Cefotaxime Sodium.	Complies.	USP 43
3.	pH	4.5 to 6.5	Complies.	USP 43
4.	Bacterial Sterility	Must be sterile.	Complies.	USP 43
5.	Bacterial Endotoxin	Not more than 0.20 EU per mg.	Complies.	USP 43
6.	Assay Cefotaxime (label claim 1gm/vial)	90.0% to 115.0%	105.0% complies	USP 43

NOTE: **Initial report has been released for the purpose to facilitate prompt regulatory action in larger public interest. Final report will be released after completion of further relevant tests.**

Remarks: *The sample is of **"Sub-Standard"** quality under the Drugs Act, 1976.*

ii. Reports No. KQ.92/2021:

(STERILE WATER FOR INJECTION)

S.No.	Test	Acceptance Criteria	Result	Reference
1.	Description	Clear sterile water, free from visible particles, preserved in single dose glass or plastic container.	Complies.	USP 43
2.	Bacterial Sterility	Must be sterile.	Complies.	USP 43
3.	Bacterial Endotoxin	Less than 0.25 EU per ml.	**Does not comply.**	USP 43

(HILIXOPHIN 500MG INJECTION)

S.No.	Test	Acceptance Criteria	Result	Reference
1.	Description	Off white powder in clear glass vial.	Complies.	Mfg. Specs.
2	Identification	The identification test must identify Ceftriaxone Sodium.	Complies.	USP 43
3.	pH	6.0 to 8.0	Complies.	USP 43
2.	Bacterial Sterility	Must be sterile.	Complies.	USP 43
3.	Bacterial Endotoxin	Not more than 0.20 EU per mg.	Complies.	USP 43
6.	Assay Ceftriaxone. (label claim 500mg/vial)	90.0% to 115.0%	100.3% complies	USP 43

NOTE: **Initial report has been released for the purpose to facilitate prompt regulatory action in larger public interest. Final report will be released after completion of further relevant tests.**

Remarks: *The sample is of **"Sub-Standard"** quality under the Drugs Act, 1976.*

03. FID, DRAP, Karachi informed that the firm has requested for retesting. The firm stated that:

"[…] we are requesting you to retest Bacterial Endotoxin test of both WFI injections, for this purpose we retest samples in our QC Dept. with three different kits and find results as given below:

Test performed	***Bioendo***	***Lonza***	***Cape-Cod***
Bulk sample	*Fail*	*Pass*	*Pass*
Sample after autoclave	*Fail*	*Pass*	*Pass*
W-20017	*Fail*	*Pass*	*Pass*
GSK WFI SPW9/1 (02-2018)	*Fail*	*Pass*	*Pass*

04. As per decision of 313th meeting of Registration Board regarding appellate testing, firm and Federal Government Analyst, CDL Karachi has been asked to submit OOS investigation dated 26-01-2022.

05. M/s. Mediate Pharmaceutical Pvt Ltd., Karachi replied they conducted investigation but found no fail results. Firm has mentioned that they cross checked the recalled product and QC retention samples and

performed bacterial endotoxin test by using three different kits out of which results of Bioendo endotoxin kit were not satisfactory. Details are:

S.no	Reagent used	Results
Lonza Endotoxin Kit		
1	Lysate reagent	Satisfactory
2	Control standard endotoxin	Satisfactory
3	Lal reagent water	Satisfactory
Cape code Endotoxin Kit		
4	Lysate reagent	Satisfactory
5	Control standard endotoxin	Satisfactory
6	Lal reagent water	Satisfactory
Bioendo Endotoxin Kit		
7	Lysate reagent	Un-satisfactory
8	Control standard endotoxin	Un-satisfactory
9	Lal reagent water	Un-satisfactory

06. While CDL, Karachi submitted OOS investigation, the result was OOS is confirmed.

Technical Evaluation of the case:

- The product was declared sub-standard on the basis of results of Bacterial endotoxin.
- Endotoxin test performed by Gel Clot method both by firm and CDL as given in USP 43.
- The method is based on visual inspection of the sample after incubation for presence of gel or otherwise.

