MINUTES OF 343rd MEETING OF REGISTRATION BOARD HELD ON 3rd–5th DECEMBER, 2024

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Drug Regulatory Authority of Pakistan
Prime Minister's National Health Complex,
Park Road, Islamabad

343rd meeting of Registration Board was held on 3rd to 5th December, 2024 in the Committee Room, Drug Regulatory Authority of Pakistan, Prime Minister's National Health Complex, Park Road, Islamabad. The meeting was chaired by Dr. Obaidullah, Chairman,Registration Board, DRAP. The meeting started with recitation of the Holy Verses.

Following members attended the meeting:

1.	Malik Muhammad Saleem, Ex Deputy Manager Production. Rhone Poulenc Rorer Pakistan, Rawalpindi.	Member
2.	Dr. Syed Asad Ali Shah, Principal Animal Husbandry In-Service Training Institute, Peshawar.	Member
3.	Mr. Imranullah Khan, Senior Drug Analyst. Rep of Director DTL, Govt. of KP	Member
4.	Dr. Ali Jan, Director, DTL, Govt. of Baluchistan Quetta	Member
5.	Mr. Muhammad Aslam, Additional Draftsman, M/o Law & Justice, Islamabad.	Member
6.	Mr. Babar Khan, Director, Division of BE&R, DRAP	Member
7.	Mr. Zeeshan Nazir Bajar, Director, Division of QA&LT, DRAP	Member
8.	Miss. Sadaf Ahmad, Assistant Director, Representative of MD&MC Division, DRAP.	Member
9.	Mr. Hafiz M. Tayyab Ali, Additional Director	Secretary
10.	Dr. Muhammad Akram, Animal Husbandry Commissioner, M/o National Food Security & Research, Islamabad.	Co-Opted Member

Following members attended the meeting via zoom link.

11.	Dr. Tehseen Fatima, Dow College of Biotechnology, Dow University of Health Sciences, Karachi.	Member
12.	Mr. Iftikhar Ahmed Choudhury, Ex-Chief Pharmacist, Hospital Pharmacist, Government of Punjab, Lahore	Member
13.	Mr. Ijaz Alvi, Director DTL Rawalpindi	Member
14.	Mr. Adnan Rizvi, Director DTL Karachi	Member
15.	Mr. Ghulam Mujtaba, Deputy Director, Representative of IPO, Islamabad.	Member

Mr. Nadeem Alamgir (Pharma Bureau), Dr.Zafar Mustafa, Mr. Jalal-ud-Din Zafar (PPMA), Mr. Amir Ilyas (PCDA) attended the meeting as observers.

Dr. Obaidullah, Chairman, Registration Board welcomed all the participants particularly newly nominated expert members and hoped that their presence in Registration Board will help in efficient working of the Board. He also acknowledged the services of those members, who have completed their tenure. Dr. Obaidullah, Chairman, Registration Board also acknowledged the services of ex-Chairman, Registration Board Dr. Muhammad Fakhruddin Aamir and appreciated his commendable efforts for efficiently conducting the proceedings of Board. The efforts of ex-secretary Registration Board, Mr. Muneeb Ahmed Cheema and Incharge PEC, Mr. Asif Jalil were also admired.

Dr. Muhammad Haseeb Tariq, Deputy Director gave a brief presentation on procedure for registration of drug and working of Registration Board covering following aspects.

1. Legal provisions, scope of Registration Board, published guidelines, applications, criteria and procedure for registration, reference regulatory authorities, international recognitions and WHO National Regulatory Authority Assessment etc was given to all members. The presentation also covered the procedure for assessment of registration applications and development of a detailed assessment reports for each application. The members were also given brief introduction to the automation initiatives of DRAP including eApp system which is now used to receive and process all registration applications. The Board members were informed that the criteria for assessment of registration application is fulfilled as per the published guidelines and all information related to the quality assessment of drug substance and drug product is analyzed and recorded. For presentation purpose and to serve as a public document only a brief assessment report is made part of the agenda and minutes.

2. The registration of each drug is performed based on criteria for safety, efficacy and quality assessment. For safety and efficacy assessment a reliance mechanism has been adopted. While the quality assessment is performed during the evaluation process, for which guidelines and SOPs have been developed. All human applications are submitted on Form 5F (CTD) and its assessment is done as per the "Guidance document for submission of application on form 5-F (CTD) for registration of pharmaceutical drug products for human use" which involves detailed assessment of drug substance and drug product. The detailed assessment is performed during evaluation and then placed before the Board for its consideration.
3. Assessment of safety and efficacy for human drugs, a reliance mechanism have been adopted. For this purpose, the Board in its 275th meeting decided to adopt 21 Reference Regulatory Authorities (RRAs) as reference for molecules/ formulations (in same dosage form and strength) along with clinical trials for human purpose. Following is the list of RRAs:
    a. Food & Drug Administration (FDA), USA.
    b. Health Canada, Canada.
    c. Therapeutic Good Administration (TGA), Australia.
    d. Pharmaceuticals and Medical Devices Agency (PMDA), Japan.
    e. Medicines and Healthcare Regulatory Agency (MHRA), UK.
    f. National Agency for the Safety of Medicine and Health Products (ANSM), France.
    g. Federal Institute for Drugs and Medical Devices, Germany.
    h. Medicines Evaluation Board, Netherland.
    i. Swissmedic, Switzerland.
    j. Austrian Agency for Health and Food Safety, Austria.
    k. Danish Medicines Agency, Denmark.
    l. Medical Products Agency, Sweeden.
    m. Norwegian Medicines Agency, Norway.
    n. Federal Agency for Medicines and Health Products, Belgium.
    o. Finnish Medicine Agency, Finland.
    p. Italian Medicine Agency (AIFA), Italy.
    q. Health Products Regulatory Authority (HPRA), Ireland.
    r. Icelandic Medicine Agency, Iceland.
    s. Spanish Agency for Medicines and Health Products, Spain.
    t. European Medicines Agency (EMA).
    u. World Health Organization (WHO).
4. Veterinary drugs are registered on the basis of application submitted on Form 5 / 5D and evidence of already registered / generic product having similar formulation.
5. Applications for registration of pharmaceutical products are assessed by Pharmaceutical Evaluation Cell and all cases, whether complete or with comments are then placed before the Board for its consideration.
6. Registration Board was also apprised about the status of pending and under consideration applications. The board was also informed about certain priority categories as defined by DRAP Authority including applications of new license / section, anticancer products, export facilitation, drugs having short availability and any other category as identified by the Authority from time to time. All priority applications are given due consideration for priority assessment and consideration. The Board thoroughly discussed the way forward for pending applications and it was decided that all manual applications submitted in 2023 shall be evaluated and placed before the Board in its upcoming meeting. In this regard Board advised the observers from Pharma Pharma Bureau, PCDA and PPMA to intimate PEC regarding any registration application submitted within Dcemeber 2023 an dwhich ahs never been considerd by Registration Board.
7. The members were apprised that for all cases considered within the meeting the assessment of GMP of the firm is performed and GMP inspection report within 3 years is required and the same is also considered and verified before issuance of registration letter.

8. Before issuance of registration letter brand name resemblance has also been checked from available record of already registered drug products.
9. The Board was informed that in the instant meeting, pharmaceutical applications of routine category as well applications of new License / new section have been evaluated and placed for consideration of the Board.

Item No. I. Confirmation of Minutes of 340th, 341st and 342nd meeting of Registration Board

a. 340th meeting of Registration Board was held on 1st October to 2nd October, 2024. Accordingly, draft minutes of the 340th meeting of Registration Board were prepared and circulated among the members through email for their perusal / approval / comments (if any). All members agreed the draft minutes. Accordingly, fair minutes were processed to Chairman, Registration Board for perusal/approval. After approval from Chairman Registration Board, fair minutes of 340th meeting of Registration Board were circulated among concerned divisions/sections for implementation.

b. 341st meeting of Registration Board was held on 26th November, 2024. Accordingly, draft minutes of the 341st meeting of Registration Board were prepared and circulated among the members through email for their perusal / approval / comments (if any). All members agreed the draft minutes. Accordingly, fair minutes were processed to Chairman, Registration Board for perusal/approval. After approval from Chairman Registration Board, fair minutes of 341st meeting of Registration Board were circulated among concerned divisions/sections for implementation.

c. 342nd meeting of Registration Board was held on 30th November, 2024. Accordingly, draft minutes of the 342nd meeting of Registration Board were prepared and circulated among the members through email for their perusal / approval / comments (if any). All members agreed the draft minutes. Accordingly, fair minutes were processed to Chairman, Registration Board for perusal/approval. After approval from Chairman Registration Board, fair minutes of 342nd meeting of Registration Board were circulated among concerned divisions/sections for implementation.

Decision: Registration Board noted the information and confirmed the minutes of 340th, 341st and 342nd meetings.

Item No. II Division of Pharmaceutical Evaluation & Registration

Pharmaceutical Evaluation Cell (PEC)

Sr. No	Name of Evaluator	Designation
1.	Mr. Ammar Ashraf Awan	Deputy Director (PEC)
2.	Dr. M. Haseeb Tariq	Deputy Director (PEC)
3.	Dr. Farhadullah	Deputy Director (PEC)
4.	Mr. Adil Saeed	Deputy Director (PEC)
5.	Mr. Shahid Nawaz	Deputy Director (PEC)
6.	Mr. M. Tahir Waqas	Deputy Director (PEC)
7.	Ms. Maham Misbah	Deputy Director (PEC)
8.	Mr. Hafiz Asif Iqbal	Deputy Director (PEC)
9.	Ms. Najia Saleem	Deputy Director (PEC)
10.	Ms. Saima Hussain	Assistant Director (PEC)
11.	Mr. Waqar Ahmed	Assistant Director (PEC)
12.	Mr. Shahrukh	Assistant Director (PEC)

Total Cases: 818

Case No. 01: Drugs for treatment of Erectile dysfunction (ED)

The matter regarding policy decision for drugs for pulmonary hypertension and erectile dysfunction etc were considered in various meetings of Registration Board. Registration Board in its 284th meeting after detailed deliberation decided as under:

Registration Board observed that the registration of drugs for treatment of erectile dysfunction and other similar medications remain pending for a long time. Most of these formulations are approved by reference regulatory authorities and available in most part of the world. Registration Board deliberated that those formulations approved by reference regulatory authorities should be considered for registration as per parameters of safety, efficacy and quality. As matter is pending since long, thus Registration Board forwarded its recommendations to DRAP's Policy Board for its approval.

The recommendations of Registration Board were considered by Policy Board in its 43rd meeting held on 22nd June, 2022 and decided as under:
The Board, having duly considered the working paper prepared by the Secretariat, and after discussion, noted that sildenafil Citrate is e life-saving drug for neonates in pulmonary hypertension, therefore, advised Registration Board to grant registration of this drug for pulmonary arterial hypertension in dry suspension / sachet form only, keeping in view its criteria of safety, efficacy and quality and availability in reference regulatory authority.

The matter was again deliberated by Policy Board in its 51st meeting held on 29-03-2024, wherein the following decision was made:
"The Board having duly considered the working paper prepared by the secretariat, and after discussion observed that matter is pending since long and drugs in this category are drugs of choice for pulmonary arterial hypertension and erectile dysfunction and their non-availability through legal channels creates difficulties for needy patient, therefore decided that registration applications of locally manufactured drugs for erectile dysfunction and pulmonary hypertension shall be considered by the Registration Board".

The decision of Policy Board is presented for the consideration of Registration Board please.

Decision: **Registration Board noted the information and decided to comply the decision of 51st meeting of the Policy Board and directed PE&R Division to process all applications of locally manufactured drugs for erectile dysfunction and pulmonary hypertension as per guidelines. The Board Authorized Chairman for processing and issuance of export registrations as per already granted authorizations.**

Case No. 02 Applications submitted on Form 5F by way of self-manufacturing

1.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hattar**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 27479 dated 23-11-2023 Rs 30,000/- dated 04-10-2023
	The proposed proprietary name / brand name	**Linamethyst 2.5/1000mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Linagliptin…2.5mg Metformin HCl ……1000mg
	Pharmacotherapeutic Group of (API)	Drugs used in diabetes, combination of oral blood glucose lowering drugs
	The status in reference regulatory authorities	Jentadueto Tablets of M/s Boehringer Ingelheim Approved by USFDA
	For generic drugs (me-too status)	Lina-Met 2.5/1000mg Tablet of M/s CCL
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Manufacturer's specifications

Evaluation by PEC[II]:

Sr.#	Observations	Firm's reply
1.	Evidence of registration of applied formulation as me-too status shall be submitted or else while differential fee for new drug product registration shall be submitted.	
2.	Documents confirming procurement of drug substance with approval of DRAP I&E Office shall be submitted.	

Decision: Deferred for submission of reply to above cited shortcomings.

2.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hattar**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals Plot #122 Phase 5, Block B, Industrial Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy. No 26692 dated 06-11-2023 Rs 30,000/- dated 04-10-2023
	The proposed proprietary name / brand name	**Linamethyst 2.5/850mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Linagliptin…2.5mg Metformin HCl ……850mg
	Pharmacotherapeutic Group of (API)	Drugs used in diabetes, combination of oral blood glucose lowering drugs

	The status in reference regulatory authorities	Jentadueto Tablets of M/s Boehringer Ingelheim Approved by USFDA
	For generic drugs (me-too status)	Lina-Met 2.5/850mg Tablet of M/s CCL
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Manufacturer's specifications

Evaluation by PEC[II]:

Sr.#	Observations	Firm's reply
1.	Evidence of registration of applied formulation as me-too status shall be submitted or else while differential fee for new drug product registration shall be submitted.	Lina-Met 2.5/850mg Tablet of M/s CCL
2.	Documents confirming procurement of drug substance with approval of DRAP I&E Office shall be submitted.	Submitted

Decision: Deferred for submission of reply to above cited shortcomings.

3.	**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)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 27152 dated 17-11-2023 Rs.75,000/- dated 10-10-2023
	The proposed proprietary name / brand name	**Linaglu-Met XR 5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Linagliptin…5mg Metformin HCl (as Extended Release) ……1000mg
	Pharmacotherapeutic Group of (API)	Drugs used in diabetes, combination of oral blood glucose lowering drugs
	The status in reference regulatory authorities	Jentadueto XR Tablets of M/s Boehringer Ingelheim Approved by USFDA
	For generic drugs (me-too status)	Linyda - Plus XR 5+1000mg Tablet of M/s Pharmevo (Pvt.) Ltd.
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's specifications

Evaluation by PEC[II]:

Sr.#	Observations	Firm's reply
1.	Documents confirming procurement of Metformin HCl, with approval of DRAP I&E Office shall be submitted	Firm has submitted Form 6 issued on 27-10-2022 by AD I&E, DRAP, Karachi.
2.	Copy of Valid GMP certificate/DML of the drug substance manufacturer shall be submitted.	Submitted

Decision: Approved.

4.	**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)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 26555 dated 03-11-2023 Rs.75,000/- dated 10-10-2023
	The proposed proprietary name / brand name	**Linaglu-Met XR 2.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Linagliptin…2.5mg Metformin HCl (as Extended Release) ……1000mg
	Pharmacotherapeutic Group of (API)	Drugs used in diabetes, combination of oral blood glucose lowering drugs
	The status in reference regulatory authorities	Jentadueto XR Tablets of M/s Boehringer Ingelheim Approved by USFDA
	For generic drugs (me-too status)	Linyda - Plus XR 2.5+1000mg Tablet of M/s Pharmevo (Pvt.) Ltd.
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's specifications

Evaluation by PEC[II]:

Sr.#	Observations	Firm's reply
1.	Documents confirming procurement of Metformin HCl, with approval of DRAP I&E Office shall be submitted	Submitted
2.	Copy of Valid GMP certificate/DML of the drug substance manufacturer shall be submitted.	Submitted

Decision: Approved.

5.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy. No. 25800 dated 25-10-2023 Rs.75,000/- dated 12-10-2023
	The proposed proprietary name / brand name	**Tazene 30gm Gel 0.1%**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram of Gel Contains: Tazarotene…0.1%
	Pharmacotherapeutic Group of (API)	Other antipsoriatics for topical use
	The status in reference regulatory authorities	Tazorac Gel 0.1% of M/s Allergan Approved by US FDA
	For generic drugs (me-too status)	Not available
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's specifications

Evaluation by PEC[II]: Tazorac gel of M/s Allergan was initially approved by US FDA in 1997 and is indicated for is a retinoid indicated for the topical treatment of plaque psoriasis of up to 20% body surface area involvement and d for the topical treatment of mild to moderate facial acne vulgaris.
Tazarotene is a member of the acetylenic class of retinoids.

Sr.#	Observations	Firm's reply

1.	Evidence of approval of required manufacturing facility i.e., "Gel (section)" issued by Licensing Division shall be submitted.	Firm has submitted letter issued by Secretary CLB dated 08-11-2023 granting renewal of DML including "Cream/Ointment/Gel (General) Section"
2.	Copy of Valid GMP certificate/DML of the drug substance manufacturer shall be submitted.	Copy of DML of the drug substance manufacturer submitted
3.	Drug substance analytical procedure from the drug substance manufacturer shall be submitted.	Firm has submitted drug substance analytical procedure form drug substance manufacturer.
4.	Documents confirming procurement of drug substance, approved by DRAP I&E office shall be submitted.	Firm has submitted clearance certificate issued by DRAP I&E office, Islamabad dated 13-06-2023
5.	Drug product stability studies of 6th month time point shall be submitted	Firm has submitted stability studies of 6th month time point for both accelerated and long term conditions.

Decision: Approved

6.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 25799 dated 25-10-2023 Rs.75,000/- dated 12-10-2023
	The proposed proprietary name / brand name	**Tazene 30gm Gel 0.05%**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram of Gel Contains: Tazarotene…0.05%
	Pharmacotherapeutic Group of (API)	Other antipsoriatics for topical use
	The status in reference regulatory authorities	Tazorac Gel 0.05% of M/s Allergan Approved by US FDA
	For generic drugs (me-too status)	Not available
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's specifications

Evaluation by PEC[II]: Tazorac gel of M/s Allergan was initially approved by US FDA in 1997 and is indicated for is a retinoid indicated for the topical treatment of plaque psoriasis of up to 20% body surface area involvement and d for the topical treatment of mild to moderate facial acne vulgaris.
Tazarotene is a member of the acetylenic class of retinoids.

Sr.#	Observations	Firm's reply
1.	Evidence of approval of required manufacturing facility i.e., "Gel (section)" issued by Licensing Division shall be submitted.	Firm has submitted letter issued by Secretary CLB dated 08-11-2023 granting renewal of DML including "Cream/Ointment/Gel (General) Section"
2.	Copy of Valid GMP certificate/DML of the drug substance manufacturer shall be submitted.	Copy of DML of the drug substance manufacturer submitted

3.	Drug substance analytical procedure from the drug substance manufacturer shall be submitted.	Firm has submitted drug substance analytical procedure form drug substance manufacturer.
4.	Documents confirming procurement of drug substance, approved by DRAP I&E office shall be submitted.	Firm has submitted clearance certificate issued by DRAP I&E office, Islamabad dated 13-06-2023
5.	Drug product stability studies of 6th month time point shall be submitted	Firm has submitted stability studies of 6th month time point for both accelerated and long term conditions.

Decision: Approved

7.	**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)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 27246 dated 20-11-2023 Rs 75,000/- dated 27-07-2023
	The proposed proprietary name / brand name	**Ipragliflozin 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: 64.25mg of Ipragliflozin L-Proline Eq. to Ipragliflozin…50mg
	Pharmacotherapeutic Group of (API)	Sodium-glucose co-transporter 2 (SGLT2) inhibitors indicated for Type 2 diabetes mellitus & Type 1 diabetes mellitus
	The status in reference regulatory authorities	Suglat Tablets Approved by PMDA Japan
	For generic drugs (me-too status)	Not available
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's specifications

Evaluation by PEC[II]: Suglat tablet of M/s Astellas was initially approved by PMDA Japan in 2014 for the Type 2 diabetes mellitus and later in 2018 PMDA has concluded that the product administered in combination with insulin therapy has efficacy in the treatment of type 1 diabetes mellitus.

The active ingredient of Suglat, Ipragliflozin L-Proline, is a sodium glucose cotransporter 2 (SGLT2) inhibitor. It lowers blood glucose levels by inhibiting glucose reuptake by SGLT2 in the proximal renal tubules, leading to increased glucose excretion in the urine.

Sr.#	**Observations**	**Firm's reply**
1.	Justification shall be submitted for not including test of "Optical rotation" and "L-proline" Cotentin the drug substance specifications, as recommended by innovator drug product literature.	
2.	Justification shall be submitted for use of Mannitol in the composition of applied product since the same has not been used by the innovator drug product.	
3.	Justification shall be submitted for variation in the dissolution parameters of dissolution medium and apparatus speed from that recommended by the innovator drug product literature.	

	4.	Complete raw data sheets declaring the details of potency of standard and calculation formula applied for the performance of Assay and Dissolution test in drug product stability studies, shall be submitted.	
	5.	Drug product stability studies of 6th month time point shall be submitted	

Decision: Deferred for submission of reply to above cited shortcomings.

8.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Focus & Rulz Pharmaceuticals Pvt Ltd. 44-Industrial Triangle Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Focus & Rulz Pharmaceuticals Pvt Ltd. 44-Industrial Triangle Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy. No 25552 dated 23-10-2023 Rs.30,000/- dated 14-09-2023
	The proposed proprietary name / brand name	**Etamol 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Paracetamol……500mg
	Pharmacotherapeutic Group of (API)	Analgesics and antipyretics, ATC Code: N02BE01
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Panadol tablet of GSK
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	USP

Evaluation by PEC[II]:

Decision: Approved.

9.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad**
	Name, address of Manufacturing site.	M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 27433 dated 22-11-2023 Rs 75,000/- dated 31-10-2023
	The proposed proprietary name / brand name	**Livia 10mg/ml Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Sildenafil as Citrate…10mg
	Pharmacotherapeutic Group of (API)	Urologicals: WHO ATC G04BE03
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Silagro of M/s Nabiqasim
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	BP

Evaluation by PEC[II]:

Sr.#	**Observations**	**Firm's reply**

1.	Copy of Valid GMP certificate/DML of the drug substance manufacturer shall be submitted.	Submitted
2.	Drug product stability studies of 6th month time point shall be submitted	Submitted
3.	In-use stability study of the re-constituted suspension shall be submitted.	Firm has submitted in-use stability data of re-constituted suspension for 14 days.

Decision: Approved. Keeping in view the criticality (pediatric demand & use) of product and to ensure fair competition, the Registration Board advised the PE&R Division to issue the registration letter of product without waiting for finalization of minutes.

10.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road,Lahore**
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road,Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 27664 dated 27-11-2023 Rs 30,000/- dated 20-09-2023
	The proposed proprietary name / brand name	**Vexa 2gm IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone Sodium Eq. to Ceftriaxone…2gm
	Pharmacotherapeutic Group of (API)	Antibiotic
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Cefxone injection of M/s Bosch pharma
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	USP
Evaluation by PEC[II]:		
Decision: Approved.		
11.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 27473 dated 23-11-2023 Rs 30,000/- dated 25-10-2023
	The proposed proprietary name / brand name	**Ersita 15/100 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ertugliflozin as L-Pyroglutamic Acid…15mg Sitagliptin as Phospate Monohydrate…100mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Trevia R2 of M/s Getz pharma
	Proposed Pack size & Price	As per SRO

	Reference to Finished product specifications	Innovator's Specification

Evaluation by PEC^{II}:

Sr.#	Observations	Firm's reply
1.	Documents confirming import of drug substances i.e., commercial invoice attested by DRAP I&E office shall be submitted.	
2.	Complete batch manufacturing record of drug product stability batches shall be submitted	
3.	Analytical record i.e., Chromatograms, raw data sheets & COAs for the drug product stability studies shall be submitted.	

Decision: Deferred for submission of reply to above cited shortcomings.

12.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wnsfeild Pharmaceuticals.** **Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 27576 dated 24-11-2023 Rs 30,000/- dated 25-10-2023
	The proposed proprietary name / brand name	**Ersita 5/100 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ertugliflozin as L-Pyroglutamic Acid…5mg Sitagliptin as Phospate Monohydrate…100mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Trevia R2 of M/s Getz pharma
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's Specification

Evaluation by PEC^{II}:

Sr.#	Observations	Firm's reply
1.	Documents confirming import of drug substances i.e., commercial invoice attested by DRAP I&E office shall be submitted.	
2.	Complete batch manufacturing record of drug product stability batches shall be submitted	
3.	Analytical record i.e., Chromatograms, raw data sheets & COAs for the drug product stability studies shall be submitted.	

Decision: Deferred for submission of reply to above cited shortcomings.

13.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winbrains Research Laboratories.** **Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate,

		Hattar, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 26696 dated 06-11-2023 Rs 30,000/-
	The proposed proprietary name / brand name	**Winpa 12.5/850 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…..12.5mg Metformin HCl……850mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Eflozin M 12.5/850 mg Tablet of M/s Scilife Pharma Private Limited
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's Specification

Evaluation by PEC^{II}:

Sr.#	Observations	Firm's reply
1.	Copy of latest GMP inspection report conduced within last three years shall be submitted for drug product manufacturer.	Firm has submitted copy of GMP certificate issued on basis of inspection conducted on 12-10-2022
2.	Documents confirming import of drug substances i.e., commercial invoice attested by DRAP I&E office shall be submitted.	Firm has submitted copy of Form 6 (License to import drugs) for both Empagliflozin and metformin HCl issued by AD I&E DRAP , Peshawar.

Decision: Approved.

14.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winbrains Research Laboratories.** **Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 26277 dated 31-10-2023 Rs 30,000/-
	The proposed proprietary name / brand name	**Winpa 5/850 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…5mg Metformin HCl…850mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Adrance -M Tablets 5mg/850mg of M/s Atco Laboratories Limited
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's Specification

Evaluation by PEC^{II}:

Sr.#	Observations	Firm's reply
1.	Copy of latest GMP inspection report conduced within last three years shall be submitted for drug product manufacturer.	Firm has submitted copy of GMP certificate issued on basis of inspection conducted on 12-10-2022
2.	Documents confirming import of drug substances i.e., commercial invoice attested by DRAP I&E office shall be submitted.	Firm has submitted copy of Form 6 (License to import drugs) for both Empagliflozin and metformin HCl issued by AD I&E DRAP , Peshawar.

Decision: Approved.

15.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 26697 dated 06-11-2023 Rs 30,000/- 25-10-2023
	The proposed proprietary name / brand name	**Winpa 12.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin HCl…1000mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Eflozin M 12.5/1000 mg Tablet of M/s Scilife
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's Specification

Evaluation by PEC^{II}:

Sr.#	Observations	Firm's reply
1.	Copy of latest GMP inspection report conduced within last three years shall be submitted for drug product manufacturer.	Firm has submitted copy of GMP certificate issued on basis of inspection conducted on 12-10-2022
2.	Documents confirming import of drug substances i.e., commercial invoice attested by DRAP I&E office shall be submitted.	Firm has submitted copy of Form 6 (License to import drugs) for both Empagliflozin and metformin HCl issued by AD I&E DRAP , Peshawar.

Decision: Approved

16.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 26695 dated 06-11-2023 Rs 30,000/- 25-10-2023
	The proposed proprietary name / brand name	**Winpa 5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…5mg Metformin HCl…1000mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Empiget-M Tablets 5mg + 1000mg of M/s Getz Pharma (Pvt) Limited
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's Specification

Evaluation by PEC[II]:

Sr.#	Observations	Firm's reply
1.	Copy of latest GMP inspection report conduced within last three years shall be submitted for drug product manufacturer.	Firm has submitted copy of GMP certificate issued on basis of inspection conducted on 12-10-2022
2.	Documents confirming import of drug substances i.e., commercial invoice attested by DRAP I&E office shall be submitted.	Firm has submitted copy of Form 6 (License to import drugs) for both Empagliflozin and metformin HCl issued by AD I&E DRAP , Peshawar.

Decision: Approved.

17.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winbrains Research Laboratories.** **Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 27740 dated 28-11-2023 Rs 30,000/- dated 14-11-2023
	The proposed proprietary name / brand name	**Winpa 25/1000 mg XR Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…25mg Metformin HCl…1000mg (as Extended Release)
	Pharmacotherapeutic Group of (API)	Antidiabetic
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Emglin Plus XR 25/1000mg Tablet of M/s PHARMEVO (PVT) LTD.
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's Specification

Evaluation by PEC[II]:

Sr.#	Observations	Firm's reply
1.	Copy of latest GMP inspection report conduced within last three years shall be submitted for drug product manufacturer.	Firm has submitted copy of GMP certificate issued on basis of inspection conducted on 12-10-2022

	2.	Documents confirming import of drug substances i.e., commercial invoice attested by DRAP I&E office shall be submitted.	Firm has submitted copy of Form 6 (License to import drugs) for both Empagliflozin and metformin HCl issued by AD I&E DRAP , Peshawar.

Decision: Approved.

18.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winbrains Research Laboratories.** **Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 27738 dated 28-11-2023 Rs 30,000/- dated 14-11-2023
	The proposed proprietary name / brand name	**Winpa 10/1000 mg XR Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…10mg Metformin HCl…1000mg (as Extended Release)
	Pharmacotherapeutic Group of (API)	Antidiabetic
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Emglin Plus XR 10/1000mg Tablet of M/s PHARMEVO (PVT) LTD.
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's Specification

Evaluation by PEC^{II}:

Sr.#	**Observations**	**Firm's reply**
1.	Copy of latest GMP inspection report conduced within last three years shall be submitted for drug product manufacturer.	Firm has submitted copy of GMP certificate issued on basis of inspection conducted on 12-10-2022
2.	Documents confirming import of drug substances i.e., commercial invoice attested by DRAP I&E office shall be submitted.	Firm has submitted copy of Form 6 (License to import drugs) for both Empagliflozin and metformin HCl issued by AD I&E DRAP , Peshawar.

Decision: Approved.

19.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winbrains Research Laboratories.** **Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 27739 dated 28-11-2023 Rs 30,000/- dated 14-11-2023
	The proposed proprietary name / brand name	**Winpa 12.5/1000 mg XR Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin HCl…1000mg (as Extended Release)
	Pharmacotherapeutic Group of (API)	Antidiabetic
	The status in reference regulatory authorities	Approved by EMA
	For generic drugs (me-too status)	Diampa-M Tablet of M/s Getz pharma
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's Specification

Evaluation by PEC^{II}:

Sr.#	Observations	Firm's reply
1.	Copy of latest GMP inspection report conduced within last three years shall be submitted for drug product manufacturer.	Firm has submitted copy of GMP certificate issued on basis of inspection conducted on 12-10-2022
2.	Documents confirming import of drug substances i.e., commercial invoice attested by DRAP I&E office shall be submitted.	Firm has submitted copy of Form 6 (License to import drugs) for both Empagliflozin and metformin HCl issued by AD I&E DRAP , Peshawar.

Decision: Approved.

20.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 27737 dated 28-11-2023 Rs 30,000/- dated 14-11-2023
	The proposed proprietary name / brand name	**Winpa 5/1000 mg XR Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…5mg Metformin HCl…1000mg (as Extended Release)
	Pharmacotherapeutic Group of (API)	Antidiabetic
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	--
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's Specification

Evaluation by PEC^{II}:

Sr.#	Observations	Firm's reply
1.	Copy of latest GMP inspection report conduced within last three years shall be submitted for drug product manufacturer.	Firm has submitted copy of GMP certificate issued on basis of inspection conducted on 12-10-2022
2.	Documents confirming import of drug substances i.e., commercial invoice attested by DRAP I&E office shall be submitted.	Firm has submitted copy of Form 6 (License to import drugs) for both Empagliflozin and metformin HCl issued by AD I&E DRAP , Peshawar.

Decision: Approved.

21.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi**
	Name, address of Manufacturing site.	M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 26711 dated 07-11-2023 Rs 30,000/- dated 20-10-2023
	The proposed proprietary name / brand name	**Pertz 15mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. to Ertugliflozin…15mg
	Pharmacotherapeutic Group of (API)	SGLT2 inhibitor.
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Eglaro tablet of M/s Pharm Evo
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's Specification
Evaluation by PEC^{II}:		
Decision: Approved.		
22.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi**
	Name, address of Manufacturing site.	M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 26710 dated 07-11-2023 Rs 30,000/- dated 20-10-2023
	The proposed proprietary name / brand name	**Pertz 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. to Ertugliflozin…5mg
	Pharmacotherapeutic Group of (API)	SGLT2 inhibitor.
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Eglaro tablet of M/s Pharm Evo
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's Specification
Evaluation by PEC^{II}:		
Decision: Approved.		
23.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 26950 dated 14-11-2023 Rs 30,000/- dated 25-10-2023
	The proposed proprietary name / brand name	**Letrum-M 2.5/850 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Linagliptin…2.5mg Metformin HCl…850mg
	Pharmacotherapeutic Group of (API)	Dipeptidyl peptidase-4 (DPP-4) inhibitors/Biguanides.
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Lina-Met 2.5/850mg Tablet of M/s CCL
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Manufacturer's Specification

Evaluation by PEC^{II}:

Sr.#	Observations	Firm's reply
1.	Copy of Valid GMP certificate/DML of the drug substance manufacturer of Linagliptin shall be submitted.	Firm has submitted copy of GMP certificate issued by DCA Andhrapradesh valid upto 12-01-2025.
2.	Composition of the excipient "Quick tab" used in the formulation shall be elaborated.	Cross povidone, Povidone, Microcrystalline cellulose, Tricalcium phosphate
3.	Justification shall be submitted for not including test of "Arginine content" in the drug product specifications as recommended by innovator drug product literature. Justification shall be submitted for specifying dissolution limit of 45minutes while the innovator drug product literature has recommended dissolution limit of within 30 minutes.	Firm has submitted revised drug product specifications including test of Arginine content and dissolution limits as within 30 minutes.
4.	Stability data for the 6th month time point shall be submitted.	Firm has submitted 6th month time point stability data along with analytical record.

Decision: Approved with Innovator's specifications. Firm shall submit fee Rs. 9000/- for pre-approval correction in drug product specifications as per SRO 1324(I)/2024 dated 30-08-, before issuance of registration letter.

24.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 27154 dated 17-11-2023 Rs 30,000/- dated 25-10-2023
	The proposed proprietary name / brand name	**Letrum-M 2.5/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Linagliptin…2.5mg Metformin HCl…500mg
	Pharmacotherapeutic Group of (API)	Dipeptidyl peptidase-4 (DPP-4) inhibitors/Biguanides.
	The status in reference regulatory authorities	Approved by US FDA

	For generic drugs (me-too status)	Lina-Met 2.5/500mg Tablet of M/s CCL
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Manufacturer's Specification

Evaluation by PEC[II]:

Sr.#	Observations	Firm's reply
1.	Copy of Valid GMP certificate/DML of the drug substance manufacturer of Linagliptin shall be submitted.	Firm has submitted copy of GMP certificate issued by DCA Andhrapradesh valid upto 12-01-2025.
2.	Composition of the excipient "Quick tab" used in the formulation shall be elaborated.	Cross povidone, Povidone, Microcrystalline cellulose, Tricalcium phosphate
3.	Justification shall be submitted for not including test of "Arginine content" in the drug product specifications as recommended by innovator drug product literature. Justification shall be submitted for specifying dissolution limit of 45minutes while the innovator drug product literature has recommended dissolution limit of within 30 minutes.	Firm has submitted revised drug product specifications including test of Arginine content and dissolution limits as within 30 minutes.
4.	Stability data for the 6th month time point shall be submitted.	Firm has submitted 6th month time point stability data along with analytical record.

Decision: Approved with Innovator's specifications. Firm shall submit fee Rs. 9000/- for pre-approval correction in drug product specifications as per SRO 1324(I)/2024 dated 30-08-, before issuance of registration letter

25.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 27155 dated 17-11-2023 Rs 30,000/- dated 25-10-2023
	The proposed proprietary name / brand name	**Letrum-M 2.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Linagliptin…2.5mg Metformin HCl…1000mg
	Pharmacotherapeutic Group of (API)	Dipeptidyl peptidase-4 (DPP-4) inhibitors/Biguanides.
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	LinaMet 2.5/500 tablet of M/s CCL
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Manufacturer's Specification

Evaluation by PEC[II]:

Sr.#	Observations	Firm's reply
1.	Copy of Valid GMP certificate/DML of the drug substance manufacturer of Linagliptin shall be submitted.	Submitted

2.	Composition of the excipient "Quick tab" used in the formulation shall be elaborated.	Cross povidone, Povidone, Microcrystalline cellulose, Tricalcium phosphate
3.	Justification shall be submitted for not including test of "Arginine content" in the drug product specifications as recommended by innovator drug product literature. Justification shall be submitted for specifying dissolution limit of 45minutes while the innovator drug product literature has recommended dissolution limit of within 30 minutes.	Firm has submitted revised drug product specifications including test of Arginine content and dissolution limits as within 30 minutes.
4.	Stability data for the 6th month time point shall be submitted.	Submitted

Decision: Approved with Innovator's specifications. Firm shall submit fee Rs. 9000/- for pre-approval correction in drug product specifications as per SRO 1324(I)/2024 dated 30-08-, before issuance of registration letter

26.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pacific Pharmaceuticals Limited.** **Plot No. 384, Sundar Industrial Estate, Lahore, Pakistan**
	Name, address of Manufacturing site.	M/s Pacific Pharmaceuticals Limited. Plot No. 384, Sundar Industrial Estate, Lahore, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 24550 dated 09-10-2023 Rs.30,000/- dated 02-08-2023
	The proposed proprietary name / brand name	**Paracetamol 300mg/2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml Contains: Paracetamol……300mg
	Pharmacotherapeutic Group of (API)	Analgesics and antipyretics, ATC Code: N02BE01
	The status in reference regulatory authorities	Approved by MHRA
	For generic drugs (me-too status)	Provas Injection 300mg/2ml M/s SAMI Pharmaceuticals (Pvt.) Ltd. F-95, S.I.T.E., Karachi Pakistan.
	Proposed Pack size & Price	5 x 2ml Ampoules; As per SRO
	Reference to Finished product specifications	Pacific's Specs

Evaluation by PEC^{II}: Submitted reference product approved could not be verified.

Decision: Deferred for evidence of approval of applied formulation by the reference regulatory authorities adopted by the Registration Board in its 275th meeting.

27.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Helix Pharma Pvt Ltd.** **Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 24353 dated 05-10-2023 Rs.75,000/- dated 26-04-2023
	The proposed proprietary name / brand name	**Ertulix-M 2.5/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. to Ertugliflozin…2.5mg Metformin HCl……500mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	The status in reference regulatory authorities	Approved by U SFDA
	For generic drugs (me-too status)	--
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	As per Innovator
Evaluation by PEC^{II}:		
Decision: Approved.		
28.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 24354 dated 05-10-2023 Rs.75,000/- dated 26-04-2023
	The proposed proprietary name / brand name	**Ertulix-M 2.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. to Ertugliflozin…2.5mg Metformin HCl……1000mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	The status in reference regulatory authorities	Approved by U SFDA
	For generic drugs (me-too status)	Gujamet 2.5/500mg Tablet of M/s CCL Pharmaceuticals (Pvt.) Ltd.
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	As per Innovator
Evaluation by PEC^{II}:		
Decision: Approved.		
29.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 24356 dated 05-10-2023 Rs.75,000/- dated 06-07-2023
	The proposed proprietary name / brand name	**Ertulix-M 7.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. to Ertugliflozin…7.5mg Metformin HCl……1000mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	The status in reference regulatory authorities	Approved by U SFDA
	For generic drugs (me-too status)	Gujamet 7.5/1000mg Tablet of M/s CCL
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	As per Innovator
Evaluation by PEC^{II}:		
Decision: Approved.		
30.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Helix Pharma Pvt Ltd.** **Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Helix Pharma Pvt Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 24355 dated 05-10-2023 Rs.75,000/- dated 06-07-2023
	The proposed proprietary name / brand name	**Ertulix-M 7.5/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. to Ertugliflozin…7.5mg Metformin HCl……500mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	The status in reference regulatory authorities	Approved by USFDA
	For generic drugs (me-too status)	Gujamet 7.5/500mg Tablet of M/s CCL
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	As per Innovator
Evaluation by PEC^{II}:		
Decision: Approved.		
31.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Herbion Pakistan Pvt Ltd. Industrial Triangle , Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Herbion Pakistan Pvt Ltd. Industrial Triangle , Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 24308 dated 04-10-2023 Rs.30,000/- dated 25-07-2023

	The proposed proprietary name / brand name	**Vidaglu-Met 50/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vildagliptin……50mg Metformin HCl……1000mg
	Pharmacotherapeutic Group of (API)	Anti-Diabetic drug
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Galmet Tablet of M/s CCL
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's specifications

Evaluation by PEC^{II}:

Sr.#	Observations	Firm's response
1.	Submit valid GMP certificate/DML for the drug substance manufacturers issued by relevant regulatory authority.	Submitted
2.	Drug substance analytical procedure shall be submitted from M/s Herbion	Submitted
3.	Long term stability data of Vildagliptin shall be submitted as per Zone IV conditions.	Submitted
4.	Justification shall be submitted for not including test of Uniformity of dosage unit by way of content uniformity for Vildagliptin in drug product specifications.	We had originally performed the test for uniformity of dosage units, but it was inadvertently omitted during the submission of the dossier. We are now submitting it for inclusion
5.	Documents confirming procurement of drug substance , approved by DRAP I&E office shall be submitted.	Submitted

Decision: Approved with Innovator's specifications. Firm shall submit fee Rs. 9000/- for pre-approval correction in drug product specifications as per SRO 1324(I)/2024 dated 30-08-, before issuance of registration letter

32.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Herbion Pakistan Pvt Ltd. Industrial Triangle , Kahuta Road, Islamabad**
	Name, address of Manufacturing site.	M/s Herbion Pakistan Pvt Ltd. Industrial Triangle , Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy. No 24307 dated 04-10-2023 Rs.30,000/- dated 25-07-2023
	The proposed proprietary name / brand name	**Vidaglu-Met 50/850 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vildagliptin……50mg Metformin HCl……850mg
	Pharmacotherapeutic Group of (API)	Anti-Diabetic drug
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Galmet Tablet of M/s CCL
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's specifications

Evaluation by PEC^{II}:

Sr.#	Observations	Firm's response
1.	Submit valid GMP certificate/DML for the drug substance manufacturers issued by relevant regulatory authority.	Submitted
2.	Drug substance analytical procedure shall be submitted from M/s Herbion	Submitted
3.	Long term stability data of Vildagliptin shall be submitted as per Zone IV conditions.	Submitted
4.	Justification shall be submitted for not including test of Uniformity of dosage unit by way of content uniformity for Vildagliptin in drug product specifications.	We had originally performed the test for uniformity of dosage units, but it was inadvertently omitted during the submission of the dossier. We are now submitting it for inclusion
5.	Documents confirming procurement of drug substance , approved by DRAP I&E office shall be submitted.	Submitted

Decision: Approved with Innovator's specifications. Firm shall submit fee Rs. 9000/- for pre-approval correction in drug product specifications as per SRO 1324(I)/2024 dated 30-08-, before issuance of registration letter

33.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy. No 26292 dated 31-10-2023 Rs.75,000/- dated 10-10-2023
	The proposed proprietary name / brand name	**Zegwin-M XR 50/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Extended Release Tablet Contains: Sitagliptin as Phosphate Monohydrate…….50mg Metformin HCl (as Extended Release Core Tablet)……500mg
	Pharmacotherapeutic Group of (API)	Anti-Diabetic drug
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Sitamet XR tablet of M/s CCL
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's specifications

Evaluation by PEC^{II}: BP monograph is available for the applied formulation.