Procedings and Decision of 326th Meeting of Registration Board.

Out of Specification (OOS) investigations and testing records submitted by M/s. Mediate Pharmaceutical (Pvt.) Ltd., Karachi and CDL, DRAP Karachi was presented before Registration Board.

After Through discussion about (OOS) Investigation report submitted by the firm and deliberation the case in detail and decided

1. not to accede the firm's request for appellate testing of this product and
2. to issue show cause notice under Section 42 of the Drugs Act, 1976 and rules framed thereunder, for suspension / cancellation of product Sterile water for injection (ampoule) Registration # 053244 manufactured by M/s. Mediate Pharmaceutical (Pvt.) Ltd., Karachi and called for personal hearing before Registration Board in this instant case.

In view of Board's decision, they have been called for personal hearing.

Procedings and Decision of 329th Meeting of Registration Board.

Mr. Muzammil Mehmood Khan, Quality Control Manager of M/s. Mediate Pharmaceutical (Pvt.) Ltd., Karachi was appeared before the Board. He submitted the same stance mentioned in their OOS report. Board asked about non satisfactory results of OOS performed by firm, self-audit report and water system qualification for which he did not provide any justifiable reply.

Registration Board after thorough discussion and considering the facts of the case along with another similar case of decided:

- *Suspension of the Registration of Sterile Water for injection, Registration No. 053244 under section 42 of the Drugs Act, 1976 read with rule 24(17) of Drug (Licensing, Registering & Advertising) rules 1976, for six months or till verification of Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) by a panel with satisfactory report; whichever is later.*
- *Submission of RCA and CAPA by the firm.*
- *Product Specific Inspection including verification of RCA and CAPA by panel of inspectors/experts to be nominated by Director QA/LT.*

AGENDA ITEM NO. 02- OOS INVESTIGATION

CASE NO. 03: **MANUFACTURE & SALE OF SUB-STANDARD STERILE WATER FOR INJECTION REG. NO. 030217, BATCH NO. 826 MANUFACTURED BY M/S. ZAFA PHARMACEUTICAL LABORATORIES (PVT.) LTD., KARACHI.**

The Federal Inspector of Drug-III / Assistant Director-XII, DRAP, Karachi inspected the premises of M/s. National Institute of Child Health (NICH) Rafeeqi Shaheed Road Karachi. on 03-02-2022 wherein the sample of drug along with other drugs were taken for the purpose of test/analysis on prescribed Form-3.

02. The Federal Government Analyst, Central Drugs Laboratory, Karachi declared the above said sample as "Sub-Standard" quality vide their test report No.KQ-2-22-000042 (Initial) dated 21st March 2022 and test report No. KQ-2-22-000041 (Final) dated 07th April 2022.

S. No.	Name of Drug	Reg; No	Batch No.	Mfg. Date	Exp. Date	Mfg.by	Result of CDL	Basis of Result
01	Zafixime 500mg Injection	027228	440	01-2021	01-2023	M/s. Zafa Pharmaceutical Laboratories (Pvt) Limited, Karachi.	Standard	-
-	Strile Water for Injection 5ml Ampoule	030217	826	08-2021	08-226	---do---	Substandard	**Sterility and bacterial endotoxin.**

03. FID, DRAP, Karachi informed that the firm has requested for retesting. The firm stated that:

i. "We have analyzed the sample of above batch in our QC laboratory and found to be standard quality, complying all the specifications of USP both physical and chemical.

ii. In this regard we again checked the Bacterial Endotoxin test in the laboratory with the specified specification (less than 0.25USP EU/ml) and the results complies the specification of USP. The sterility is under test because it takes 14 days to complete."