Decision: Approved with BP specifications. Firm shall submit fee Rs. 9000/- for pre-approval correction in drug product specifications as per SRO 1324(I)/2024 dated 30-08-, before issuance of registration letter

34.	**Deleted due to repetition of case at Sr. # 14.**	
35.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore**
	Name, address of Manufacturing site.	M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy. No 26292 dated 31-10-2023 Rs.75,000/- dated 10-10-2023
	The proposed proprietary name / brand name	**Manisart 30/10 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Delapril HCl…30mg Manidipine HCl…10mg
	Pharmacotherapeutic Group of (API)	ACE inhibitors and calcium antagonists. ATC code: C09B B12 (Treatment of essential arterial hypertension)
	The status in reference regulatory authorities	Approved by AEMPS of Spain
	For generic drugs (me-too status)	--
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Manufacture specifications

Evaluation by PEC[II]:

Sr.#	Observations	Firm's response
1.	Justification shall be submitted for not using Riboflavin in the formulation of applied product as used by the innovator drug product.	• Riboflavin is included as an excipient in the formulation of the innovator product and does not contribute to any therapeutic effects. Therefore, it has not been incorporated into the formulation of the applied product. Riboflavin is employed as an antioxidant in the formulation to enhance product stability. It is used as an antioxidant in formulation, after 6th month stability it is evident that the product formulation is stable without riboflavin. • We require the tablet to be white in color, but riboflavin is imparting an undesired color, which is not necessary for the formulation.
2.	Justification shall be submitted for using surfactant in the dissolution medium for the performance of dissolution test.	Practically, no surfactant was used in dissolution testing of Manidipine and Delapril tablet which is also evident in CDP report but there was a typographical error in the testing method or specs, amendment have been made in the said document and same is attached for your reference.

Decision: Deferred for review of applied formulation for regulatory status in other reference regulatory authorities.

36.	**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)

	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy. No 24351 dated 05-10-2023 Rs.75,000/- dated 18-08-2023
	The proposed proprietary name / brand name	**Sotiff 200mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Sotagliflozin……200mg
	Pharmacotherapeutic Group of (API)	Drugs used in diabetes, sodium-glucose cotransporter 2 (SGLT2) inhibitors
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	--
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC[II]:

Sr.#	Observations	Firm's response
1.	Submit details of the characterisation studies of drug substance performed by the drug substance manufacturer for establishment of the polymorphic form of the drug substance.	Firm has referred to the following studies performed by drug substance manufacturer.: • FTIR • NMR • Mass Spectroscopy • Powdee X-Ray diffraction • Thermogravimetric analysis
2.	Justification shall be submitted for not including test of moisture content in drug product specifications as recommended by the innovator drug product literature.	We have performed the loss on drying test by moisture analyzer in mixing stage. Moreover, we included this test in our drug product standard analytical procedure.
3.	Stability studies data of drug product shall be submitted for the 6th month time point.	The 6th Month stability data along with raw data and related records has been submitted

Decision: The Board was apprised that the applied formulation has been declared as "Withdrawn" by EMA. Registration Board hence decided to defer the instant application for clarification regarding the reason of withdrawal in EMA as well as confirmation of regulatory status of applied formulation in reference regulatory authorities, other than US FDA.

37.	**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)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 24352 dated 05-10-2023 Rs.75,000/- dated 15-09-2023
	The proposed proprietary name / brand name	**Sotiff 400mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Sotagliflozin……400mg
	Pharmacotherapeutic Group of (API)	Drugs used in diabetes, sodium-glucose cotransporter 2 (SGLT2) inhibitors
	The status in reference regulatory authorities	Approved by US FDA

	For generic drugs (me-too status)	--
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC[II]:

Sr.#	Observations	Firm's response
1.	Submit details of the characterisation studies of drug substance performed by the drug substance manufacturer for establishment of the polymorphic form of the drug substance.	Firm has referred to the following studies performed by drug substance manufacturer.: • FTIR • NMR • Mass Spectroscopy • Powdee X-Ray diffraction • Thermogravimetric analysis
2.	Justification shall be submitted for not including test of moisture content in drug product specifications as recommended by the innovator drug product literature.	We have performed the loss on drying test by moisture analyzer in mixing stage. Moreover, we included this test in our drug product standard analytical procedure.
3.	Stability studies data of drug product shall be submitted for the 6th month time point.	The 6th Month stability data along with raw data and related records has been submitted

Decision: The Board was apprised that the applied formulation has been declared as "Withdrawn" by EMA. Registration Board hence decided to defer the instant application for clarification regarding the reason of withdrawal in EMA as well as confirmation of regulatory status of applied formulation in reference regulatory authorities, other than US FDA.

38.	**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)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 24321 dated 04-10-2023 Rs.30,000/- dated 05-09-2023
	The proposed proprietary name / brand name	**Linamet 2.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Linagliptin…2.5mg Metformin HCl…1000mg
	Pharmacotherapeutic Group of (API)	Anti-Diabetic drug
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Lina-Met 2.5/500 of M/s CCL
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC[II]:

Sr.#	Observations	Firm's response
1.	Submit valid DML/GMP certificate of the drug substance manufacturer of drug substance	

	manufacturers issued by the relevant regulatory authority of country of origin.	
2.	In contrary to the innovator drug product literature from the US FDA & EMA, the section declares the solubility of Empagliflozin in water as "practically insoluble". Justification shall be submitted in this regard.	
3.	Analytical Method Verification studies of drug substances including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	
4.	Justification shall be submitted for not including test of "Enantiomeric purity" in the drug substance specifications of Linagliptin	
5.	Justification shall be submitted for the seal coating applied on Metformin HCl core, while referring to the innovator drug product formulation.	
6.	Justification shall be submitted for proposed quantity of Arginine in the formulation.	
7.	Justification shall be submitted on basis of performance based evidence for adding 10% overage of "Empagliflozin" & "Linagliptin" in the applied batch formulation.	
8.	Justification shall be submitted for test of Arginine content in drug product specifications.	
9.	Clearance certificate for the import of Linagliptin issued by DRAP I&E office shall be submitted.	
10.	Justification shall be submitted for the ascending trend & significant change of Assay results of Empagliflozin and Linagliptin in drug product stability studies.	

Decision: Deferred for submission of reply to above cited shortcomings.

39.	**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)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 24321 dated 04-10-2023 Rs.30,000/- dated 05-09-2023
	The proposed proprietary name / brand name	**Linamet 2.5/850 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Linagliptin…2.5mg Metformin HCl…850mg
	Pharmacotherapeutic Group of (API)	Anti-Diabetic drug
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	--
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC[II]:

Sr.#	**Observations**	**Firm's response**
1.	Submit valid DML/GMP certificate of the drug substance manufacturer of drug substance	

	manufacturers issued by the relevant regulatory authority of country of origin.	
2.	In contrary to the innovator drug product literature from the US FDA & EMA, the section declares the solubility of Empagliflozin in water as "practically insoluble". Justification shall be submitted in this regard.	
3.	Analytical Method Verification studies of drug substances including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	
4.	Justification shall be submitted for not including test of "Enantiomeric purity" in the drug substance specifications of Linagliptin	
5.	Justification shall be submitted for the seal coating applied on Metformin HCl core, while referring to the innovator drug product formulation.	
6.	Justification shall be submitted for proposed quantity of Arginine in the formulation.	
7.	Justification shall be submitted on basis of performance based evidence for adding 10% overage of "Empagliflozin" & "Linagliptin" in the applied batch formulation.	
8.	Justification shall be submitted for test of Arginine content in drug product specifications.	
9.	Clearance certificate for the import of Linagliptin issued by DRAP I&E office shall be submitted.	
10.	Justification shall be submitted for the ascending trend & significant change of Assay results of Empagliflozin and Linagliptin in drug product stability studies.	

Decision: Deferred for submission of reply to above cited shortcomings.

40.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi**
	Name, address of Manufacturing site.	M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 24349 dated 05-10-2023 Rs.75,000/- dated 08-09-2023
	The proposed proprietary name / brand name	**Scilina-M XR 5/2.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin …… 5mg Linagliptin ..…. 2.5mg Metformin HCl (as extended release)……1000mg
	Pharmacotherapeutic Group of (API)	Combination of orall blood glucose lowerinig drugs
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Emlip XR 5/2.5/1000mg Tabs of M/s The Searle Company
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC[II]:

Sr.#	**Observations**	**Firm's response**

1.	Submit valid DML/GMP certificate of the drug substance manufacturer of drug substance manufacturers issued by the relevant regulatory authority of country of origin.	Submitted
2.	In contrary to the innovator drug product literature from the US FDA & EMA, the section declares the solubility of Empagliflozin in water as "practically insoluble". Justification shall be submitted in this regard.	On behalf of Scilife Pharma, we would like to address the discrepancy regarding the solubility specification of Empagliflozin water. In contrast to the solubility information in the innovator drug product literature from the US FDA and EMA, which lists Empagliflozin as "practically insoluble" in water, the initial specification mistakenly reflected otherwise. The API manufacturer has confirmed that the solubility information provided was a typographical error and should align with the established literature. In response, the manufacturer has share corrected specification and COA and we are sharing the updated documents to reflect this correction.
3.	Analytical Method Verification studies of drug substances including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	Submitted.
4.	Justification shall be submitted for not including test of "Enantiomeric purity" in the drug substance specifications of Linagliptin	On behalf of Scilife Pharma, we acknowledge that the "Enantiomeric Purity" test was not initially included in the drug substance specification of Linagliptin by API manufacturer. However, we they have now revised the specification to include this test and are sharing the CoA in line with the updated specifications,
8.	Justification shall be submitted for not including test of Arginine content in drug product specifications.	On behalf of Scilife Pharma (Pvt.) Limited, classified as an excipient in our formulation and, therefore we acknowledge that Arginine content was initially was not included in the finished product specification for Empagliflozin-Linagliptin-Metformin XR 5mg 2.5mg+ 1000mg Tablet (R&D-ELM-254, Version 01). However, we have now revised our specification to include Arginine content as a quality parameter. QC release specifications and stability batches for this product. We are committed to ensuring that Arginine content will continue to be included in the stability. We kindly request your acceptance of this amendment to our specification. Updated Finish Product Specification of Empaglifozin Linagliptin Metformin XR +5mg+2.5mg 1000mg Tablet has been submitted.

9.	Clearance certificate for the import of Linagliptin issued by DRAP I&E office shall be submitted.	Firm has submitted copy of License to import issued by I&E DRAP, Karachi dated 14-06-2022 for 0.5Kg Linagliptin.
10.	Justification shall be submitted for the ascending trend & significant change of Assay results of Empagliflozin and Linagliptin in drug product stability studies.	We acknowledge the acending trend observed in assay results during stability studies: The pointwise justification is as under: • All the results of Empagliflozin and Linagliptin obtained at accelerated and real time conditions are within the specified limit of (90.0 -110.0)% that is considered satisfactory and acceptable. • In addition to that, all the results of Empagliflozin and Linagliptin are also within the stringent limit of (95.00 – 105%) shows that the satisfactory trend and within acceptable limits. • All the results obtained at 3rd month on both the conditions are also satisfactory and do not significant and acceptable. • The results obtained of all three batches (152B23, 153B23, 154B23) at 6 months on accelerated condition while only one batch (152B23) of real time condition at 6 month having slightly ascending trend. The ascending trend depicting the significant change of assay while in actual it is due to analytical error of many factors and do not truly due to the product formulation manufacturing process and stability studies so it would be considered acceptable. • The above facts that the product Scilina-M XR (5/2.5/1000)mg tablets is stable and satisfactory while the ascending trend is due to analytical error additionally the results are within the specified limit of (90.0-110.0) % even within stringent limit of (95.0-105.0) % therefore you are requested to kindly consider satisfactory and acceptable.

Decision: Approved. Firm shall submit following before issuance of registration letter:

- **Fee for pre-registration variation as per SRO as per SRO1324 (I)/2024 dated 30-08-2024.**
- **Revised Product development protocol to address the significant change observed in submitted drug product stability studies.**

41.	**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)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 24551 dated 09-10-2023 Rs.30,000/- dated 12-09-2023
	The proposed proprietary name / brand name	**Daysita-M XR 100/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Sitagliptin as Phosphate Monohydrate…100mg Metformin HCl…….1000mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Sita-Met XR Tablets by CCL
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC[II]:

Sr.#	Observations	Firm's response
1.	Submit valid DML/GMP certificate of the drug substance manufacturer of Metformin HCl issued by the relevant regulatory authority of country of origin.	Submitted
2.	Justification shall be submitted for claiming innovator specifications for applied drug product while the BP monograph is available for the applied formulation	Product was developed in 2022. At the time of product development and initial stability studies, Drug product was not available in Pharmacopoeia so in-house method was developed and validated. Furthermore drug product BP monograph of Metformin and Sitagliptin prolonged release tablet was published in 2023.
3.	Complete batch manufacturing record of stability batches shall be submitted.	Submitted.

Decision: Approved with BP specifications. Firm shall submit fee Rs. 9000/- for pre-approval correction in drug product specifications as per SRO 1324(I)/2024 dated 30-08-, before issuance of registration letter

42.	**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)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 24316 dated 04-10-2023 Rs.30,000/- dated 31-08-2023
	The proposed proprietary name / brand name	**Daysita-M XR 50/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Sitagliptin as Phosphate Monohydrate…50mg Metformin HCl (as extended release core)…….500mg
	Pharmacotherapeutic Group of (API)	Antidiabetic

	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Sita-Met XR Tablets by CCL
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC[II]:

Sr.#	Observations	Firm's response
1.	Submit valid DML/GMP certificate of the drug substance manufacturer of Metformin HCl issued by the relevant regulatory authority of country of origin.	Submitted
2.	Justification shall be submitted for claiming innovator specifications for applied drug product while the BP monograph is available for the applied formulation	Product was developed in 2022. At the time of product development and initial stability studies, Drug product was not available in Pharmacopoeia so in-house method was developed and validated. Furthermore drug product BP monograph of Metformin and Sitagliptin prolonged release tablet was published in 2023.
3.	Complete batch manufacturing record of stability batches shall be submitted.	Submitted.

Decision: Approved with BP specifications. Firm shall submit fee Rs. 9000/- for pre-approval correction in drug product specifications as per SRO 1324(I)/2024 dated 30-08-, before issuance of registration letter

43.	**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)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 24317 dated 04-10-2023 Rs.30,000/- dated 31-08-2023
	The proposed proprietary name / brand name	**Daysita-M XR 50/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Sitagliptin as Phosphate Monohydrate…50mg Metformin HCl (as extended release core)…….1000mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Sita-Met XR Tablets by CCL
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC[II]:

Sr.#	Observations	Firm's response
1.	Submit valid DML/GMP certificate of the drug substance manufacturer of Metformin HCl issued by the relevant regulatory authority of country of origin.	Submitted

2.	Justification shall be submitted for claiming innovator specifications for applied drug product while the BP monograph is available for the applied formulation	Product was developed in 2022. At the time of product development and initial stability studies, Drug product was not available in Pharmacopoeia so in-house method was developed and validated. Furthermore drug product BP monograph of Metformin and Sitagliptin prolonged release tablet was published in 2023.
3.	Complete batch manufacturing record of stability batches shall be submitted.	Submitted.

Decision: Approved with BP specifications. Firm shall submit fee Rs. 9000/- for pre-approval correction in drug product specifications as per SRO 1324(I)/2024 dated 30-08-, before issuance of registration letter

44.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan**
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 24542 dated 09-10-2023 Rs.30,000/- dated 28-08-2023
	The proposed proprietary name / brand name	**Daglozin-M XR 5/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin Propanediol Monohydrate Eq. to Dapagliflozin……5mg Metformin HCl (Extended release) …….500mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Xiga-Met XR Tablets by CCl.
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC^{II}:

Decision: Approved.

45.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan**
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 24543 dated 09-10-2023 Rs.30,000/- dated 28-08-2023
	The proposed proprietary name / brand name	**Daglozin-M XR 5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains:

		Dapagliflozin Propanediol Monohydrate Eq. to Dapagliflozin……5mg Metformin HCl (Extended release) …….1000mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Xiga-Met XR Tablets by CCl.
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications
Evaluation by PEC^{II}:		
Decision: Approved.		
46.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Aptcure Pvt Ltd** **8- Pharma City, 30 km Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Aptcure Pvt Ltd 8- Pharma City, 30 km Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 26290 dated 31-10-2023 Rs.30,000/- dated 20-10-2023
	The proposed proprietary name / brand name	**Dapacure 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin Propanediol Monohydrate Eq. to Dapagliflozin …… 5mg
	Pharmacotherapeutic Group of (API)	Inhibitor of SGLT2
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Xiga Tablets by CCl.
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC^{II}:

Sr.#	Observations	Firm's response
1.	Submit valid DML/GMP certificate of the drug substance manufacturers issued by the relevant regulatory authority of country of origin.	
2.	Submit drug substance specifications, analytical procedure and analytical method verification studies of drug substance from M/s Aptcure.	
3.	Submitted drug substances specifications are not as per the USP monograph of Dapagliflozin propane diol. Justification shall be submitted in this regard.	
4.	Submitted results of CDP studies shall be justified against the solubility profile of the Dapagliflozin declare din the innovator drug product literature.	
5.	Justification shall be submitted for the adopted dissolution parameters for performance of dissolution test since it varies from that recommended by the innovator drug product literature e.g., dissolution medium, time point rpm …	
6.	Submitted drug product analytical procedure is for Pitavastatin calcium instead of the applied product of Dapagliflozin tablet.	

7.	Submit analytical method verification studies for the Assay method of Dapagliflozin tablet.	
8.	Submit details for section 3.2.P.6	
9.	Submit evidence of procurement for the drug substance, i.e., clearance certificate, issued by DRAP I&E office	
10.	Justification shall be submitted for the dispensed quantity of Dapagliflzin propanediol monohydrate for the manufacturing of trial batches against the potency determined in drug substance analysis.	

Decision: Deferred for submission of reply to above cited shortcomings.

47.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Aptcure Pvt Ltd** **8- Pharma City, 30 km Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Aptcure Pvt Ltd 8- Pharma City, 30 km Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 27571 dated 24-11-2023 Rs 30,000/- dated 20-10-2023
	The proposed proprietary name / brand name	**Dapacure 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin Propanediol Monohydrate Eq. to Dapagliflozin …… 10mg
	Pharmacotherapeutic Group of (API)	Inhibitor of SGLT2
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Xiga Tablets by CCl.
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC^{II}:

Sr.#	Observations	Firm's response
1.	Submit valid DML/GMP certificate of the drug substance manufacturers issued by the relevant regulatory authority of country of origin.	
2.	Submit drug substance specifications, analytical procedure and analytical method verification studies of drug substance from M/s Aptcure.	
3.	Submitted drug substances specifications are not as per the USP monograph of Dapagliflozin propane diol. Justification shall be submitted in this regard.	
4.	Submitted results of CDP studies shall be justified against the solubility profile of the Dapagliflozin declare din the innovator drug product literature.	
5.	Justification shall be submitted for the adopted dissolution parameters for performance of dissolution test since it varies from that recommended by the innovator drug product literature e.g., dissolution medium, time point rpm …	
6.	Submitted drug product analytical procedure is for Pitavastatin calcium instead of the applied product of Dapagliflozin tablet.	
7.	Submit analytical method verification studies for the Assay method of Dapagliflozin tablet.	
8.	Submit details for section 3.2.P.6	

9.	Submit evidence of procurement for the drug substance, i.e., clearance certificate, issued by DRAP I&E office	
10.	Justification shall be submitted for the dispensed quantity of Dapagliflzin propanediol monohydrate for the manufacturing of trial batches against the potency determined in drug substance analysis.	

Decision: Deferred for submission of reply to above cited shortcomings.

48.	**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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 23614 dated 25-09-2023
	Details of fee submitted	Rs.30,000/- dated 02-08-2023
	The proposed proprietary name / brand name	**Ibrosync 80/80 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sugar Coated Tablet Contains: Phloroglucinol Dihydrate Eq. to Phloroglucinol…80mg Trimethyl Phloroglucinol…80mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs.
	The status in reference regulatory authorities	Approved by ANSM of France.
	For generic drugs (me-too status)	Anafortan Plus Tablets by AGP (Private) Ltd.
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Pacific specifications

Evaluation by PEC[II]:

Sr.#	Observations	Firm's response
1.	Submit valid DML/GMP certificate of the drug substance manufacturers issued by the relevant regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Nanjing pharmaceutical Association valid till 18-12-2024
2.	Submit details of Trimethyl phloroglucinol in section 3.2.S	Submitted.
3.	Submit evidence of procurement for the drug substances, issued by DRAP I&E office.	Firm has submitted clearance certificate issued by DRAP I&E, Lahore office dated 15-02-2023.
4.	Drug product stability data of 6th month time point shall be submitted.	Submitted.