04. As per decision of 313th meeting of Registration Board regarding appellate testing, firm and Federal Government Analyst, CDL Karachi has been asked to submit OOS investigation dated 01-09-2022

05. Ms. Zafa Pharma, Karachi submitted testing method and test report. Federal Government Analyst, CDL Karachi submitted that OOS is valid.

06. Firm has submitted recall log as per prescribed formats. Area FID was requested to inspect the premises to reconcile/verify the quantities of stock.

Technical evaluation of OOS investigation:

- Firm has not submitted performance testing results of Bacterial Endotoxin test, moreover the sterility testing method is just refered to USP 43, however complete performance record including growth promotion test results as required under USP general chapter <71> for performance of sterility testing are not submitted.

- Further, submitted sterility testing data mentioned incubation results for 12 days whereas the required incubation period is 14 days' sterility observation period for growth of bacterial colonies.
- ***In addition, another sample of Water for Injection Batch No 799 has been declared substandard from CDL and NIH both***.

Procedings and Decision of 329th Meeting of Registration Board.

Registration Board after considering the facts of the case along with another similar case of substandard sterile water for injection batch no. 799 of M/s. Zafa Pharmaceutical Laboratories (Pvt) Limited, Karachi (case no. 01). Further, two samples (Batch no. 739 and 751) took by Provincial inspector of drugs were also declared as adulterated and substandard. These batches were failed on Sterility test. Board after detailed discussion decided not to accede the firm's request of retesting and further directed to club case no 1 and 3 and issue show cause notice with personal hearing under section 42 of Drug Act 1976 read with rule 24(17) of Drug (Licensing, Registering & Advertising) rules 1976, to the firm.

CASE NO. 04: MANUFACTURE & SALE OF SUB-STANDARD DRUG (TEMPRIN SUSPENSION) BATCH NO. TM070 MANUFACTURED BY M/S. KOHS PHARMACEUTICALS (PVT) LTD., P/8 S.I.T.E HYDERABAD.

The Federal Inspector of Drug, Karachi inspected the premises of M/s. KOHS Pharmaceuticals Pvt Ltd., Karachi. on 07-12-2022 wherein the sample of drug along with other drugs were taken for the purpose of test/analysis on prescribed Form-3.

Name of Product	Manufactured by	Reg. no.	Batch no.	Mfg. Date	Exp. Date	Remarks of CDL
Temprin suspension	Ms. KOHS Parmaceuticals (Pvt.) Ltd., Hyderabad.	061763	TM070	Dec 22	Nov24	Substandard on the basis of Assay test

02. The Federal Government Analyst, Central Drugs Laboratory, Karachi declared the above said sample as "Sub-Standard" quality vide their test report No.KQ-12-22-000248 dated 07-03-2023.

03. Results of CDL on the basis of which sample under reference has been declared as Sub-Standard quality are reproduced as under:-

S.No.	Test	Aceptance creteria	Result	Reference
1	Description	Pink coloured suspension	Pink coloured suspension containing while lumps with a hard cake of powder settled at the bottom of the bottle which cannot be re-dispersed on vigorous shaking. **Does not comply.**	Mfg. Specs.
2	Identification	The identification test must identify Paracetamol	Complies	BP 2022
3	Assay Paracetamol (Label claim 120mg/ 5ml)	95.0% to 105.0%	69.38%- **Does not complies**	BP 2022

Remarks:- 1) The sample is of **"Sub-Standard"** quality under the Drugs Act, 1976.

04. FID, DRAP, Karachi informed that the firm has requested for retesting. The firm stated that: they retested the QC sample and found as per specification i.e. 98.4%. they further added:

> "The physical condition of our suspension is clear and results are within the limits. May be your sample is not miscible and not shake well due to cold season and temperature so the percentage is decrease."