Decision: Deferred for submission of valid DML/GMP certificate of drug substne manufacturer issued by relevant regulatory authority f country of origin.

49.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore**
	Name, address of Manufacturing site.	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 23767 dated 27-09-2023
	Details of fee submitted	Rs.30,000/- dated 08-09-2023
	The proposed proprietary name / brand name	**Dibian-XR 5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin (Immediate Release)..…5mg Metformin HCl (Extended Release)…1000mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs.
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	Xenglu Met XR tablet of M/s Hilton Pharma
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications
Evaluation by PEC^{II}:		
Decision: Approved.		
50.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma Pvt Ltd.** **44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan**
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 23150 dated 20-09-2023
	Details of fee submitted	Rs.30,000/- dated 28-08-2023
	The proposed proprietary name / brand name	**Daglozin-M XR 10/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin Propanediol Monohydrate Eq. to Dapagliflozin…....10mg Metformin HCl (extended release)……1000mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs (WHO ATC: A10BD)
	Reference to Finished product specifications	Innovator's Specs
	Proposed Pack size	7's, 10's, 14's, 20's, , 28's, 30's, 50's, 60's & 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Xiga-Met XR tablet 10/1000 of M.s CCl Pharmaceuticals.
Evaluation by PEC^{II}:		
Decision: Approved.		
51.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma Pvt Ltd.** **44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan**
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 23150 dated 20-09-2023
	Details of fee submitted	Rs.30,000/- dated 28-08-2023
	The proposed proprietary name / brand name	**Daglozin-M XR 10/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dapagliflozin Propanediol Monohydrate Eq. to Dapagliflozin…..10mg Metformin HCl (extended release)……500mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs (WHO ATC: A10BD)
	Reference to Finished product specifications	Innovator's Specs
	Proposed Pack size	7's, 10's, 14's, 20's, , 28's, 30's, 50's, 60's & 100's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Dapxiga XR tablet of M/s Ferozsons
Evaluation by PEC[II]:		
Decision: Approved.		
52.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio Mark Pharmaceuticals.** **Plot No. 527, Sundar Industrial Estate,Lahore**
	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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 22777 dated 15-09-2023
	Details of fee submitted	Rs.30,000/- dated 13-09-2023
	The proposed proprietary name / brand name	**Perfen 267mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each IR Film Coated Tablet Contains: Pirfenidone…267mg
	Pharmacotherapeutic Group of (API)	Immunosuppressants, other immunosuppressants, ATC code: L04AX05 Indicated in adults for the treatment of idiopathic pulmonary fibrosis (IPF)
	Reference to Finished product specifications	Innovator's Specs
	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)	Mac-Fenid tablet tablet of M/s Macter

Evaluation by PEC[II]:

Section#	Observations	Firm's reply

1.6.5	Copy of Valid GMP certificate/DML of the drug substance manufacturer shall be submitted.	Submitted
3.2.S.7	Submitted drug substance stability studies data does not reflect the name of the drug substance.	Firm has submitted stability sheets from drug substance manufacturer i.e., M.s ZCL Chemicals Ltd.
3.2.S.4.4	COA of relevant batch of drug substance used for the manufacturing of drug product stability batches shall be submitted.	Submitted
3.2.P.5.1	• Reference shall be submitted for the dissolution parameters applied for the test of dissolution.	Firm has referred to the US FDA literature review of the innovator drug product i.e., Esbriet tablets.

Decision: Approved.

53.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio Mark Pharmaceuticals.** **Plot No. 527, Sundar Industrial Estate,Lahore**
	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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 22778 dated 15-09-2023
	Details of fee submitted	Rs.30,000/- dated 13-09-2023
	The proposed proprietary name / brand name	**Perfen 801mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each IR Film Coated Tablet Contains: Pirfenidone…801mg
	Pharmacotherapeutic Group of (API)	Immunosuppressants, other immunosuppressants, ATC code: L04AX05 Indicated in adults for the treatment of idiopathic pulmonary fibrosis (IPF)
	Reference to Finished product specifications	Innovator's Specs
	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)	Mac-Fenid tablet tablet of M/s Macter

Evaluation by PEC^{II}:

Section#	Observations	Firm's reply
1.6.5	Copy of Valid GMP certificate/DML of the drug substance manufacturer shall be submitted.	Firm hassubmitted valid GMP certificate issued by Food And Drugs Control Administration, Gujarat.
3.2.S.7	Submitted drug substance stability studies data does not reflect the name of the drug substance.	Firm has submitted stability sheets from drug substance manufacturer i.e., M.s ZCL Chemicals Ltd.
3.2.S.4.4	COA of relevant batch of drug substance used for the manufacturing of drug product stability batches shall be submitted.	Submitted

3.2.P.5.1	• Justification shall be submitted for the limits applied for the test for weight variation of tablet. • Reference shall be submitted for the dissolution parameters applied for the test of dissolution.	Firm has referred to the dissolution parameters from US FDA literature.
3.2.P.8.3	Stability data for the 6th month time point shall be submitted.	Firm has submitted 6th month time point stability data along with analytical record.

Decision: Approved. Manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of this drug.

54.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Werrick Pharmaceuticals. 216-217,I-10/3, Industrial Area, Islamabad**
	Name, address of Manufacturing site.	M/s Werrick Pharmaceuticals. 216-217,I-10/3, Industrial Area, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 23475 dated 22-09-2023 Rs.30,000/-
	Details of fee submitted	Rs.30,000/- dated 05-06-2023
	The proposed proprietary name / brand name	**Wardy Plus XR 12.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Film Coated Tablet Contains: Empagliflozin (as immediate release layer)…12.5mg Metformin HCl (as Extended Release)…1000mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs. (A10BD20)
	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	USFDA Approved.
	For generic drugs (me-too status)	Xenglu-Met XR tablets of Hilton Pharma,

Evaluation by PEC^{II}:

Decision: Approved.

55.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Werrick Pharmaceuticals. 216-217,I-10/3, Industrial Area, Islamabad**
	Name, address of Manufacturing site.	M/s Werrick Pharmaceuticals. 216-217,I-10/3, Industrial Area, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & Details of fee submitted	Form 5F: Dy.No 26296 dated 31-10-2023 Rs.30,000/- dated 19-10-2023
	The proposed proprietary name / brand name	**Wardy Plus XR 25/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Film Coated Tablet Contains: Empagliflozin (as immediate release layer)…25mg Metformin HCl (as Extended Release)…1000mg

	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs. (A10BD20)
	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	USFDA Approved.
	For generic drugs (me-too status)	Xenglu-Met XR tablets of Hilton Pharma,
Evaluation by PEC[II]:		
Decision: Approved.		
56.	**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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 22611 dated 14-09-2023
	Details of fee submitted	Rs.30,000/- dated 01-09-2023
	The proposed proprietary name / brand name	**Soglu-Met 12.5/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin HCl…500mg
	Pharmacotherapeutic Group of (API)	Sodium-glucose co-transporter 2 (SGLT2) inhibitors. biguanide class of antidiabetics
	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	USFDA Approved.
	For generic drugs (me-too status)	Xenglu-Met tablets of Hilton Pharma,
Evaluation by PEC[II]:		
Decision: Approved.		
57.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore**
	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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 22334 dated 11-09-2023
	Details of fee submitted	Rs.30,000/- dated 06-03-2023
	The proposed proprietary name / brand name	**Glulina-E 5/25 mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Linagliptin…5mg Empagliflozin…25mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs. A10BD19
	Reference to Finished product specifications	Innovator's Specs
	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)	**Brand Name:** Linjardy tablet of M/s CCL Pharmaceuticals
Evaluation by PEC[II]:		
Decision: Approved.		
58.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio Mark Pharmaceuticals.** **Plot No. 527, Sundar Industrial Estate,Lahore**
	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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 23487 dated 22-09-2023
	Details of fee submitted	Rs.30,000/- dated 13-09-2023
	The proposed proprietary name / brand name	**Empamet 12.5/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin…….12.5 mg Metformin HCl …..500mg
	Pharmacotherapeutic Group of (API)	Antidiabetic combination
	Reference to Finished product specifications	Innovator's Specs
	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)	Diampa-M 5/500 of M/s Getz pharma

Evaluation by PEC[II]:

Sr.#	Observation	Firm's response
1.	Submit following: • Complete batch manufacturing record of stability batches shall be submitted. • Analytical method validation studies for the applied drug product.	Submitted

Decision: Approved.		
59.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio Mark Pharmaceuticals.** **Plot No. 527, Sundar Industrial Estate,Lahore**
	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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 23488 dated 22-09-2023
	Details of fee submitted	Rs.30,000/- dated 13-09-2023
	The proposed proprietary name / brand name	**Empamet 12.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Empagliflozin…….12.5 mg Metformin HCl …..1000mg
	Pharmacotherapeutic Group of (API)	Antidiabetic combination
	Reference to Finished product specifications	Innovator's Specs
	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)	Diampa-M 5/500 of M/s Getz pharma

Evaluation by PEC^{II}:

Sr.#	Observation	Firm's response
1.	Submit following: • Complete batch manufacturing record pf stability batches shall be submitted. • Analytical method validation studies for the applied drug product.	Submitted

Decision: Approved.

60.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore**
	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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 22781 dated 15-09-2023
	Details of fee submitted	Rs.30,000/- dated 13-09-2023
	The proposed proprietary name / brand name	**Tapent IR 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each IR Film Coated Tablet Contains: Tapentadol as HCl…100mg
	Pharmacotherapeutic Group of (API)	Opioid analgesic
	Reference to Finished product specifications	Innovator's Specs
	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)	Tapento tablet of M/s Sami pharmaceuticals

Evaluation by PEC^{II}:

Section#	Observations	Firm's reply
1.6.5	Copy of Valid GMP certificate/DML of the drug substance manufacturer shall be submitted.	Submitted

3.2.P.2.2.1	Results of individual units shall be submitted in CDP studies.	Submitted
3.2.P.8.3	Documents confirming procurement of Tapentadol shall be submitted with the approval of DRAP I&E office.	Firm has submitted License to Import issued by DRAP I&E office dated 30-06-2022 for Tapentadol HCl (3Kg)

Decision: Approved.

61.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore**
	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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 22780 dated 15-09-2023
	Details of fee submitted	Rs.30,000/- dated 13-09-2023
	The proposed proprietary name / brand name	**Tapent IR 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each IR Film Coated Tablet Contains: Tapentadol as HCl…50mg
	Pharmacotherapeutic Group of (API)	Opioid analgesic
	Reference to Finished product specifications	Innovator's Specs
	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)	Tapento tablet of M/s Sami pharmaceuticals

Evaluation by PEC[II]:

Section#	Observations	Firm's reply
1.6.5	Copy of Valid GMP certificate/DML of the drug substance manufacturer shall be submitted.	Submitted
3.2.P.2.2.1	Results of individual units shall be submitted in CDP studies.	Submitted
3.2.P.5.3	Results of peak purity shall be submitted for performance of specificity parameter in analytical method validation studies.	Submitted
3.2.P.8.3	Documents confirming procurement of Tapentadol shall be submitted with the approval of DRAP I&E office.	Firm has submitted License to Import issued by DRAP I&E office dated 30-06-2022 for Tapentadol HCl (3Kg)

Decision: Approved.

62.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad**
	Name, address of Manufacturing site.	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 22827 dated 18-09-2023
	Details of fee submitted	Rs.30,000/- dated 08-08-2023
	The proposed proprietary name / brand name	**Ertu 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. to Ertugliflozin…..5mg
	Pharmacotherapeutic Group of (API)	Drugs used in diabetes, Sodium glucose co-transporter 2 (SGLT2) inhibitors, ATC code: A10BK04.
	Reference to Finished product specifications	Manufacturer Specs
	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)	Ertuvia tablet of M/s Ferozsons

Evaluation by PEC[II]:

Sr.#	Observation	Firm's response
1.	Latest GMP inspection report of drug product manufacturer, conducted within last three years shall be submitted.	Firm has submitted copy of GMP certificate issue don basis of inspection conducted on 14-02-2024.
2.	Relevant information of section 3.2.S.4.1, 3.2.s.4.2 & 3.2.S.4.3 from drug product manufacturer shall be submitted.	Firm has submitted drug substance specifications and analytical procedure, while analytical method verification studies have not been submitted from M/s Saffron.
3.	Justification shall be submitted for use of SLS in the product formulation as reference product has not used it.	SLS is widely used excipient in oral dosage forms as wetting agent or as lubricating agent. We use only 2mg/tablet in Ertu 5mg tablet and 4mg/tablet in Ertlu 15mg tablet.
4.	Reference shall be submitted for the dissolution parameters applied for the performance of dissolution test in batch release of drug product.	Firm has referred to the general chapters of European and British Pharmacopoiea
5.	Clarification shall be submitted for the Assay results of drug substance declare din COA from M/s Saffron, whether it is for Ertugliflozin-LPGA or Ertugliflozin base only.	COA of API shows Assay of Ertugliflozin L-GPA but we analyse the values of LPGA and give the multiplyinig factor for Ertugliflozin base as Etugliflozin-LPGA.

Decision: Approved with Innovator's specifications. Firm shall submit fee Rs. 9000/- for pre-approval correction in drug product specifications as per SRO 1324(I)/2024 dated 30-08-, before issuance of registration letter

63.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad**
	Name, address of Manufacturing site.	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 22826 dated 18-09-2023
	Details of fee submitted	Rs.30,000/- dated 08-08-2023
	The proposed proprietary name / brand name	**Ertu 15mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. to Ertugliflozin…15mg
	Pharmacotherapeutic Group of (API)	Drugs used in diabetes, Sodium glucose co-transporter 2 (SGLT2) inhibitors, ATC code: A10BK04.
	Reference to Finished product specifications	Manufacturer Specs
	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)	Ertuvia tablet of M/s Ferozsons

Evaluation by PEC[II]:

Sr.#	Observation	Firm's response
1.	Latest GMP inspection report of drug product manufacturer, conducted within last three years shall be submitted.	Firm has submitted copy of GMP certificate issue don basis of inspection conducted on 14-02-2024.
2.	Relevant information of section 3.2.S.4.1, 3.2.s.4.2 & 3.2.S.4.3 from drug product manufacturer shall be submitted.	Firm has submitted drug substance specifications and analytical procedure, while analytical method verification studies have not been submitted from M/s Saffron.
3.	Justification shall be submitted for use of SLS in the product formulation as reference product has not used it.	SLS is widely used excipient in oral dosage forms as wetting agent or as lubricating agent. We use only 2mg/tablet in Ertu 5mg tablet and 4mg/tablet in Ertlu 15mg tablet.
4.	Reference shall be submitted for the dissolution parameters applied for the performance of dissolution test in batch release of drug product.	Firm has referred to the general chapters of European and British Pharmacopoiea.
5.	Clarification shall be submitted for the Assay results of drug substance declare din COA from M/s Saffron, whether it is for Ertugliflozin-LPGA or Ertugliflozin base only.	COA of API shows Assay of Ertugliflozin L-GPA but we analyse the values of LPGA and give the multiplying factor for Ertugliflozin base as Etugliflozin-LPGA.

Decision: Approved with Innovator's specifications. Firm shall submit fee Rs. 9000/- for pre-approval correction in drug product specifications as per SRO 1324(I)/2024 dated 30-08-, before issuance of registration letter.

64.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 21696 dated 01-09-2023
	Details of fee submitted	Rs.30,000/- dated 18-04-2023
	The proposed proprietary name / brand name	**Dypa-M XR 10/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Extended Release Tablet Contains: Dapagliflozin Propanediol Monohydrate as Immediate Release Coated Layer…10mg Metformin HCl as Extended Release Core Tablet…500mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs (WHO ATC: A10BD)
	Reference to Finished product specifications	Innovator's Specs
	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)	Xiga-Met XR tablet of M.s CCl Pharmaceuticals.
65.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wnsfeild Pharmaceuticals.** **Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 21694 dated 01-09-2023
	Details of fee submitted	Rs.30,000/- dated 18-04-2023
	The proposed proprietary name / brand name	**Dypa-M XR 5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Extended Release Tablet Contains: Dapagliflozin Propanediol Monohydrate as Immediate Release Coated Layer…5mg Metformin HCl as Extended Release Core Tablet…1000mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs (WHO ATC: A10BD)
	Reference to Finished product specifications	Innovator's Specs
	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)	Xiga-Met XR tablet of M.s CCl Pharmaceuticals.
66.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wnsfeild Pharmaceuticals.** **Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 21692 dated 01-09-2023
	Details of fee submitted	Rs.30,000/- dated 18-04-2023
	The proposed proprietary name / brand name	**Dypa-M XR 10/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Extended Release Tablet Contains: Dapagliflozin Propanediol Monohydrate as Immediate Release Coated Layer…10mg Metformin HCl as Extended Release Core Tablet…1000mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs (WHO ATC: A10BD)
	Reference to Finished product specifications	Innovator's Specs
	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)	Xiga-Met XR tablet of M.s CCl Pharmaceuticals.
67.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 21693 dated 01-09-2023
	Details of fee submitted	Rs.30,000/- dated 18-04-2023
	The proposed proprietary name / brand name	**Dypa-M XR 2.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Extended Release Tablet Contains: Dapagliflozin Propanediol Monohydrate as Immediate Release Coated Layer…2.5mg Metformin HCl as Extended Release Core Tablet…1000mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs (WHO ATC: A10BD)
	Reference to Finished product specifications	Innovator's Specs
	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)	Xiga-Met XR tablet of M.s CCl Pharmaceuticals.
68.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**

	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 22333 dated 11-09-2023
	Details of fee submitted	Rs.30,000/- dated 18-04-2023
	The proposed proprietary name / brand name	**Dypa-M XR 5/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Extended Release Tablet Contains: Dapagliflozin Propanediol Monohydrate as Immediate Release Coated Layer…5mg Metformin HCl as Extended Release Core Tablet…500mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs (WHO ATC: A10BD)
	Reference to Finished product specifications	Innovator's Specs
	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)	Xiga-Met XR tablet of M.s CCl Pharmaceuticals.

Evaluation by PEC^{II}:

Sr/#	Observations	Firm's response
1.	Clarification shall be submitted regarding the formulation of applied product, whether it is bi-layer by way of compression or bi-layer by way of active coating.	The formulation method is bi-layer by way of compression.
2.	Complete batch manufacturing record for the stability batches shall be submitted.	Submitted.

Decision: Registration Board approved the applications of Dypa-M XR 10/500 mg Tablet, Dypa-M XR 5/1000 mg Tablet, Dypa-M XR 10/1000 mg Tablet, Dypa-M XR 2.5/1000 mg Tablet & Dypa-M XR 5/500 mg Tablet as per following label claims respectively:

i. "Each Film Coated biayer Tablet Contains:

Dapagliflozin as Propanediol Monohydrate …… 10mg
Metformin HCl (as Extended Release)…500mg"

ii. "Each Film Coated biayer Tablet Contains:

Dapagliflozin as Propanediol Monohydrate …… 5mg
Metformin HCl (as Extended Release)…1000mg"

iii. "Each Film Coated biayer Tablet Contains:

Dapagliflozin as Propanediol Monohydrate …… 10mg
Metformin HCl (as Extended Release)…1000mg"

iv. "Each Film Coated biayer Tablet Contains:

Dapagliflozin as Propanediol Monohydrate …… 2.5mg

Metformin HCl (as Extended Release)…1000mg"

v. "Each Film Coated biayer Tablet Contains:

Dapagliflozin as Propanediol Monohydrate …… 5mg
Metformin HCl (as Extended Release)…500mg"

Firm shall submit fee for pre-approval correction in label claim for each strength as per SRO 1324(I)/2024 dated 30-08-, before issuance of registration letter.

69.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wnsfeild Pharmaceuticals.** **Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 21695 dated 01-09-2023
	Details of fee submitted	Rs.30,000/- dated 04-08-2023
	The proposed proprietary name / brand name	**Zegwin-M XR 50/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Extended Release Tablet Contains: Sitagliptin Phosphate Monohydrate as Immediate Release Coated Layer…50mg Metformin HCl as Extended Release Core Tablet……1000mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs (WHO ATC: A10BD)
	Reference to Finished product specifications	Innovator's Specs
	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)	Sita-Met XR tablet of M.s CCl Pharmaceuticals.
Evaluation by PEC[II]:		
Decision: Approved.		
70.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wnsfeild Pharmaceuticals.** **Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 21699 dated 01-09-2023
	Details of fee submitted	Rs.30,000/- dated 04-08-2023

	The proposed proprietary name / brand name	**Zegwin-M XR 100/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Extended Release Tablet Contains: Sitagliptin Phosphate Monohydrate as Immediate Release Coated Layer…100mg Metformin HCl as Extended Release Core Tablet……1000mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs (WHO ATC: A10BD)
	Reference to Finished product specifications	Innovator's Specs
	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)	Sita-Met XR tablet of M.s CCl Pharmaceuticals.
Evaluation by PEC^{II}:		
Decision: Approved.		
71.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd.** **Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 24783 dated 11-10-2023 Rs.75,000/- dated 25-09-2023
	The proposed proprietary name / brand name	**Rebamid 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Rebamipide…100mg
	Pharmacotherapeutic Group of (API)	Belongs to the class of other drugs used in the treatment of peptic ulcer and gastro-oesophageal reflux disease (GERD) WHO ATC Code: A02BX14
	The status in reference regulatory authorities	Mucosta 100mg Tablets Approved by PMDA Japan
	For generic drugs (me-too status)	--
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	JP specifications

Evaluation by PEC^{II}:

Rebamipide is an antiulcer drug classified as a gastric mucosal defence factor enhancer. Increases endogenous prostaglandins, increases blood flow to the gastric mucosa, and increases the amount of mucus in the gastric mucosa. It was approved in July 2009 by PMDA of Japan.