05. As per decision of 313th meeting of Registration Board regarding appellate testing, Firm and Federal Government Analyst, CDL Karachi has been asked to submit OOS investigation dated 19-04-2022

06. Ms. KOHS Pharmaceuticals (Pvt.) Ltd., Hyderabad submitted dated 02-03-2023 that they rechecked their sample which comply and it was standard. (Paracetamol 98.1%).

07. Firm has been directed to submit recall details as per Recall guidelines, reply awaited.

Technical Evaluation of OOS Investigation:

i. The product was declared as sub-standard on the basis Physical description and Assay test.
ii. There may be issues during formulation development, manufacturing processes, quality of API, and instability of product.
iii. Firm has requested for retesting of the product through Appellate Laboratory however, did not provide method of testing and OOS report, while CDL concluded that OOS is valid.

Proceedings and Decision of 329th Meeting of Registration Board.

Out of Specification (OOS) investigations and testing records submitted by M/s. KOHS Pharmaceuticals (Pvt.) Ltd., Hyderabad and CDL, DRAP Karachi was presented before Registration Board.

The Board deliberated the case in detail and decided not to accede the firm's request for appellate testing and to issue show cause notice under section 42 of Drug Act 1976 read with rule 24(17) of Drug (Licensing, Registering & Advertising) rules 1976, for suspension/cancellation/ prosecution in Drug Court of the subject cited drug to M/s. KOHS Pharmaceuticals (Pvt.) Ltd., Hyderabad and called them for personal hearing before Registration Board.

CASE NO. 05: MANUFACTURE & SALE OF SUB-STANDARD OPHTH-CARB STERILE INTRAOCULAR SOLUTION BATCH NO. OP154 MANUFACTURED BY M/S OPHTH PHARMA (PVT) LTD., KARACHI

The Federal Inspector of Drug, Karachi inspected the pharmacy of Ms. Aga Khan University Hospital, Karachi on 27-02-2023 on their complaint that the drug causes redness/irritation of eyes when used and their own lab also finds some bacterial rods/contamination upon microbial examination. FID took the sample of drug for the purpose of test/analysis on prescribed Form-3. Details are:

Name of Product	Manufactured by	Reg. no.	Batch no.	Mfg. Date	Exp. Date	Remarks of CDL
Ophth-Carb Sterile Intraocular solution	Ms. Ophth Pharma (Pvt.) Ltd., Karachi	026964	OP154	12-2022	11-2024	Sub-Standard on the basis of sterility test.

02. The Federal Government Analyst, Central Drugs Laboratory, Karachi declared the above said sample as "Sub-Standard" quality vide their test report No.KQ-2-23-000033 dated 08-03-2023.

03. Results of CDL on the basis of which sample under reference has been declared as Sub-Standard quality are reproduced as under:-

S.No.	Test	Aceptance creteria	Result	Reference
1	**Sterility**	Must be sterile	Does not comply	USPNF 2022

Remarks: 1) The Federal Inspector of Drugs concerned has referred the sample with remarks The sample is taken from Aga Khan University Hospital, Stadium Road, Karachi pharmacy on their complaint that the drug causes redness/irritation of eyes when used and their own lab also finds some bacterial rods/contamination upon microbial examination. Hence, sterility and other microbial bio-burden tests may kindly be carried out on priority". Therefore, sterility test has been performed only,

2)The sample is of "**Sub-Standard**" quality under the Drugs Act. 1976..

04. FID, DRAP, Karachi informed that the firm has requested for retesting. The firm stated following points:

i. "Before marketing of the product we had tested the sterility of the batch, it found satisfactory.
ii. On the basis of the sterility test report the batch has been dispatched.
iii. Furthermore, we had performed third party testing of sterility of the said batch.
iv. We haven't received any complaint from any other side regarding this batch.
v. We have repeatedly tested our product and the result also complies with USP standard (documents attached for your reference), we are confident that our product, OPHTH-CARB batch No. 154 complies to 100% United State Pharmacopeia.
vi. Ophth Pharma is producing Ophth Carb from early 2002 and serving institutes since about last 16 years. We take all the precautions at each and every processing step. All the raw material and distilled water used in production are subjected to LAL test prior to production.
vii. Storage condition at the end of the product purchaser is very important. Improper storage condition particular hot weather can alter the chemical nature of the product."

05. As per decision of 313th meeting of Registration Board regarding appellate testing, Firm and Federal Government Analyst, CDL Karachi has been asked to submit OOS investigation dated 19-04-2022

06. Ms. Ophth Pharma (Pvt.) Ltd., Karachi submitted OOS investigation and complete testing record. The conclusion of OOS investigation reports is reproduced as:

> "There are no significant risk factors detected in sterile manufacturing, and in quality control processes according to the joint inquiry, overall area qualification checks and manufacturing process assessments. The sterility reports' third-party confirmation is also convincing and backs up our internal investigation. For the sake of OOS inquiry, manufacturing processes and facility qualifications such as sterile area qualifications and terminal sterilization were thoroughly inspected and their conclusions were recorded. The retention samples evaluated by a third party were also reported to pass the appropriate sterility test of the product, which is strong evidence of good cGMP protocols. The total inquiry concluded that no substantial infractions were discovered."

07. OOS investigation from FGA, CDL Karachi has been received; final decision was OOS is valid. Remarks of Laboratory manager reproduced as:

> "Since the sample failed in repeat test with respect to sterility. It is of substandard quality."

08. Firm has been directed to submit recall details as per Recall guidelines.

Technical Evaluation of OOS Investigation:

i. Sterility report of CDL, Karachi showed that sample was failed on Day 6th of sterility test. While reports attached by firm showed the results were as per specification.
ii. Sample has been taken by FID, Karachi on a complaint received from Ms. Aga Khan Hospital, Karachi that the drug causes redness/irritation of eyes when used and their own lab also finds some bacterial rods/contamination upon microbial examination.

Proceedings and Decision of 329th Meeting of Registration Board.

Out of Specification (OOS) investigations and testing records submitted by M/s. Ophth Pharma (Pvt.) Ltd., Karachi and CDL, DRAP Karachi was presented before Registration Board.

The Board deliberated the case in detail and decided not to accede the firm's request for appellate testing and to issue show cause notice under section 42 of Drug Act 1976 read with rule 24(17) of Drug (Licensing, Registering & Advertising) rules 1976 for suspension/cancellation/ prosecution in Drug Court of the subject

cited drug to M/s. Ophth Pharma (Pvt.) Ltd., Karachi and called them for personal hearing before Registration Board.

CASE No. 06: <u>MANUFACTURE & SALE OF SUBSTANDARD LETIRIX SYRUP, BATCH NO. L2033, MANUFACTURED BY M/S. ALLIANCE PHARMACEUTICALS (PVT) LIMITED, PESHAWAR.</u>

Federal Inspector of Drug, DRAP, Peshawar visited the premises of M/s Alliance Pharmaceuticals (Pvt) Limited, 112-A, Hayatabad Industrial Estate, Peshawar on 16-10-2020 wherein the sample of Letirix Syrup, Batch No. L-0233, Manufactured by M/s. Alliance Pharmaceuticals (Pvt) Limited, Peshawar was drawn under Schedule-V (1) (C) of DRAP Act, 2012 read with section 18 (1) (C) of the Drugs Act, 1976 for the purpose of test/analysis. Details are as under;

S. N0.	Name of Drug	Reg. No.	Batch No.	Mfg. Date	Exp. Date	Mfg. By	Basis of Sub-Standard
01	Letirix Syrup	068438	L2033	10-020	09-022	M/s. Alliance Pharmaceuticals (Pvt) Limited, Peshawar	Assay does not comply

02. Federal Government Analyst, CDL, Karachi vide their test report No.IP.130/2020 dated 04-01-2021 declared the above said sample as of substandard quality. Test results of the CDL, Karachi are reproduced as under:

S.No.	Test	Specification	Result	Reference
01.	Description	Clear, colourless syrup which is free from black particles.	Complies.	Mfg. Specs.
02.	Identification	The identification test must identify Levocetrizine Hydrochloride.	Complies	Mfg. Specs.
03.	pH	3.0 to 5.0	3.90-Complies	Mfg. Specs.
04.	**<u>Assay</u>** **Levocetrizine 2HCl Label claim 2.5mg/5ml)**	90.0% to 110.0%	**69.5%** **<u>Does not comply.</u>**	Mfg. Specs.