Sr.#	Observations	Firm's reply
1.	Valid GMP certificate/DML of the drug substance manufacturer issued by the relevant regulatory authority of country of origin shall be submitted.	Submitted
2.	Drug product stability studies of 6th month time point shall be submitted	Submitted
3.	Documents confirming procurement of drug substance with the approval of DRAP I&E Office shall be submitted.	Firm has submitted clearance certificate issued by DRAP I&E office dated 21-06-2023

Decision: Approved.		
72.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Sami Pharmaceuticals Pvt Limited.** **F-95, S.I.T.E, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Sami Pharmaceuticals Pvt Limited. F-95, S.I.T.E, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 22150 dated 08-09-2023
	Details of fee submitted	Rs.30,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Empoli-LT 25/5 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…25mg Linagliptin…5mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs.
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	Diamap LT tablet of M/s Getz Pharma
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications
73.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Sami Pharmaceuticals Pvt Limited.** **F-95, S.I.T.E, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Sami Pharmaceuticals Pvt Limited. F-95, S.I.T.E, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 22149 dated 08-09-2023
	Details of fee submitted	Rs.30,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Empoli-LT 10/5 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…10mg Linagliptin…5mg
	Pharmacotherapeutic Group of (API)	Combinations of oral blood glucose lowering drugs.
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	Diamap LT tablet of M/s Getz Pharma
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC[II]:

Sr.#	Observation	Firm's response
1.	Latest GMP inspection report of drug product manufacturer, conducted within last three years shall be submitted.	Firm has submitted copy of GMP certificate issue don basis of inspection conduct dated 01-07-2024.

	2.	Copy of Valid GMP certificate/DML of the drug substance manufactures shall be submitted.	Submitted
	3.	• Documents confirming import of drug substance, issued with approval of DRAP I& E Office shall be submitted for Linagliptin.	Firm has submitted copy of License to import issued by IE& DRAP, Karachi office dated 24-11-2022.
Decision: Registration Board approved the applications of Empoli-LT 25/5 mg Tablet & Empoli-LT 10/5 mg Tablet.			
74.	**Name, address of Applicant / Marketing Authorization Holder**		**M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore**
	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)
	Application Form Dy. No / Tracking ID & date of submission & Details of fee submitted		Form 5F: Dy.No 22779 dated 15-09-2023 Rs.30,000/- dated 13-09-2023
	The proposed proprietary name / brand name		**Nepco CR 330mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		Each Film Coated Extended Release Tablet Contains: Pregabalin…330mg
	Pharmacotherapeutic Group of (API)		Anti convulsant
	Reference to Finished product specifications		Innovator's Specs
	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)		Preneu CR 330mg Tablet of M/s Nabiqasim
Evaluation by PEC:			
Decision: Approved.			
75.	**Name, address of Applicant / Marketing Authorization Holder**		**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.		M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant		☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted		Form 5F: Dy.No 25896 dated 26-10-2023 Rs.75,000/- dated 16-10-2023
	The proposed proprietary name / brand name		**Trelint 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit		Each Film Coated Tablet Contains: Trelagliptin as Succinate…50mg
	Pharmacotherapeutic Group of (API)		Dipeptidyl peptidase-4 inhibitor
	The status in reference regulatory authorities		Zafatek Tablets Approved by PMDA Japan
	For generic drugs (me-too status)		Trelaget of M/s Getz pharma
	Proposed Pack size & Price		As per SRO
	Reference to Finished product specifications		Innovator's specifications

Evaluation by PEC[II]:

Sr.#	Observations	Firm's reply
1.	Drug product stability studies of 6th month time point shall be submitted	Firm has submitted 6th month time point stability data along with analytical record.

Decision: Approved.

76.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 25897 dated 26-10-2023 Rs.75,000/- dated 16-10-2023
	The proposed proprietary name / brand name	**Trelint 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Trelagliptin as Succinate…100mg
	Pharmacotherapeutic Group of (API)	Dipeptidyl peptidase-4 inhibitor
	The status in reference regulatory authorities	Zafatek Tablets Approved by PMDA Japan
	For generic drugs (me-too status)	Trelaget of M/s Getz pharma
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's specifications

Evaluation by PEC[II]:

Sr.#	Observations	Firm's reply
1.	Drug product stability studies of 6th month time point shall be submitted	Firm has submitted 6th month time point stability data along with analytical record.

Decision: Approved.

77.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5F: Dy.No 24301 dated 04-10-2023 Rs.75,000/- dated 14-09-2023
	The proposed proprietary name / brand name	**Nadiflox 1% Cream**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram Contains: Nadifloxacin…10mg
	Pharmacotherapeutic Group of (API)	Quinolone Antibiotics indicated for skin infection, deep skin infection, sores (purulent inflammation)
	The status in reference regulatory authorities	Aquachim Cream 1% of M/s Otsuka Approved by PMDA of Japan

	For generic drugs (me-too status)	--
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's specifications

Evaluation by PEC[II]:

Sr.#	Observations	Firm's reply
1.	Evidence of approval of required manufacturing facility i.e. "Cream section, from CLB shall be submitted.	Firm has submitted letter issued by Secretary CLB dated 03-03-2023 wherein renewal for DML has been granted for sections including "Oral Hygiene (Mouth Wash)/Semisolid & Toothpaste.
2.	Copy of Valid GMP certificate/DML of the drug substance manufacturer shall be submitted.	Submitted.
3.	Drug substance analytical procedure shall be submitted from M/s Kaizen.	Firm has submitted drug substance analytical procedure.
4.	Documents confirming import/procurement of Drug substance, issued by the DRAP I&E office shall be submitted.	Firm has submitted copy of commercial invoice attested by DRAP I&E Karachi dated 20-10-2020.

Decision: Deferred for clarification regarding the manufacturing facility for applied dosage form, whether it will be manufactured in section of Mouthwash and Toothpaste or approved as separate section of "Cream/Ointmet."

Case no.: 02 Applications submitted on Form 5F by way of contract-manufacturing

78.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Getz Pharma Pvt Ltd. 29-30/27, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s Herbion Pakistan Pvt Ltd. Industrial Triangle , Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 27025 dated 15-11-2023 Rs 75,000/- dated 19-09-2023
	The proposed proprietary name / brand name	**Rupadin 1mg/ml Oral Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Rupatadine Fumarate Eq. to Rupatadine…1mg
	Pharmacotherapeutic Group of (API)	Antihistamine for systemic use.
	The status in reference regulatory authorities	Rupatadine Oral Solution 1mg/ml marketed by M/s Aspire Pharma Ltd., UK. MHRA Approved.
	For generic drugs (me-too status)	Not available
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's specifications.

Evaluation by PEC[II]: Rupatadine oral solution is indicated in indicated for the symptomatic treatment of:
- Allergic rhinitis (including persistent allergic rhinitis) in children aged 2 to 11 years
- Urticaria in children aged 2 to 11 years.

Decision: Approved.

79.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Seatle Pvt Ltd. 45 Km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Martin Dow Marker Limited 7, Jail Road, Quetta,

		Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 26379 dated 01-11-2023 Rs.75,000/- dated 01-08-2023
	The proposed proprietary name / brand name	**Sugamax 200mg/2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml ampoule Contains: Sugammadex Sodium Eq. to Sugammadex…..200mg
	Pharmacotherapeutic Group of (API)	Modified gamma Cyclodextrin indicated for Reversal of neuromuscular blockade induced by Rocuronium or Vecuronium in adult
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Sugammadex injection of M/s Bajwa pharmaceuticals
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's specifications

Evaluation by PEC[II]:

Sr.#	Observations	Firm's reply
1.	Valid DML/GMP certificate of the drug substance manufacturer issued by relevant regulatory authority of country of origin shall be submitted.	
2.	Justification shall be submitted for the significant change reported in the results of assay test during accelerated stability studies,	

Decision: Deferred for submission of reply to above cited shortcomings.

80.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Vision Pharmaceuticals. Plot # 22,23, 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)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy. No 26709 dated 07-11-2023 Rs 75,000/- dated 31-10-2023
	The proposed proprietary name / brand name	**Flovis-M 12.5/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin HCl…500mg
	Pharmacotherapeutic Group of (API)	Sodium-glucose co-transporter 2 (SGLT2) inhibitors. biguanide class of antidiabetics
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Xenglu-Met tablets of Hilton Pharma
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's specifications.

Evaluation by PEC[II]:

Decision: Approved.

81.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Davis Pharmaceuticals Laboratories. Plot No. 121, Industrial Triangle, Kahuta Road, Isalamabad**
	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)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 1846 dated 14-01-2021 Rs.50,000/- dated 21-12-2020
	The proposed proprietary name / brand name	**Ceftione 1g IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone Sodium…1g
	Pharmacotherapeutic Group of (API)	Antibiotic
	The status in reference regulatory authorities	MHRA approved
	For generic drugs (me-too status)	Topcef Injection of Ceftriaxone Sodium by Pride Pharmaceuticals
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	USP

Evaluation by PEC^{II}:

The applied product to be manufactured by M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad, Pakistan has already been approved by Registration Board in its 327th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

Applicant firm	M/s Bio-Next Pharmaceuticals. Plot No. 50, Street No. S-10, RCCI, Rawat
Manufacturer firm	M/s Bio-Labs (Pvt) Ltd. Plot No 145, Industrial Triangle, Kahuta road, Islamabad.
Brand Name	**Nextone Injection 1g IV**

Decision: Approved.

82.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Davis Pharmaceuticals Laboratories. Plot No. 121, Industrial Triangle, kahuta Road, Isalamabad**
	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)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 7104 dated 03-03-2021 Rs.50,000/- dated 28-12-2020
	The proposed proprietary name / brand name	**Ceftione 500mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone Sodium…500mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	The status in reference regulatory authorities	MHRA approved
	For generic drugs (me-too status)	Topcef injection of ceftriaxone sodium by pride Pharmaceuticals

	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specification

Evaluation by PEC[II]:

The applied product to be manufactured by M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad, Pakistan has already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

Applicant firm	M/s Islam Pharmaceutical, 7Km Pasrur Road Sialkot, Islamabad from M/s Bio-Labs (Pvt) Ltd
Manufacturer firm	M/s Bio-Labs (Pvt) Ltd. Plot No 145, Industrial Triangle, Kahuta road, Islamabad.
Brand Name	**Celine Injection 500mg IV**

Decision: Approved.

83.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Davis Pharmaceuticals Laboratories. Plot No. 121, Industrial Triangle, kahuta Road, Isalamabad**
	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)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 7861 dated 10-03-2021 Rs.50,000/- dated 28-12-2020
	The proposed proprietary name / brand name	**Ceftione 250mg IM Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone sodium Eq. to Ceftriaxone…250mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	The status in reference regulatory authorities	MHRA approved
	For generic drugs (me-too status)	Topcef Injection of Ceftriaxone Sodium by Pride Pharmaceuticals 025876
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specification

Evaluation by PEC[II]:

The applied product to be manufactured by M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad, Pakistan has already been approved by Registration Board in its 316th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

Applicant firm	M/s Islam Pharmaceutical, 7Km Pasrur Road Sialkot, Islamabad from M/s Bio-Labs (Pvt) Ltd
Manufacturer firm	M/s Bio-Labs (Pvt) Ltd. Plot No 145, Industrial Triangle, Kahuta road, Islamabad.
Brand Name	**Celine Injection 250mg IM**

Decision: Approved.

84.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Invictus Pharmaceuticals. Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi**
	Name, address of Manufacturing site.	M/s Bio-next Pharmaceuticals. Plot No. 50, Street No. S-10, RCCI, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 27888 dated 08-10-2021 Rs.75,000/- dated 20-09-2021
	The proposed proprietary name / brand name	**Troga 500mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Meropenem as Trihydrate…500mg
	Pharmacotherapeutic Group of (API)	Carbapenem
	The status in reference regulatory authorities	Merrem Injection (USFDA Approved)
	For generic drugs (me-too status)	Meronem Injection by ICI Pakistan Ltd.
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	USP

Evaluation by PEC[II]:

The applied product to be manufactured by M/s Bio-next Pharmaceuticals. Plot No. 50, Street No. S-10, RCCI, Rawat, Pakistan has already been approved by Registration Board in its 307th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

Applicant firm	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad
Manufacturer firm	M/s Bio-next Pharmaceuticals. Plot No. 50, Street No. S-10, RCCI, Rawat, Pakistan
Brand Name	**BIOPORE 500 mg Injection IV**

Decision: Approved.

85.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Invictus Pharmaceuticals.** **Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi**
	Name, address of Manufacturing site.	M/s Bio-next Pharmaceuticals. Plot No. 50, Street No. S-10, RCCI, Rawat
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 27889 dated 08-10-2021 Rs.75,000/- dated 20-09-2021
	The proposed proprietary name / brand name	**Troga 1g IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Meropenem as Trihydrate…1g
	Pharmacotherapeutic Group of (API)	Carbapenem
	The status in reference regulatory authorities	Merrem Injection (USFDA Approved)
	For generic drugs (me-too status)	Meronem Injection by ICI Pakistan Ltd.
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	USP

Evaluation by PEC[II]:

The applied product to be manufactured by M/s Bio-next Pharmaceuticals. Plot No. 50, Street No. S-10, RCCI, Rawat, Pakistan has already been approved by Registration Board in its 307th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

Applicant firm	M/s Bio-Labs (Pvt) Ltd. Plot No. 145, Industrial Triangle Kahuta Road Islamabad
Manufacturer firm	M/s Bio-next Pharmaceuticals. Plot No. 50, Street No. S-10, RCCI, Rawat, Pakistan
Brand Name	**BIOPORE 1g Injection IV**

Decision: Approved.

86.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cortex Pharmaceuticals.** **Plot # 16-A, SS-4, RCCI, Rawat, Rawalpindi, Punjab**
	Name, address of Manufacturing site.	M/s Shawan Pharmaceuticals. Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 22422 dated 12-09-2023 Rs.75,000/- dated 11-08-2023
	The proposed proprietary name / brand name	**PD-Xime 100mg Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Dry Suspension Contains: Cefixime as Trihydrate…100mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Caricef dry powder suspension of M/s Sami
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	USP

Evaluation by PEC^{II}:

The applied product to be manufactured by M/s Shawan Pharmaceuticals. Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi, Pakistan has already been approved by Registration Board in its 336th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

Applicant firm	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate,Lahore
Manufacturer firm	M/s Shawan Pharmaceuticals. Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi.
Brand Name	**Cefit 100mg Dry Suspension**

Decision: Approved.

87.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cortex Pharmaceuticals.** **Plot # 16-A, SS-4, RCCI, Rawat, Rawalpindi, Punjab**
	Name, address of Manufacturing site.	M/s Shawan Pharmaceuticals. Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 22423 dated 12-09-2023 Rs.75,000/- dated 11-08-2023
	The proposed proprietary name / brand name	**PD-Xime 200mg Dry Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Dry Suspension Contains: Cefixime as Trihydrate…200mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Caricef DS dry powder suspension of M/s Sami
	Proposed Pack size & Price	As per SRO

	Reference to Finished product specifications	USP

Evaluation by PEC[II]:

The applied product to be manufactured by M/s Shawan Pharmaceuticals. Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi, Pakistan has already been approved by Registration Board in its 336th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

Applicant firm	M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate,Lahore
Manufacturer firm	M/s Shawan Pharmaceuticals. Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi.
Brand Name	**Cefit 200mg Dry Suspension**

Decision: Approved.

88.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio-next Pharmaceuticals. Plot No. 50, Street No. S-10, RCCI, Rawat**
	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)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 19774 dated 09-08-2023 Rs.75,000/- dated 26-07-2023
	The proposed proprietary name / brand name	**Colinext 3 MIU Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to Colistin Base Activity 102mg…3 MIU
	Pharmacotherapeutic Group of (API)	Polymyxins ATC Code: J01XB01
	The status in reference regulatory authorities	Colistimethate sodium 3 MIU, powder for solution for injection - (colistin methasulfonate sodium salt) - PL 34328/0016; UK/H/6255/003/DC MHRA Approved.
	For generic drugs (me-too status)	ColimeTHate Inj 3MIU Reg No. 108905 M/s Tabros Pharma Karachi.
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	USP Specifications.

Evaluation by PEC[II]:

The applied product to be manufactured by M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad, Pakistan has already been approved by Registration Board in its 331st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

Applicant firm	M/s Bio-Labs (Pvt.) Ltd. Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.
Manufacturer firm	M/s Bio-Labs (Pvt.) Ltd. Plot No. 145, Industrial Triangle Kahuta Road, Islamabad**.** DML No. 000296
Brand Name	**COLICRAFT 100mg Injection**

Decision: Approved.

89.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio-next Pharmaceuticals. Plot No. 50, Street No. S-10, RCCI, Rawat**

	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)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 21290 dated 29-08-2023 Rs.75,000/- dated 27-07-2023
	The proposed proprietary name / brand name	**Colinext 4.5 MIU Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium Eq. to Colistin Base Activity 150mg…4.5 MIU
	Pharmacotherapeutic Group of (API)	Polymyxins ATC Code: J01XB01
	The status in reference regulatory authorities	COLISTIMETHATE SODIUM EQ 150MG BASE/VIAL USFDA Approved.
	For generic drugs (me-too status)	CBA 150 Injection Reg. No. 103783 Imported by Biocare Pharma Lahore
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	USP Specifications.

Evaluation by PEC[II]:

The applied product to be manufactured by M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad, Pakistan has already been approved by Registration Board in its 331st meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

Applicant firm	M/s Bio-Labs (Pvt.) Ltd. Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.
Manufacturer firm	M/s Bio-Labs (Pvt.) Ltd. Plot No. 145, Industrial Triangle Kahuta Road, Islamabad**.** DML No. 000296
Brand Name	**COLICRAFT 150mg Injection**

Decision: Approved. Registration letter will be issued upon submission of analytical record for the submitted drug product stability data including chromatograms/spectrums etc.

90.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Lawari International Pharmaceuticals Valley Road, Gul KADU Saidu Sharif Swat, KPK**
	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)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 27662 dated 27-11-2023 Rs 75,000/- dated 05-06-2023
	The proposed proprietary name / brand name	**Ondwari 8mg/4ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml Contains: Ondansetron as Hcl Dihydrate…8mg
	Pharmacotherapeutic Group of (API)	5-HT3 antagonist
	The status in reference regulatory authorities	Setronon injection 8mg/4ml by M/s Teva Pharmaceutical Works Private Limited Company, H-2100 Gödöllo, Tánasics Mihaly. Út 82. Hungary, MHRA Approved
	For generic drugs (me-too status)	ONSET Injection 8mg/4ml by M/s Pharmedic

		Laboratories (Pvt) Ltd. Reg. No. 025996
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	USP

Evaluation by PEC[II]:

The applied product to be manufactured by M/s Bio-Labs (Pvt) Ltd. Plot No 145, Industrial Triangle, Kahuta road, Islamabad, Pakistan has already been approved by Registration Board in its 340th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

Applicant firm	M/s Alliance Pharmaceutical Pvt Ltd. 112 A, Hayatabad Industrial Estate, Peshawar
Manufacturer firm	M/s Bio-Labs (Pvt) Ltd. Plot No 145, Industrial Triangle, Kahuta road, Islamabad.
Brand Name	**Allosetron 8mg/4ml Injection**

Decision: Approved.

91.	**Name, address of Applicant / Marketing Authorization Holder**	**Reliance Pharma** **Plot No. 8, Street No. S-8 RCCI Industrial Estate, Rawat, Islamabad, Pakistan**
	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)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 25448 dated 20-10-2023 Rs.30,000/- dated 05-10-2023
	The proposed proprietary name / brand name	**Relitams 0.4mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Tamsulosin Hcl Extended Release Pellets 0.2% eq. to Tamsulocin...0.4mg
	Pharmacotherapeutic Group of (API)	Alpha blockers
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Tamsolin Capsule by Getz
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	USP

Evaluation by PEC[II]:

The applied product to be manufactured by M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad, Pakistan has already been approved by Registration Board in its 340th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

Applicant firm	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
Manufacturer firm	M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad
Brand Name	**VISTAMS 0.4mg Capsule**

Decision: Approved. Registration letter will be issued upon submission of pre-registration variation for change of title of the applicant firm as per SRO 1324(I)/2024 dated 30-08-, before issuance of registration letter

92.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Valor Pharmaceuticals.** **124/A Industrial Triangle, Kahuta Road Islamabad**
	Name, address of Manufacturing site.	M/s Biogen Life Sciences.