Remarks: *<u>The sample is **"Sub-Standard"** under the Drugs Act, 1976.</u>*

03. The firm didn't agree to the results of CDL, Karachi and requested for retesting under Section 22(4) of the Drugs Act, 1976 and rules framed there under.

04. In light of Supreme court judgement of "C.P.1692-L/2020, C.P.1792-L/2020 and C.P.5-L/2021" and firm's request for appellate testing, the case was discussed in 307th meeting of Registration Board. Board decided:

"To direct the firm to submit justification/scientific grounds for Appellate testing within 7 days."

05. The decision has been communicated to the firm vide office letter of even number dated 29-09-2021.

06. M/s. Alliance Pharmaceuticals (Pvt) Ltd, Peshawar vide Ref. No. AL/QC/021/014 dated 07-09-2021 in response to the decision letter of 307th meeting of Registration Board dated 03-09-2021. The stance of the firm is as follows:

"With reference to your letter No.F.03-15/2021-QC (307-RB) dated 3rd Sep, 2021, in which we M/S Alliance Pharmaceuticals (Pvt) Ltd are directed to submit justification/scientific ground for Appellate testing by the Drugs Registration Board.

The Assay performed by Central Drugs Testing Laboratory of the cited above syrup on HPLC method while we M/S Alliance Pharmaceuticals (Pvt) Ltd adopted an extraction followed by UV/Visible Spectroscopic method, which is a valid method. (Method validation report attached).

Alter CDL Karachi Report we M/S Alliance Pharmaceuticals (pvt) Ltd retested the retain sample and market return of the same batch cited above on both HPLC and Extraction followed by UV and we observed interference in the retention time of API by an excipient on HPLC method.

As our product is of internal specifications and not included in any pharmacopeia, so we adopted Extraction followed by UV method. It is kindly requested to please consider our request for Appellate testing and perform the Assay of the batch cited above through extraction followed by UV method (Method and its results attached)."

07. Case was discussed in 313th Meeting of Registration Board, Board after thorough deliberations and considering the facts of the case decided to ask/request Federal Government Analyst, Karachi to provide OOS investigation and complete testing record on which the product is declared as of Substandard quality.

08. Decision was communicated vide office letter of even numbers dated 16-12-2021 with subsequent reminders dated 31-01-2022, 01-04-2022, 13-04-2022, 01-07-2022 and 25-10-2022. Response is still awaited. It is also important to mention that the sample has been expired.

Proceedings and Decision of 329th Meeting of Registration Board.

The Board deliberated the case in detail and decided not to accede the firm's request for appellate testing and to issue show cause notice under section 42 of Drug Act 1976 read with rule 24(17) of Drug (Licensing, Registering & Advertising) rules 1976 to M/s Alliance Pharmaceuticals (Pvt) Limited, Peshawar for suspension/cancellation/ prosecution in Drug Court of the subject cited drug and called Firm for personal hearing before Registration Board.

CASE No. 07: MANUFACTURING AND SALE OF SUB-STANDARD ALCAZAR INJECTION, BATCH NO.37, MANUFACTURED BY M/S PHARMEDIC LABORTORIES,16-KM MULTAN ROAD, LAHORE

01. Assistant Director (Import & Export), DRAP, Lahore, took the sample of product namely Alcazar Injection containing Diclofenac Sodium, Batch No.37, Mfg. Date 02-2021, Expiry date 02-2023 from the export consignment of the M/s Pharmedic Laboratories (Pvt). Ltd, 16-Km Multan road Lahore and send to CDL, Karachi for test /analysis purposes.

2. CDL vide their test/analysis report EXP-7-22-000007 dated 16-10-2022 declared, as of sub-standard quality on the basis of PH non-compliance with submitted reference manufacturers specification. Details of CDL report are given as under:

S. No.	Test	Acceptance Criteria	Result	Reference
1.	Description	A clear, almost colorless liquid filled in 3ml printed	Complies	Mfg. Specs

		ambered glass ampoule		
1.	Identification	The identification test must identify Diclofenac Sodium	Complies	Mfg. Specs
2.	pH	3.3 to 4.0	**8.10 Doesn't Complies**	Mfg. Specs
4.	Sterility	Must be sterile	Complies	USP 43
5.	Visible Particle Matter	Meet the requirements	Complies	USP 43
6.	Assay. Diclofenac Sodium (Label Claim 75mg/3ml)	90.0% to 110.0%	101.93% Complies	Mfg. Specs
7.	Endotoxin	Not more than 14.0 EU/mg of Diclofenac Sodium	Complies	Mfg. Specs

REMARKS: - The sample is of **Sub-Standard** quality under the Drug Act 1976.

3. A medical product alert for recall of substandard product from market and for uploading on DRAP website for information of general public was issued accordingly.

4. Assistant Director conveyed report of CDL to firm vide letter No. 11-02-2022 to the firm and inquired status of export consignment and also required names of management and technical staff for the firm and asked firm to explain their position in this regard.

5. Firm submitted their reply dated 31-10-2022 and intimated that consignment of 5237 packs is exported to Afghanistan and is consumed and no complaints received from importer, moreover they claim that they have followed Mfg specs and submitted their method of Analysis along with manufacturing product specifications PH range 7.8-8.8.

6. AD submitted the case to division of QA/LT vide letter No. 11731/2022 dated 15-12-2022 under section 19(7) of Drugs Act 1976 and schedule V of DRAP Act 2012 for action in respect of contraventions against M/s Pharmedic Labortories (Pvt) Ltd,16-Km Multan road, Lahore along with name of management of firm involved as under,

1. Waqar Ahmad Sheikh (CNIC No 35202-9152354-3) Director,
2. Shoaib Iftikhar Baig,(CNIC No. 35202-2797305-5) Production Incharge
3. Muhammad Numan Ahmad(CNIC No. 35202-2745122-9) Quality Control Incharge

7. Accordingly, CDL was asked to provide attested copy of MOA submitted by firm mentioning the range of p.H of manufacturing specification. CDL vide letter No.1-1/13, DRAP (CDL)/SRK dated 01-03-2023 submitted copy of MOA of Inj Alcazar, where in the pH range is mentioned as 3.3- 4.3.

8. Means while firm has submitted a corrigendum dated 07-04-2023 stating that the MOA which was submitted to CDL, Khi has typographical error/ overlook by analyst, regarding pH range specification of Inj. Alcazar as 3.3 – 4.0 and their actual manufacturer specification of Inj Alcazar is 7.8 – 8.8.As Injection Diclofenac Sodium is yet non compendial formulation therefore firm has manufacturing specification and firm has also submitted testing results of market available product of Inj. Diclofenac Sodium having pH. range of 7.8 – 8.8.

Proceedings and Decision of 329th Meeting of Registration Board.

The Board deliberated the case in detail and decided to issue show cause notice under section 42 of Drug Act 1976 read with rule 24(17) of Drug (Licensing, Registering & Advertising) rules 1976 for suspension/cancellation/ prosecution in Drug Court of the subject cited drug to M/s Pharmedic Laboratories (Pvt). Ltd., Lahore and called them for personal hearing in the forth coming meeting of Registration Board.

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