		8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 27024 dated 15-11-2023 Rs 75,000/- date not clear
	The proposed proprietary name / brand name	**Tageval 50mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Tigecycline…50mg
	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use, Tetracycline
	The status in reference regulatory authorities	Tygacil 50mg powder for solution for infusion of M/s Pfizer Limited, UK (MHRA Approved).
	For generic drugs (me-too status)	Tygacil 50mg Injection (Reg. No. 045642) by M/s Pfizer Pharma.
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	USP

Evaluation by PEC[II]:

The applied product to be manufactured by M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan has already been approved by Registration Board in its 339th meeting based on the data of same batches of drug product as submitted in the instant case. The details of the already approved product are as follows:

Applicant firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
Manufacturer firm	M/s Biogen Life Sciences. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
Brand Name	**Tygagen 50mg Injection**

Decision: Approved.

93.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Crystolite Pharmaceuticals.** **Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Friends Pharma Pvt Ltd. 31-km, Ferozepur Road, Lahore, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 23762 dated 27-09-2023 Rs.75,000/- date not mentioned
	The proposed proprietary name / brand name	**Ultra-White 600mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Glutathione as sodium…….600mg
	Pharmacotherapeutic Group of (API)	Antidote
	The status in reference regulatory authorities	Approved by AIFA of Italy
	For generic drugs (me-too status)	Gluto 600mg injection of M/s MTI Medical (Pvt.) Ltd.
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	**In-House Specifications**

Evaluation by PEC^{II}:

Sr.#	Observations	Firm's reply
1.	Documents confirming procurement of drug substance, with approval of DRAP I&E Office shall be submitted for the batch no. used in the manufacturing of submitted drug product stability batches.	Firm ha submitted copy of commercial invoice along with Form 3, Form 7 and DHL receipt.
2.	Copy of Valid GMP certificate/DML of the drug substance manufacturer shall be submitted.	Submitted

Decision: Registration Board while considering the submitted manufacturing method of Lyophilisation of bulk solution of L-Glutathione reduced neutralised with sodium bicarbonate decided to approve the instant application with Innovator's specifications and change of brand name. Firm shall submit fee Rs. 9000/- for pre-approval correction in drug product specifications as per SRO 1324(I)/2024 dated 30-08-, before issuance of registration letter

Case no.: 03 Applications submitted along with stability data

94.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road,Lahore**
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road,Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5D: Dy.No 13999 dated 07-03-2019 Rs.50,000/- dated 06-03-2019
	The proposed proprietary name / brand name	**Gluta Dry Powder Vial**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Glutathione Sodium Salt 643mg Eq to Glutathione 600mg
	Pharmacotherapeutic Group of (API)	Antidote
	The status in reference regulatory authorities	Approved by AIFA of Italy
	For generic drugs (me-too status)	--
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's specifications
95.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road,Lahore**
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road,Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form 5D: Dy. No 13434 dated 07-03-2019 Rs.50,000/- dated 07-03-2019
	The proposed proprietary name / brand name	**Gluta Dry Powder Vial**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Glutathione …… 600mg
	Pharmacotherapeutic Group of (API)	Antidote
	The status in reference regulatory authorities	Approved by AIFA of Italy
	For generic drugs (me-too status)	--

	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's specifications

STABILITY STUDY DATA			
Name of Manufacturer	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore		
Manufacturer of API	M/s Hangzhou Lingeba Technology Co. Ltd. Address: No.268 Moganshan Road, YuanYang building 2316,Hangzhou City, Zhejiang province		
API Lot No.	LGB20200325		
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: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 months Real Time: 0, 3, 6 months		
Batch No.	GTA_i T1-21	GTAi T2-22	GTAi T3-22
Batch Size	1000 vials	1000 vials	1000 vials
Manufacturing Date	12-2021	01-2022	01-2022
No. of Batches	03		
Date of Submission	18-11-2022		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT	
Documents To Be Provided	**Status**
Certificate of analysis of API.	Submitted
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate for M/s Hangzhou Lingeba Technology Co. Ltd. issued by Hangzhou Chemical Medical Industry Association valid upto 27-08-2023.
Protocols followed for conduction of stability study and details of tests.	Submitted
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Submitted
Documents confirming import of API etc.	The firm has submitted copy of invoice for the purchase of L-Glutathione (5Kg), attested by Assistant Director (I & E) DRAP, Lahore dated 06-07-2020.

Evaluation by PEC^{II}: Firm has submitted letter no. F.1-3/2003-Lic (Vol-I) issued by Secretary CLB dated 29-01-2019 granting the conversion of "Biotech Lyophilization section" into "General Lyophilization section".

Sr.#	Observations	Firm's response
1.	Copy of valid GMP certificate/DML of the drug substance manufacturer , issued by the relevant regulatory authority of country of origin shall be submitted.	Submitted
2.	The innovator product has declared following label claim: "*One vial of powder contains:*	We confirm that our formulation is aligned with the innovator product approved by AIFA (Italy's Regulatory Authority). The active Pharmaceutical ingredient (API) utilized is L-Glutathione reduced, which undergoes

	646 mg of glutathione sodium salt corresponding to 600 mg of glutathione". In contrary to the above cited reference, the submitted data declares that the applied formulation only contains "L-Glutathione reduced" instead of the sodium salt of Glutathione. Justification shall be submitted in this regard.	conversion to Glutathione sodium during manufacturing process as part of the formulation procedure. We acknowledge that the previously submitted label claim incorrectly referenced base molecule Glutathione rather than the final form Glutathione (sodium salt).
3.	Justification shall be submitted for not including test of Water content/Loss on drying in drug product specifications.	Firm has submitted revised drug product specifications.

Proceedings: The Board was apprised with the innovator's product manufacturing method wherein reduced glutathione is neutralized by sodium bicarbonate until desired pH is achieved. The drug product specifications of innovator drug product include test of sodium content also, the limits of which depends upon the amount of NaHCO3 used during the freeze-drying process in order to have required pH value.

Decision: Registration Board considered the fact that the firm has applied Sodium hydroxide (NaOH) instead of Sodium bicarbonate during formulation process, which is in deviation to the innovator drug product literature and also firm has not provided any reference for the applied manufacturing method, hence the Board decided to approve the above application of "Gluta Dry Powder Vial" submitted vide "Dy. No 13999 dated 07-03-2019" while firm shall submit following before issuance of registration letter:

- **Fee for pre-registration variation i.e., Rs. 9000/- as per SRO as per SRO1324 (I)/2024 dated 30-08-2024.**
- **Revised product development studies wherein manufacturing method shall include neutralisation of L-Glutathione reduced by sodium bicarbonate, for conversion into Glutathione sodium along with drug product stability studies data for newly manufactured stability batches till 3rd month time point at both accelerated and long term stability conditions.**
- **Drug product specifications including test of "Sodium content".**

Registration Board further decided to dispose of the other application of "Gluta Dry Powder vial" submitted vide Dy. No 13434 dated 07-03-2019 and stand rejected.

Case no.: 04 Deferred applications

96.	M/s Glitz Pharma, Plot No. 265, Industrial Triangle Kahota Road Islamabad	Glitpro 150mg Tablets Each tablet contains:- Bupropion HCL ……. 150mg	Form 5 12-08-2014 Dy No.3291 Rs.8000/= Rs.12,000/= 07-06-2010 1x10's 2x10's 3x10's 5x10's 10x10's As Per SRO	Zyban® 150 mg prolonged release tablets Local Availability: Wellburtin XL 150 mg by M/s GSK Pakistan Last inspection report of 10-02-2016 submitted with compliance remarks	Deferred for confirmation of formulation whether modified release or otherwise
	Previous decision: **Registration Board in its 263rd meeting deferred the case for following reason:** Deferred for confirmation of formulation whether modified release or otherwise.				
	Evaluation by PEC:				
	Decision of 283rd meeting: Deferred for revision of formulation along with fee since the reply of the firm is not clear and the reference product is available as prolonged release tablet.				

	Firm's response: Firm has submitted fee of Rs. 37000 vide deposit slip no. 6579647291 for pre-registration variation along with following revised label claim: "Each extended release tablet contains: Bupropion HCl ….. 150mg (USP specs.") Me-too reference of applied formulation is of Zyban SR Tablet 150mg of M./s Seraph Pharmaceuticals (Reg.# 093380)	
	Decision: Approved as per revised label claim as under: **"Each extended release tablet contains:** **Bupropion HCl ….. 150mg** **(USP specs.")**	
97.	**Name and address of manufacture / Applicant**	**M/s Glitz Pharma Plot No 2610. Industrial Triangle. Kahuta Road, Islamabad**
	Brand Name + Dosage Form+Strength	Rivas 6mg Capsule
	Composition	Each Capsule Contains: Rivastigmine Tartrate eq to Rivastigmine……..6mg
	Dairy No. date of R &I fee	Form-5 Dy.No 23626 dated 09-07-2018 Rs.20,000/- 06-07-2018
	Pharmacological Group	Anticholinesterases
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	10's, 20's, 30's, 50', 60's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Rivastigmine 6mg capsule (contains Rivastigmine Hydrogen Tartrate eq to Rivastigmine…6mg) , MHRA Approved
	Me-too-status	Rivsaff Capsule 6mg by M/s Saffron Pharmaceuticals (R# 081396)
	GMP Status	The firm was inspected on 16-01-2019 and conclusion of inspection was: Keeping in view the observations noted during inspections as narrated above, the panel is of the opinion that the firm has rectified the observations noted in the previous panel inspection conducted on 16th January, 2019 and decided to recommend the issuance of GMP certificate.
	Remark of the Evaluator [XI]	• The firm did not revise the label claim as per reference formulation along with submission of applicable fee.
	Decision of 312th meeting: Deferred for revision of the label claim as per reference formulation along with submission of applicable fee	
	Firm's response: Firm has submitted fee of Rs. 37000 vide deposit slip no. 3910089670 for pre-registration variation along with following revised label claim: "Each capsule contains: Rivastigmine hydrogen tartrate ….. 6mg (USP specs.")	
	Decision: Approved as per revised label claim as under: **"Each capsule contains:** **Rivastigmine hydrogen tartrate ….. 6mg** **(USP specs.")**	
98.	**Name and address of Manufacturer / Applicant**	**M/s Glitz Pharma, Plot No. 265, Industrial triangle Kahuta Road, Islamabad.**
	Brand Name + Dosage Form + Strength	Fenda tablet 10mg
	Composition	Each film coated tablet contains: Methylphenidate hydrochloride…. 10mg
	Diary No. Date of R&I & fee	DyNo.3910; 31-01-2018; Rs. 20,000/-
	Pharmacological Group	CNS Stimulant
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack Size & Demanded Price	10's, 20's, 14's, 28's, 30's, 50's, 100's: Rs.120/-
	Approval status of product in Reference Regulatory Authorities	Approved in TGA
	Me-too status	Leadophen tablets 10mg of Leads Pharma Pvt Ltd.

	GMP status	Panel inspection conducted on 19-09-17 unanimously recommended grant of cGMP Certificate.
	Remarks of Evaluator	Applied formulation is film coated tablet which is different from Reference product i.e. uncoated tablet. Submit Form 5, Master formulation & manufacturing method either in line with reference product also required fee for revision of formulation or evidence of reference product as film coated tablet.
	Decision of 293rd meeting: Deferred for revision of formulation along with requisite fee, since reference product is available as uncoated tablet whereas firm has applied for film coated tablet.	
	Firm's response: Firm has submitted fee of Rs. 37000 vide deposit slip no. 18749727326 for pre-registration variation along with following revised label claim: "Each tablet contains: Methylphenidate hydrochloride…. 10mg (USP specs.)"	
	Decision: Approved as per revised label claim as under: **"Each tablet contains:** **Methylphenidate hydrochloride…. 10mg** **(USP specs.)"**	

99.	**Name, address of Applicant / Importer**	**M/s Himmel Pharmaceuticals Pvt Ltd.** **Ground Floor, 6-Judicial Colony, Phase I (Extension), Shahrah Nazria e Pakistan, Lahore**
	Details of Drug Sale License of importer	License No: 05-352-0065-016174D Address: Ground Floor, 6-Judicial Colony, Phase I (Extension), Shahrah Nazria e Pakistan, Lahore Validity: 06-02-2024 Status: Drug License by way of Distributor
	Name and address of marketing authorization holder (abroad)	M/s Hainan Poly Pharm. Co., Ltd. Guilinyang Economic Development Zone, Haikou, Hainan Province, 571127, China
	Name, address of manufacturer(s)	M/s Hainan Poly Pharm. Co., Ltd. Guilinyang Economic Development Area, Haikou, Hainan Province, 571127, China
	Name of exporting country	China
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 20795 dated 23-08-2023
	Details of fee submitted	Rs.75,000/- dated 27-07-2023
	The proposed proprietary name / brand name	**Daptomycin 0.5gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Daptomycin…0.5gm
	Pharmacotherapeutic Group of (API)	Antibacterials for systemic use, Other antibacterials, ATC code: J01XX09
	Reference to Finished product specifications	European Pharmacopoeia
	The status in reference regulatory authorities	Approved by EMA
	For generic drugs (me-too status)	Not available
	Proposed Pack size	1's:As per SRO
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP (No. 20230041) issued by Hainan Provincial Medical Products Administration valid till 01-05-2025. The certificate does

		confirm the free sale status of the product in country of Origin along with GMP of the manufacturing unit. **GMP:** Firm has submitted legalized copy of GMP certificate No. HI20190005 issued by Hainan Provincial Medical Products Administration, valid upto 29-01-2024
	Details of letter of authorization / sole agency agreement	Firm has submitted "Letter of Authorization" from M/s Hainan Poly Pharm. Co., Ltd. Guilinyang Economic Development Zone, Haikou, Hainan Province, 571127, China for applied product.
	Stability studies of drug product	Real time (24 months): 5ºC ± 3 ºC Accelerated (6 months): 25ºC/60%RH

Evaluation by PEC[II]: The case was deferred in 340th meeting of Registration Board for below mentioned observations to which firm has responded as mentioned against each:

Sr.#	Observation	Firm's response
1.	Valid copy of Drug Sale License of the applicant shall be submitted.	Submitted.
2.	Notarized copy of sole agency agreement shall be submitted.	Letter of Authorization has been submitted from M/s Hainan Poly Pharm. Co., Ltd. in name of M/s Himmel Pharmaceuticals Pvt Ltd**.**
3.	Justification shall be submitted for the declared appearance as powder of drug substance, since as per reference product literature the drug substance is provided as frozen concentrate instead of lyophilised powder.	The manufacturing process of the proposed generic product, Daptomycin for Injection, including Compounding, Filtration, Filling and Lyophilization. During Compounding process, the drug substance will be dissolved in the water for injection, since the formulated amount of drug substance can be completely dissolved in the water for injection (the solubility of drug product can be found in Section 3.2.P.2.1.2.3 in the original submitted dossier), the form of the drug substance will not affect the manufacturing process and the drug product quality. Therefore, whether the drug substance is frozen concentrate or lyophilised powder, the drug product quality will not be affected. In addition, three batches of drug product have been manufactured with the drug substance in lyophilised powder form, stability studies (Stress study, Accelerated stability study and Long-term stability study) have been conducted, the detailed stability data are provided in section 3.2.P.8.3, which indicates that the drug product can be stable within the proposed shelf-life. Also the comparison of drug product quality with the reference product is provided

		In the Response to comment 5 below, the quality of the proposed generic product are equivalent or even better than the reference product. In conclusion, although the drug substance is not in frozen concentrate, it is still acceptable to be used for the drug product manufacturing.
4.	Clarification shall be submitted for the analytical studies performed for the characterisation of drug substance to establish amino acid sequencing and structure.	The drug substance manufacturer, Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd. has characterized the drug substance amino acid sequencing and structure via the combination of HRMS, 1H-NMR, 13C-NMR, DEPT, 1H1H-COSY, HSQC, HMBC, TOCSY, ROESY, infrared absorption spectroscopy, UV-VIS absorption spectroscopy. Additionally, chiral amino acid analysis was employed to characterize the absolute stereochemistry of the Daptomycin sample. Comparison of circular dichroism (CD) spectroscopy, chiral amino acid analysis, chiral HPLC analysis, infrared absorption spectroscopy, UV-VIS absorption spectroscopy with those of the reference listed drug (RLD) provided further proof of structure
5.	Drug substance specifications, analytical procedure and analytical method verification studies from the drug product manufacturer shall be submitted.	Please be informed that the drug substance specification, analytical procedure and analytical method verification studies from the drug product manufacturer has already been submitted. All the files are located in section 3.2.S.4, with the folder named "daptomycin-DS manufacturer".
6.	Justification shall be used for use of drug substance in powder form, since reference product has declared the physical state of drug substance as frozen concentrate.	Refer to point 1.
7.	Pharmaceutical equivalence of the applied drug shall be established with 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	Firm has submitted tabulated results for the reference and applied product. Details of the reference product have not been provided.
8.	The submitted manufacturing procedure of the drug product does not include the process of "thawing of the active substance" & "pre-filtration" as recommended by the innovator drug	As is justified in the Response to comment 1, the drug substance used for manufacturing the generic product is a lyophilized powder rather than

	product literature. Justification shall be submitted in this regard.	the frozen concentrate. Therefore, the "thawing of the active substance" is not needed. Pre-filtration is not employed in the manufacturing process of the generic product, instead, two 0.22μm sterilizing filters (Supplier: Millipore; Model: CVGL71TP3) in series are used in the filtration process. Please be informed that the manufacturing process is company specific and does not have to be consistent with the innovator drug product literature. The acceptability of not using pre-filtration is justified in following three points: • The Bioburden of the bulk solution (un-filtered solution) is low. • The two 0.22μm sterilizing filters in series can ensure the sterility of the drug product
9.	Justification shall be submitted for not including test of powder fill weight and container closure integrity, as recommended by innovator drug product.	• Please be informed that, instead of powder fill weight, the test of Uniformity of dosage units is included in the drug product specification. • Although the powder fill weight is not included in the specification, during the test of Uniformity of dosage units, the powder weight will be tested, what's more, the consistency of each unit will also be evaluated in this test. • The container closure integrity is evaluated via the vacuum decay method,
10.	Justification shall be submitted for the Assay limits of 95%-115% for the drug product shelf life specifications.	As is indicated in section 3.2.P.1, section 3.2.P.2.3.4.2 and section 3.2.P.3.2, there is an overfill of 5% in the drug product. The theoretical amount of drug substance, Daptomycin, per vial should be 525 mg (labelled amount of 500 mg × (100%+5%) = 525 mg). Therefore, the theoretical assay of the drug product should be 105%, considering the variation of manufacturing and the testing, the range of ±10% is always proposed for the assay testing,

			hence the limits of 95%-115% for the drug product shelf life specification is proposed.
	11.	Justification shall be submitted for the limits of 4.0 – 5.0 for pH test in shelf life specifications while the in-process limit for pH was kept 4.5 - 5.0	Based on the scientific discussion of CUBICIN (recommending bulk solution pH range of 4.5~5.0) and pH selection experiments (bulk solution stability indicates pH range of 3.9~5.4, drug product stability indicates pH range of 4.2~5.1), in order to ensure the consistency of different batches, a narrow pH range of 4.5~5.0 of bulk solution (i.e. in-process limit) is proposed.
	12.	Compatibility study with the reconstitution diluent shall be submitted.	Submitted.

Decision: Deferred for submission of scientific justification for variation of manufacturing method of drug substance and drug product from that of the innovator drug product.

100.	**Name, address of Applicant / Importer**	**M/s AMB HK Enterprises (pvt) Ltd., 2nd floor Plaza 60 commercial, Block-K, Phase 1, DHA, Lahore.**
	Details of Drug Sale License of importer	License No: 05-352-0058-066904D Address: AMB HK Enterprises (Pvt) Ltd., 2nd floor, plaza 60 commercial, Bock-K, Phase-1, DHA, Lahore. Validity: 24-02-2023 Godown: N/A Status: License to sell drugs as a Distributor
	Name and address of marketing authorization holder (abroad)	M/s Hebei Tiancheng Pharmaceutcal Co.,Ltd., No. 18, Jinguang street, Economic &Technological Development zone, Changzhou City, Hebei Province, China. (Headd Office)
	Name, address of manufacturer(s)	M/s Hebei Tiancheng Pharmaceutcal Co.,Ltd., No. 51, Jinguang street, Economic &Technological Development zone, Changzhou City, Hebei Province, China.
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate) • Copy of DML No. HEBEI20150098 valid till 12/11/2025 issued by Hebei Medicla Products Administrtaion is submitted. • Copy of GMP certificate no. HE20180059 valid till 16/07/2023 issued Hebei FDA.	
	Details of letter of authorization / sole agency agreement:	
	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. 30343 : 26-10-2022
	Details of fee submitted	PKR 150,000/-: 19-06-2022
	The proposed proprietary name / brand name	**Movtin Injection 1g IV** **Powder for injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Creatine Phosphate Sodium Injection……1g
	Pharmaceutical form of applied drug	Powder for injection
	Pharmacotherapeutic Group of (API)	ATC: C01EB06 other drugs used in heart diseases
	Reference to Finished product specifications	In-house
	Proposed Pack size	1's
	Proposed unit price	Rs. 1200/- for 1's
	The status in reference regulatory authorities	-
	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 and product.
	Name, address of drug substance manufacturer	M/s Hebei Tiancheng Pharmaceutcal Co.,Ltd., east of Jingsi street, west area of Lingang economic & technological development zone, Canghzhou, Hebei 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)	• Real time stability studies have been conducted at 40oC±2 RH 75%±5 for 36 months of 3 batches • Accelerated stability study is conducted at 30oC±2 and 65%RH±5% for 24 months of 3 batches Batches: 20171102, 20171103, 20171104
	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, detail of impurities 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	The firm has submitted analytical method validations/ verification studies for the drug substance as well as for the drug product including specificity, accuracy, precision, linearity, LOD / LOQ (for impurities), system suitability etc.
	Container closure system of the drug product	Low borosilicate glass vial s with Halogenated butyl rubber stopper
	Stability study data of drug product, shelf life and storage conditions	• Real time stability studies have been conducted at 30oC±2 and 65%RH±5% for 24 months of 3 batches Batch numbers: F11812091, F11812101, F11812111 • Accelerated stability studies is conducted at 40oC±2 and 75%RH±5% for 6 months of 3 batches Batches: 110331, 1103311, 1104011

Evaluation by PEC:

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Sr. No.	Observations
1	Please provide evidence of approval of the applied in same strength is reference regulatory authorities as approved in 275th meeting of Registration Board.
2	Provide pharmaceutical equivalence studies for the applied product against the innovator's / reference product along with the detail of batch number, expiry, date of manufacturing, approval status if reference country etc.
3	Compatibility study of excipient with the drug substance are required.
4	Since the product is powder for injection and the detail of accompanying reconstitution diluents have not been provided. Please detail of method of administration along with the detail of all the diluents used for reconstitution along with the compatibility studies of the formulation with the diluents.
5	As per submitted dossier, the specifications for the drug product are BP while the product is not present in BP, please clarify and submit Rs. 7,500/- fee for revision of specifications as per notification number No.F.7-11/2021-B&A/DRAP dated 07-05-2021.
6	Provide product specific sole agency agreement for the applied product.
7	Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
8	Provide original, legalized and valid CoPP confirming the free sale of the applied product in exporting country and GMP status of the manufacturing facility.

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: Firm has submitted following:

- Reference of approval of applied formulation by three European countries i.e., Romania, Slovakia & Poland for the brand of Neoton. Web links of said references are as under:

Romania: https://www.anm.ro/_/_RCP/RCP_6986_10.10.14.pdf
Slovakia: https://www.sukl.sk/hlavna-stranka-1/english-version/special-pages/medical-product-detail?page_id=842&lie_id=44895
Poland: https://rejestry.ezdrowie.gov.pl/api/rpl/medicinal-products/4685/characteristic

- Pharmaceutical Equivalence studies against the Neoton Injection of Alfasigma, Poland.
- Compatibility studies with the reconstitution diluent.

- Original Legalized Foreign Agency Agreement from M/s Hebei Tiancheng Pharmaceutcal Co.,Ltd in name of M/s AMB HK Enterprises (Pvt) Ltd.
- Original Legalized COPP (No. Hebei20210501)

Decision of 333rd meeting: Registration Board deferred the case for submission of following:

- Details of the countries where the drug product is being exported by the M/s Hebei Tiancheng Pharmaceutical Co., Ltd. China.
- Regulatory Status of applied formulation in other countries.

Firm's response: Firm has submitted registration certificate no. DV/X 02287/10/16 issued by Ministry of Health of the Republic of Uzbekistan with following details:
Brand name: Revarton
Composition: Creatine phosphate sodium 1gm
Dosage form: Powder for solution for injection
Manufacturer: Hebei Tiancheng Pharmaceutical Co., Ltd.

Decision: Deferred for confirmation of regulatory status of the applied formulation in reference regulatory authorities adopted by Registration Board in its 275th meeting of Registration board.

101.	**Name, address of Applicant / Importer**	**M/s Biocare Pharmaceutica. 807 Shadman-1, Lahore, Pakistan**
	Details of Drug Sale License of importer	**License No:** 05-352-0063-032069D **Address: 807 Shadman-1, District Lahore**. **Address of Godown:** First floor 8-C, Street No. 3, Near LGS School, Shah Jamal District Lahore. **Validity:** 17-04-2027. **Status:** License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	Shandong Luoxin Pharmaceutical Group Stock Co., Ltd. **Address:-** Luoqi Road, Linyi High and New Technology Industries Development Zone Shandong Province, PR China. 276017.
	Name, address of manufacturer(s)	Shandong Luoxin Pharmaceutical Group Stock Co., Ltd. **Address Manufacturing site :-** Luoqi Road, Linyi High and New Technology Industries Development Zone Shandong Province, PR China. 276017.
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 840 dated 10-01-2023
	Details of fee submitted	Rs.75,000/- dated 30-12-2022
	The proposed proprietary name / brand name	**Bionem 300mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Biapenem…300mg
	Pharmacotherapeutic Group of (API)	Carbapenem antibiotic
	Reference to Finished product specifications	In-House or Innovator Spec. (National specification issued by China National Medical Products Administration with the approval No. YBH04172014) .

	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP with certificate No. 20225016, issued by Shandong Provincial Medical Products Administration (People's Republic of China) valid till 05-6-2024. 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 countries on CoPP are mentioned including Pakistan.</u> Firm has also submitted Legalized GMP certificateno. SD20180816 issued by Shandong Food And Drug Administration, in name of Shandong Luoxin Pharmaceutical Group Stock Co., Ltd., Luoqi Road, Linyi High and New Technology Industries Development Zone Shandong Province valid till 25-11-2024
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of legalized distribution agreement signed by both parties Biocare Pharmaceutica & Shandong Luoxin Pharmaceutical Group Stock Co., Ltd. Agreement clearly mention Aboard License Holder/manufacturer Shandong Luoxin Pharmaceutical Group Stock Co., Ltd., appoints M/s Biocare Pharmaceutica to register/market/sell/Distribute its product Bionem (Biapenem) 0.3 gm in Pakistan. Agreement is Valid with 12 months renewal clause.

EVALUATION OF DATA	
Proposed Pack size	--
Proposed unit price	Rs. 5200/vial-
The status in reference regulatory authorities	Approved by PMDA of Japan
For generic drugs (me-too status)	Not available.
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Name, address of drug substance manufacturer	Shandong Luoxin Pharmaceutical Group Hengxin Pharmaceutical Co., Ltd. Address No. West Side of Yanbin Road, Economic Development Zone, Feixian, Linyi City, Shandong Province, China.
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per Module 3.2.S.
Module-III Drug Product:	Firm has submitted data of drug product as per Module 3.2.P.
Pharmaceutical Equivalence	Pharmaceutical equivalence has been established by conducting all the quality tests against the reference brand: - Omegacin (Biapenem) produced by Meiji Seika Pharma Co., Ltd, Japan.
Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
Container closure system of the drug product	Biapenem for Injection is packed in injection vials made of low borosilicate glass tubing covered with halogenated butyl rubber stoppers sealed with aluminum-plastics combination caps.

Stability study data of drug product, shelf life and storage conditions	• 24 months real time stability data at 30°C ± 2°C / 65% ± 5%RH (Zone IVA) of 03 batches (320103001, 320103002, 320103003) is Submitted. • 06 month accelerated stability data 40°C ± 2°C / 75% ± 5%RH of 03 batches (320103001, 320103002, 320103003) is submitted.

Evaluation by PEC^{II}: The case was deferred in 336th meeting of Registration Board, for following observations to which firm has responded as detailed against each:

Section no.	Observations	Firm's response
1.6.5	Submit valid DML/GMP certificate issued by the relevant regulatory authority for the drug substance manufacturer.	Submitted
3.2.S.4.1	Justification shall be submitted for variation in proposed limits of test of "optical rotation test" i.e., -30^{o} - -36^{o} from that recommended by the innovator literature i.e., -31^{o} - -36^{o}	The limit of "optical rotation test" has been revised to -31° - -36° in the specification of Biapenem same as that of the innovator
3.2.P.2.6	Compatibility study of applied drug product with the recommended re constitution diluents shall be submitted.	Submitted
3.2.S.7.3	Justification shall be submitted for not performing test of identification & sterility of drug substance during stability studies.	Firm has submitted revised stability summary sheets.
3.2.P.3.1	Submitted DML of the drug product manufacturer does not include scope for manufacturing facility of "Carbapenem dry powder injection".	According our manufacturer – Shandong Luoxin Pharmaceutical, China Response: There is a dedicated workshop (Workshop 1303) with separate premises and facilities to manufacture the "Carbapenem" products in their site.
3.2.P.3.3	Description of the sterility process of the applied product shall be submitted.	Our Manufacturer Shandong Luoxin Pharmaceuticals reply: Please note that this API is sterile when purchased from the API manufacturer. The sterile API is filled into the sterilized vials using the filling machine in the Grade A laminar flow under Grade B area, which guarantee the aseptic conditions during the filling process. When aseptic operations are performed, microbiological monitoring are frequent using a combination of methods such as settle plates, volumetric air sampling, glove, gown and surface sampling, also there is on-line monitoring system to monitor the dust particles, air

			speed and pressure differential of the Grade A laminar flow.
	3.2.P.5.1	Justification shall be submitted for variation in proposed limits of test of "pH" i.e., 4 - 6 from that recommended by the innovator literature i.e., 4.5-5.8. Justification shall be submitted for the proposed limit of "Weight variation test" i.e., NMT±7%, with reference to the pharmacopoeial provisions.	As per our manufacturer Shandong Luoxin Pharmaceutical Response: Please note that the percentage deviation for the powder injections (Average mass: more than 40mg) is NMT 10% for the Weight variation test according to the General Notices 2.9.5 "Uniformity of Mass of single-dose preparations" of European Pharmacopoeia. However, considering the product in good quality status, the proposed limit of the weight variations is tightened to be NMT 7.0% in the dossier of 3.2.P.5.1. Specification of Biapenem for Injection 0.3g.

Decision: Approved as per policy of inspection of manufacturer abroad. Registration letter will be issued upon submission of analytical record for the submitted drug product stability data including chromatograms/spectrums etc.

102.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Venus Pharma (DML # 000300)** **23-km, Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s Venus Pharma (DML # 000300) 23-km, Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	GMP certificate valid up to: 13-09-2025
	Evidence of approval of manufacturing facility	Not provided
	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 27407 dated 27-09-2022
	Details of fee submitted	PKR 30,000/-: Dated 31-05-2022 Slip # 125635671
	The proposed proprietary name / brand name	**Cyanocobalamin Injection 2cc**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml contains: Cyanocobalamin ……...……500 mcg
	Pharmaco-therapeutic Group of (API)	Cyanocobalamin
	Pharmaceutical form of applied drug	IM Injection

	Reference to Finished product specifications	USP Specification
	Proposed Pack size	2ml x 25's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Not available
	For generic drugs (me-too status)	**Brand Name:** Cyanocobalamin Injection 2cc **Manufacturer:** M/s Ameer Pharma. **Reg.** # 049054. **Brand Name:** Adcyna Injection 500mcg/2ml **Manufcaturer:** Ameer & Adnan Pharmaceuticals (Pvt) Ltd., 47 Sundar Industrial Estate Lahore, Lahore. **Reg.** # 78924.
	Name and address of API manufacturer.	Name: M/s YUXING Biotechnology (Group) Co. Ltd. Address: XiCheng District, Ningjin County, Bebei Province, China. GMP validity : 29-11-2024
	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, 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 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, 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)	Accelerated stability data for 06 months Climatic conditions: 40°C ± 2°C / 75% ± 5% RH. Real time stability data for 60 months Climatic conditions: 30°C ± 2°C / 65% ± 5% RH
	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	**Brand Name:** Cyanocobalamin Injection **Manufacturer:** M/s Ameer Pharma **Testing Parameters:** USP specifications
	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	Name: M/s YUXING Biotechnology (Group) Co. Ltd. Address: XiCheng District, Ningjin County, Bebei Province, China.	

API Lot No.	C210720D	
Description of Pack (Container closure system)	Clear Glass Ampoules	
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 (Months)	
Batch No.	CTD-02	CTD-04
Batch Size	4.2 L	4.2 L
Manufacturing Date	10/2021	10/2021
Date of Initiation	25-10-2021	25-10-2021
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)	Not required.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Quantity:** 5kg **Dated:** 27-08-2021
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 analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	UV spectroscopy
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:

Section	Observations	Reply of the firm
1.3.4	• Please submit valid / fresh GMP certificate of your firm issued by DRAP OR inspection report conducted within last three years for confirmation of GMP compliance status of the manufacturing facility.	Submitted
	• For the manufacturing facility of Liquid Injectable (vials & ampoules – General Section), please submit evidence of Section approval in the meeting of Central Licensing Board.	Firm submitted the renewal of DML mentioning the section.
1.5.9	• Please submit evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	In RRA (USFDA & ANSM), the formulation is available in 1000mcg/ml. but firm requested to consider their formulation of 500 mcg/2ml on the basis of vitamin policy.
1.6.5	• Please submit the GMP certificate of API manufacturer issued by Regulatory Authority of Country of Origin and should be inforce till date.	Submitted

3.2.P.8	• Please submit DRAP clearance documents for API import.	Submitted
	• Please submit details of three stability batches such as manufacturing date, batch size, date of initiating testing, API Lot#.	Submitted

Decision of 335th meeting: Deferred for the evidence of RRA

Firm's response: Firm has requested to consider it against the me-too product.

Decision: Deferred for review of formulation with reference to the regulator status of applied formulation in reference regulatory authorities adopted by Registration Board in its 275th meeting.

103.	**Name and address of manufacturer / Applicant**	**M/s Shaigan Pharmaceuticals, Pvt Ltd, 14 km Adyala Road, Rawalpindi**
	Brand Name +Dosage Form + Strength	**Bacteriostatic WFI**
	Diary No. Date of R& I & fee	Dy.No.804 02-09-2016 Rs.20,000/-
	Composition	Each ml contains: Benzyl alcohol USP….9.0mg
	Pharmacological Group	Diluent for Injection
	Type of Form	Form 5
	Finished Product Specification	USP Specs)
	Pack size & Demanded Price	1's vial 1ml,2ml,3ml,4ml 5ml,6ml 7ml,8ml,9ml 10ml,12ml,16ml (Rs5/-,Rs8/-,Rs.10/- Rs.15/-,Rs25/-)
	Approval status of product in Reference Regulatory Authorities.	--
	Me-too status	WFI by GSK (Pak)
	GMP status	Inspection report dated 17-08-2016 recommended for the grant of additional sections
	Previous Remarks of the Evaluator.	Firm has submitted copy of GMP inspection report conducted on 13-12-2012, stating that firm has following approved sections: i. Tablet section ii. Capsule section iii. Semisolid (cream/ointment) section iv. Liquid Syrup section v. Cephalosporin dry powder for suspension. vi. Cephalosporin Capsule vii. Cephalosporin Dry powder for injections viii. Liquid Injectable (Ampoule and vials) ix. Ophthalmic preparations (eye drops) x. Lyophilized Powder for injections
	Previous Decision	Deferred in 267th meeting of Registration Board for clarification of composition as Brand name states WFI, whereas in composition Benzyl alcohol is mentioned.
	Evaluation of Firm's reply	• Firm has referred to USP monograph of "Bacteriostatic Water for injection" which states as under: "Bacteriostatic Water for Injection is prepared from Water for Injection that is sterilized and suitably packaged, containing one or more suitable antimicrobial agents." • Reference of international availability is required for pack size and container closure system.
	Decision of 270th meeting: Deferred for clarification of indications/intended use & reference of international availability for applied pack size/volume and container closure system.	
	Firm's response: We would like to submit the following information in response to the above queries raised for our product. **INDICATIONS/INTENDED USE:** Bacteriostatic Water for Injection is used as a diluent for reconstitution. **RRA Reference.**	

Bacteriostatic WFI is available as combo pack & approved in (TGA) under the registered brand name (SOLU-MEDROL) by Pfizer International.

Reference link:

https://medicinesdatabase.be/human-use/medicines?search=%7B%term%22:%22solu-medrol%22%7D

Me-too status:

Brand Name	Registration Holder	Registration Number
SOLU-MEDROL	**Pfizer Pakistan Ltd.**	Injection: **104514**
		Diluent: **031265**

Pack size & Container closure.

Type I labeled Glass vial with rubber stopper and flip off seal of 7.8ml.

(In line with innovator product Solu-Medrol Injection).

Accordingly, we revise the Form 5 along with full fee vide deposit slip no. 6200360275 for the standardization of label claim.

Decision: Registration Board while considering the fat that the applied formulation is a solvent for the recontitution of dry powder injection of Methylprednisolone, decided to defer the instant application for clarification regarding the details of the registration status, in name of M/s Shaigan Pharmaceuticals, Pvt Ltd, 14 km Adyala Road, Rawalpindi, of intended drug product i.e., Methyl prednisolone injection, for which applied diluent will be used.

104.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Wimits Pharmaceuticals, Plot No. 129, Sunder Industrial Estate Raiwind Road, lahore.**
	Name, address of Manufacturing site.	M/s. Wimits Pharmaceuticals, Plot No. 129, Sunder Industrial Estate Raiwind Road, lahore. DML No. 000789
	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 08.09.2021 based on inspection conducted on 08.09.2021 valid till 07.09.2023.
	Evidence of approval of manufacturing facility	Syrup (General Human) Section approval letter vide No. 1-51/2004-Lic dated 07.02.2014 is submitted.
	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. 10567 dated 27.04.2022
	Details of fee submitted	PKR 30,000/- Slip No. 052420933396 dated 08.04.2022
	The proposed proprietary name / brand name	**MAVINATE 12.5mg/4ml Syrup**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml contains; Dimenhydrinate BP……..12.5mg
	Pharmacotherapeutic Group of (API)	ANTIHISTAMINES FOR SYSTEMIC USE, Aminoalkyl ethers. ATC Code: R06AA11
	Pharmaceutical form of applied drug	Almost colourless, clear oral solution with characteristic odour of cherry.

	Reference to Finished product specifications	USP Specifications.
	Proposed Pack size	60ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Could not be verified
	For generic drugs (me-too status)	Gravinate Liquid Reg. No. 014409 M/s Searle Company Ltd. Lahore.
	Name and address of API manufacturer.	M/s S.S. Pharmachem, K-44/45, M.I.D.C. Tarapur Boisar, Maharashtra, 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, 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 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, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. Batch No. SAM/DMN/0520014 QC No. R2009010
	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. Batches: SAM/DMN/001, SAM/DMN/002, SAM/DMN/003.
	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	**Test product:** Dimenhydrinate 12.5mg/4ml Syrup batch No. Mfg. Exp. . **Reference product:** Gravinate 12.5mg/4ml Syrup, Batch No.____ mfg.: _____, Exp. ____ manufactured by M/s Searle Pakistan Pvt. Ltd. **Tests done:** physical characteristics, identification,

		Assay, pH, filled volume, packing.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug substance as well as drug product.

STABILITY STUDY DATA			
Manufacturer of API	M/s S.S. Pharmachem, K-44/45, M.I.D.C. Tarapur Boisar, Maharashtra, India.		
API Lot No.	VTZD21001		
Description of Pack (Container closure system)	White coloured, round shaped compressed tablets packed in Alu-PVC 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.	TDH001	TDH002	TDH003
Batch Size	72 bottles	74 bottles	76 bottles
Manufacturing Date	07.2021	07.2021	07.2021
Date of Initiation	05.07.2021	08.07.2021	11.07.2021
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)	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. 6094894 dated 31.08.2020 is submitted. The certificate is issued by FDA Maharashtra India. Valid till 30.07.2021
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Dimenhydrinate BP Batch No.: SAM/DMN0520014 Mfg. date: 05.2020 Exp. date: 04.2025 Quantity: 100Kgs Invoice No.: 09/2020-21 Invoice date: 25.07.2020 Clearance date: 28.08.2020 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.	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
1.	-	Evidence of product approval in RRA is required.
2.	3.2.P.2.2	Batch numbers, manufacturing dates and expiry dates of both test product and reference product (Gravinate) use in pharmaceutical equivalence are not mentioned. Pictorial evidence of reference product is also not submitted.

Decision of 331stmeeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Firm's response: Firm has requested to consider the product against the decision of 179th meeting of Authority while referring to the following me-too product:

"Gravinate Liquid 12.5mg/4ml of "The Searle Company Limited" (Reg.# 014409)

Decision: Deferred for review of formulation with reference to the regulator status of applied formulation in reference regulatory authorities adopted by Registration Board in its 275th meeting.

105.	**Name and address of manufacturer /Applicant**	**M/s Life Pharmaceutical Company (DML # 0000194) 24-III Industrial Estate Multan.**
	Brand Name +Dosage Form + Strength	Bebate Ointment 0.05 % w/w
	Composition	Each gram off ointment contains Betamethasone di-propionate … 0.05% w/w
	Diary No. Date of R& I & fee	*Duplicate Dossier* *Dy. No. 21230 dated 28-07-2022* Dy. No. 5986 dated 23-05-2011 *(verified)* Rs.8000/- dated 23-05-2011 *(photocopy)* Rs.12000/- dated 12-21-2013 *(photocopy)*
	Pharmacological Group	Corticosteroid
	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.	Health Canada approved formulation
	Me-too status	Provate by Don Valley
	GMP status	Latest GMP not provided
	Remarks of the Evaluator[3].	• Submit fresh inspection report and section approval letter issued from Central Licensing Board.
	Decision of 333rd meeting: Deferred for the submission of following: • Evidence of Section approval from Licensing Division. • Latest GMP inspection report conducted within last three years. • Registration Board further decided that verification of fee challan will be done as per decision of 285th meeting of Registration Board.	
	Firm's response: Firm has submitted copy of letter no. F.1-30/84-Lic (Vol.I) (M-227) issued by secretary CLB dated 24-06-2011 for the grant of Additional sections including "cream/ointment (General) section. Firm has also submitted copy of GMP inspection report dated 25-04-2024 concluding satisfactory level of GMP compliance.	
	Decision: Approved. Verification of fee challan will be done as per decision of 285th meeting of Registration Board.	
106.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Axis Pharmaceuticals. Value Addition City, 3-B, 1.5km, Khurrianwala-**

		Sahianwala Road, Faisalabad
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals. Value Addition City, 3-B, 1.5km, Khurrianwala-Sahianwala Road, Faisalabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 18837 dated 24-07-20j23
	Details of fee submitted	Rs.30,000/- dated 06-07-2023
	The proposed proprietary name / brand name	**Empaglif-M 12.5/1000mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin HCl…1000mg
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	Xenglu Met tablet of M/s Hilton
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications
107.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Axis Pharmaceuticals.** **Value Addition City, 3-B, 1.5km, Khurrianwala-Sahianwala Road, Faisalabad**
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals. Value Addition City, 3-B, 1.5km, Khurrianwala-Sahianwala Road, Faisalabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 17325 dated 11-07-2023
	Details of fee submitted	Rs.30,000/- dated 09-06-2023
	The proposed proprietary name / brand name	**Empaglif-M 12.5/850mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin…12.5mg Metformin HCl…850mg
	Pharmacotherapeutic Group of (API)	**Metformin HCl:** Biguanide class of Anti-diabetics ATC code: A10BA02 **Empagliflozin:** Sodium-glucose co-transporter 2 (SGLT2) inhibitors. ATC code: A10BK03
	The status in reference regulatory authorities	US FDA Approved.
	For generic drugs (me-too status)	Xenglu Met tablet of M/s Hilton

	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC[II]: Above cases were deferred in 340th meeting of registration Board for the following observations to which firm has replied as detailed against each:

Sr.#	Observation	Firm's response
1.	Latest GMP inspection report of drug product manufacturer, conducted within last three years shall be submitted.	Firm has submitted copy of GMP certificate issued on basis of inspection conducted on 03-07-2024.
2.	Valid DML/GMP certificate of the drug substance manufacturer of Metformin HCl issued by relevant regulatory authority of country of origin shall be submitted.	Submitted.
3.	Declaration of solubility of Empagliflozin in water as "practically insoluble" shall be justified with reference to the innovator drug product literature.	Firm has submitted revised section of 3.2.S part.
4.	Justification shall be submitted for the limits of optical rotation test applied for Empagliflozin.	Limits have been adopted from drug substance manufacturer COA.
5.	COA of reference/working standard used for analysis of drug substances shall be submitted.	Submitted
6.	Justification shall be submitted for the declared quantity of Empagliflozin and Metformin HCl in the master formulation considering the label claim.	Quantity for Empagliflozin & Metformin-HCl were taken after potency adjustment.
7.	Innovator drug product literature states as under: "To combine the low amount of Empagliflozin with the relatively high quantity of metformin hydrochloride, a wet granulation process with granulation liquid containing Empagliflozin was chosen." • In contrast to above cited reference, applied formulation has been formulated by granulating dry mix of Metformin HCl & Empagliflozin with binder solution. Justification shall be submitted in this regard.	Empagliflozin was geometrically mixed with the pre-mix material to uniformly distribute the API and to avoid risk of being entrapped along with binder and may cause delay in drug release. Moreover, Content Uniformity has been performed and complies the specification, ensuring uniform distribution of the drug substanc
8.	Justification shall be submitted for not including Content uniformity test as critical quality attribute at any sampling stage of Process validation protocol.	Revised Manufacturing Process Validation Protocol (proposed) including test for Content Uniformity is submitted.
9.	Variation in the standard and sample concentrations of	Empagliflozin and Metformin-HCl are in fixed dose combination having three different

	Empagliflozin applied in the test of Dissolution, shall be justified along with linearity performance of the Dissolution method	combination strengths (i.e. 12.5/500mg, 12.5/850mg & 12.5/1000mg) and concentration of Metformin-HCl is adjusted in sample preparation with respect to standard concentration. Moreover, linearity for Empagliflozin in dissolution test has been performed covering concentration range for all three strengths
10.	• 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". • Justification shall be submitted for the concentration range adopted for performance of the Accuracy parameter with reference to the standard and sample concentrations applied in Assay test. • Concentration range applied for the performance of Linearity test in drug product analytical method validation studies does not cover the concentration applied for the content uniformity test of Empagliflozin. Justification shall be submitted in this regard.	Single injection runs for both analytes separately and in combination have been performed during method development study confirming respective retention times for both analyte. Accuracy parameter has been performed by taking 90.0 – 110.0% concentration range using single strength of fixed dose combination (which covers all three concentration range for Metformin-HCl). Moreover, the concentration range specified in Assay as well as Content Uniformity are same as per SOP and is included in the linearity concentration range.

Decision: Registration Board approved the applications of Empaglif-M 12.5/1000mg Tablet & Empaglif-M 12.5/850mg Tablet. Firm shall submit fee of pre-registration variation i.e., Rs. 9,000/- for each strength as per SRO1324 (I)/2024 dated 30-08-2024.

108.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scilife Pharma (Pvt.) Ltd., 16, K.O.C.H.S. Amir Khusro Road, Karachi-75350, Pakistan**
	Name, address of Manufacturing site.	M/s Scilife Pharma (Pvt.) Ltd., Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi
	GMP status of the Finished product manufacturer	Renewal of license granted on 01/06/2021 Tablet, Capsule, Ointment/Cream, Sachet, Dry Powder Inhalaer & Dry Powder suspension (General) sections approved. Last inspection conducted on 16-11-2021 and concludes that firm was considered to be operating at Good level of compliance
	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)
	Dy. No. and date of submission	Dy.No 4783 dated 14-02-2022
	Details of fee submitted	Rs.30,000/- dated 20-05-2022
	The proposed proprietary name / brand name	**Sciampa-M XR 12.5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin (as Immidiate Release Coating) ……. 12.5mg Metformin HCl (as Extended Release Core) …….1000mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-hyperglycemic agents (A10BD20)
	Reference to Finished product specifications	Manufacturer's
	Proposed Pack size	14's & 28's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	**Synjardy XR** 12.5mg/1gm extended release tablet by Boehringer Ingelheim (**U.S. FDA** Approved).
	For generic drugs (me-too status)	**XENGLU-MET XR** of M/s HILTON PHARMA (PVT.) LTD
	Name and address of API manufacturer.	**API manufacturer of Empagliflozin** Name: Fuxin Long Rui Pharmaceutical CO., Ltd. Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **API manufacturer of Metformin Hydrochloride** Name: Shouguang Fukang Pharmaceutical Co., Ltd. Address: North-East of Dongwaihuan Road, Dongcheng Industrial Area
	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 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	Firm has submitted stability study data of 3 batches of both API at accelerated as well as real time conditions.

		The real time stability data of Empagliflozin conducted at 30±2°C, 65%±5% RH. The stability study data is till 26 months. The real time stability data of Metformin hydrochloride conducted at 30±2°C, 75%±5% RH. The stability study data is 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.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted Compartitive dissolution profile against Xenglu Met XR 5+1000mg Tablet of Hilton Pharma.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.

STABILITY STUDY DATA

API Lot No.	A-35212009047 / H-E-20201125-D03-E06-02		
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, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	046B21	047B21	048B21
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	03-2021	03-2021	03-2021
No. of Batches	03		

109.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scilife Pharma (Pvt.) Ltd., 16, K.O.C.H.S. Amir Khusro Road, Karachi-75350, Pakistan**
	Name, address of Manufacturing site.	M/s Scilife Pharma (Pvt.) Ltd., Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi
	GMP status of the Finished product manufacturer	Renewal of license granted on 01/06/2021 Tablet, Capsule, Ointment/Cream, Sachet, Dry Powder Inhalaer & Dry Powder suspension (General) sections approved. Last inspection conducted on 16-11-2021 and concludes that firm was considered to be operating at Good level of compliance
	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)
	Dy. No. and date of submission	Dy.No 4175 dated 14-02-2022
	Details of fee submitted	Rs.30,000/- dated 20-05-2022
	The proposed proprietary name / brand name	**Sciampa-M XR 5/1000 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Empagliflozin (as Immidiate Release Coating) ……. 5mg Metformin HCl (as Extended Release Core) …….1000mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Anti-hyperglycemic agents (A10BD20)
	Reference to Finished product specifications	Manufacturer's
	Proposed Pack size	14's & 28's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	**Synjardy XR** 5mg/1gm extended release tablet by Boehringer Ingelheim (**U.S. FDA** Approved).
	For generic drugs (me-too status)	**XENGLU-MET XR** of M/s HILTON PHARMA (PVT.) LTD (Reg #105268)
	Name and address of API manufacturer.	**API manufacturer of Empagliflozin** Name: Fuxin Long Rui Pharmaceutical CO., Ltd. Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China **API manufacturer of Metformin Hydrochloride** Name: Shouguang Fukang Pharmaceutical Co., Ltd. Address: North-East of Dongwaihuan Road, Dongcheng Industrial Area
	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 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	Firm has submitted stability study data of 3 batches of

		both API at accelerated as well as real time conditions. The real time stability data of Empagliflozin conducted at 30±2°C, 65%±5% RH. The stability study data is till 26 months. The real time stability data of Metformin hydrochloride conducted at 30±2°C, 75%±5% RH. The stability study data is 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.
	Pharmaceutical equivalence and comparative dissolution profile	Firm has submitted Compartitive dissolution profile against Xenglu Met XR 5+1000mg Tablet of Hilton Pharma.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.

STABILITY STUDY DATA

API Lot No.	A-35212009047 / H-E-20201125-D03-E06-02		
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, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	049B21	050B21	051B21
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	03-2021	03-2021	03-2021
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 Glusimet XR 50/500mg Tablets & Glusimet XR 50/1000mg Tablets which was conducted on 16th July, 2020 and was presented in 296th meeting of Registration Board held on 8th - 10th September, 2020. 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.	**Empagliflozin** Copy of DML certificate No. Liao20150233 issued by FDA of Liaoning Province valid till 20/12/2022 & GMP Certificate No. LN210014 valid till 25-05-2024. **Metformin HCl:** Copy of GMP certificate No. SD20190888 issued by CFDA valid till 12/03/2024.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Firm has submitted copy of form 5, invoice (invoice# HN201110-J) cleared by DRAP Karachi office dated 09-02-2021 specifying import 10Kg Empagliflozin (Batch# H-E-20201125-D03-E06-02). **Metformin HCl:** Firm has submitted copy of invoice from Shouguang Fukang Pharmaceutical Co., Ltd. cleared by DRAP Karachi office dated 19-01-2021 specifying import 2000Kg Metformin HCl (Batch# A-35212009047
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: Above cases were deferred in 335th meeting of registration Board for the following observations to which firm has replied as detailed against each:

Section#	Observations	Firm's response
1.6.5	Submit valid DML/GMP certificate of M/s Fuxin Long Rui, issued by relevant authority of country of origin.	Submitted
	Empagliflozin	
3.2.S.1.3	➢ In contrary to the innovator drug product literature from the US FDA & EMA, the section declares the solubility of Empagliflozin in water as "practically insoluble". Justification shall be submitted in this regard.	The solubility under the property item in the drug standard is a rough measurement of solubility, a physical constant that can be used as a reference for refining or preparation and is not an indicator for product quality. If solubility is used as quality indicator specific solvent solubility testing method sand limit requirements should be separately specified under the inspection items.
3.2.S.4	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted.	Submitted
3.2.S.5	Submitted COA of working standard declares expire date as 18-04-2018, whereas drug substance analysis has been performed subsequent to this date.	Firm has submitted record of working standards used for analysis.
	Metformin HCl	

3.2.S.4	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer shall be submitted. • Standard declares expire date as 18-04-2018, whereas drug substance analysis has been performed subsequent to this date.	Submitted. Firm has submitted record of working standards used for analysis.
3.2.S.5	• Submitted COA of working used by M.s Scilife for performance of drug substance analysis.	Submitted
3.2.S.7.3	• Long term stability studies as per Zone IV conditions shall be submitted.	Submitted till 3rd month time point. Moreover firm has referred to the decision of 297th meeting of Registration Board
3.2.P.1	• Justification shall be submitted on basis of performance based evidence for adding overage of "Empagliflozin" in the applied batch formulation.	Firm has submitted that excess material has been added to compensate the loss during coating process.
3.2.P.8.3	• Justification shall be submitted for the ascending trend of Assay results in stability studies. • Justification shall be submitted for the in-process tests adopted for the confirmation of dissolution profile of Metformin HCl core and assay content of Empagliflozin. • Minimum handling capacities of the equipments used in the production of stability trial batches, shall be submitted. • Justification shall be submitted for the significant changes in Assay results of Empagliflozin reported in accelerated stability studies. • Reconciliation record for the imported quantity of Empagliflozin shall be submitted.	We acknowledge the ascending trend observed in assay results during stability studies. The observed variations in assay results may be attributed to the Empagliflozin API coating process. Firstly, the coating process of the APl is a fundamental step, and variation in coating weights can possibly lead to variations in assay results. However, it is important that, despite this factor, all results consistently fall within the predefined assay limits. Consequently, these observed variations arc well within acceptable tolerances. This underscores the fact that the product's quality remains intact and in compliance with regulatory requirements. Therefore, the reported results are accurate and valid. The variations are insignificant and do not compromise the product's quality or its adherence to regulatory standards. • Firm has referred to the dissolution testing results of Metformin HCl core tablets. The variation observed in Sciampa M XR 12.5/1000mg (Batch #046B21 and 047B21) and Sciampa M XR 5/1000mg Tablet (Batch #050B21 and 051B21) are attributed to the inherent variability in the

			coating process of Empagliflozin over Metformin core tablets, which can exhibit slight variability from tablet to tablet. As these R&D batches are manufacture in small-scale, where slight variations in coating arc expected. This specific coating technique can result in minor differences in assay results, while ensuring product integrity. Despite these observed variations, all results remain well within the acceptable range of 90% to 110%. Furthermore, no degradation were observed in any of the batches. It is our commitment to optimize and validate our commercial batches at a larger scale, effectively controlling these inherent variations In conclusion, I would like to emphasize that these observed changes fall within the expected variation limits and do not indicate a significant change in the product.

Decision: Registration Board approved the applications of Sciampa-M XR 12.5/1000 mg Tablet & Sciampa-M XR 5/1000 mg Tablet. Firm shall submit following before issuance of registration letter:

- **Fee of pre-registration variation i.e., Rs. 9,000/- for each strength as per SRO1324 (I)/2024 dated 30-08-2024.**
- **Long term stability studies of drug substance as per Zone IV conditions.**

110.	Name, address of Applicant / Importer	M/s The Schazoo Pharmaceutical Laboratories (Pvt.) Ltd. Kalalwala Stop, 20Km Lahore- Jaranwala Road, District Sheikhupura, Pakistan.
	Details of Drug Sale License of importer	License No: 05-354-0076-059245D Address: Kalalwala Stop, 20Km Lahore- Jaranwala Road, District Sheikhupura, Pakistan. Validity: 25-09-2022 Status: License to sell drugs as distributor Renewal: Firm has submitted a receipt of renewal but it does not contain any date
	Name and address of marketing authorization holder (abroad)	M/s BDR Pharmaceuticals International Pvt. Ltd R.S.No. 578, Near Effluent Channel Road, Village: Luna, Ta: Padra, Dist : Vadodara– 391 440, (India).
	Name, address of manufacturer(s)	M/s BDR Pharmaceuticals International Pvt. Ltd R.S.No. 578, Near Effluent Channel Road, Village: Luna, Ta: Padra, Dist : Vadodara– 391 440, (India).
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized CoPP certificate (No. 022105) valid till 07-11-2019 issued by Food & Drugs Control Administration, Gujarat, India. 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.
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization certificate from M/s BDR Pharmaceuticals International Pvt. Ltd

	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. 17603 dated 16-06-2022
	Details of fee submitted	PKR 75,000/- dated 13-04-2022
	The proposed proprietary name / brand name	Arbit Tablets USP 500mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Abiraterone acetate …… 500mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Other hormone antagonists and related agents
	Reference to Finished product specifications	USP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	ZYTIGA 500 mg Janssen-Cilag International NV USFDA 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	BDR Life Sciences Private Limited R.S.NO.578, Near Effluent, Channel Road, Village Luna – 391 440, Ta.Padra, Dist. VADODARA, India
	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 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 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	Pharmaceutical equivalence studies against the innovator product of Zytiga tablet 250mg while CDP studies have bene performed in three dissolution mediums of pH 1.2, 4.5 & 6.8 against the Zytiga 250mg tablet.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product as per USP monograph.
	Container closure system of the drug product	HDPE Container
	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 / 75% ± 5% RH for 36 months.

Remarks of Evaluator:

Section#	Observation
1.1	Fee for registration has been submitted from header of DML instead of DSL. Submit valid copy of DSL.
1.3	Submit original legalized valid COPP since the submitted COPP was expired at the time of submission of registration application. Submit evidence of approval for the required manufacturing facility "Tablet (steroid)" for the applied formulation.
3.2.P.2.2.1	Submit justification for performing Pharmaceutical equivalence studies against the Zytiga 250mg tablet while the applied strength is 500mg.

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: Firm has submitted following vide their letter no. ref; SPL/BDR/3147 vide R&I dated 21-06-2023.

Section#	**Observation**	**Firm's response**
1.1	Fee for registration has been submitted from header of DML instead of DSL. Submit valid copy of DSL.	Not submitted
1.3	Submit original legalized valid COPP since the submitted COPP was expired at the time of submission of registration application. Submit evidence of approval for the required manufacturing facility "Tablet (steroid)" for the applied formulation.	Original Legalized COPP no. MFG/WHO GMP/COPP/2023/1951221591 issued by food 7 Drugs Control Administration, Gujarat, with following particulars: • Product license holder: M/s BDR Pharmaceuticals International Pvt. Ltd R.S.No. 578, Near Effluent Channel Road, Village:

			Luna, Ta: Padra, Dist : Vadodara– 391 440, (India). • Free sale status in country of origin (India): Yes. • GMP status of the manufacturer endorsed: Yes. • Validity: 09-01-2026 Firm has also submitted copy of GMP certificate no. 1711454 (valid till 07-11-2019) issued by Food & Drugs Control Administration in name Of M/s BDR Pharmaceuticals International Pvt. Ltd R.S.No. 578, Near Effluent Channel Road, Village: Luna, Ta: Padra, Dist : Vadodara– 391 440, Gujarat State (India) declaring availability of Tablet & Capsule (Cytotoxic) section.
	3.2.P.2.2.1	Submit justification for performing Pharmaceutical equivalence studies against the Zytiga 250mg tablet while the applied strength is 500mg.	We BDR Pharmaceutical In. pvt. Ltd hereby justify that the Bioequivalence study with the title "A randomized open label balanced two period two sequence single dose two way crossover oral bioequivalence study of our Arbiraterone acetate 500mg tabklets of BDR Pharmaceutical international pvt. Ltd compare with Zytiga 250mg tablets of Janssen biotech inc., Horsham at a dose of 500mg (2 / 250mg) in a 36 healthy human adult male subjects under fasting conditions has started on Jan 2017 and completed on 02-02-2017 and complete don 02-02-2017. At the time of BE Study for Arbirtaerone tablet USP only Zytiga 250mg (N202379 001) HAS LISTED AS Rld IN ORANGE BOOK. Zytiga 500mg tablets has listed as RLD in Apr, 14, 2017. Therefore we selected the Zytiga 250mg as RLD against of the Arbirtaerone tablets 500mg.

Decision of 330th meeting: Deferred for following:

- Full fee of registration from the head of Drug Sale License.
- Pharmaceutical equivalence and CDP studies against the relevant strength i.e., 500mg of the Innovator drug product.
- Further deliberation regarding requirement of manufacturing facility for applied formulation.

Firm's response: Firm has submitted following:

- Fee of Rs. 300,000/- vide deposit slip no. 88723738083 from the head of DSL.
- CDP studies against the reference product of Zytiga 500mg tablet in three dissolution mediums of physiologic pH 1.2, 4.5 & 6.8.

Decision: Approved as per policy of inspection of manufacturer abroad. Registration letter will be issued upon submission of analytical record for the submitted drug product stability data including chromatograms/spectrums etc.		
111.	**Name, address of Applicant / Importer**	**M/s Al-Habib Pharmaceuticals Plot No. 81, Block B, SMCHS, Karachi, Pakistan**
	Details of Drug Sale License of importer	License No: 339 Address: **81-B, Block. B, SMCHS, Karachi, Pakistan** Address of Godown: Plotno. 396/7 & 393/8 Sectorr, 7-A KIA Karachi Validity: 18-05-2024 Status: Drug License by way of Whole Sale.
	Name and address of marketing authorization holder (abroad)	M/s Hainan Poly Pharm. Co., Ltd. Guilinyang Economic Development Area, Haikou, Hainan Province, China
	Name, address of manufacturer(s)	M/s Hainan Poly Pharm. Co., Ltd. Guilinyang Economic Development Area, Haikou, Hainan Province, China
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 35675 dated 08-12-2022
	Details of fee submitted	Rs.150,000/- dated 26-01-2022
	The proposed proprietary name / brand name	**Kunyrin 100mg/Vial Lyophillized Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Leucovorin Calcium…100mg
	Pharmacotherapeutic Group of (API)	Detoxifying agents for antineoplastic treatment (V03AF)
	Reference to Finished product specifications	USP
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted copy of CoPP (No. 20210112) valid till 07-11-2023 issued by Haina Medical Product Administration of 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. The name of importing countries on CoPP is mentioned Pakistan. Firm has also submitted copy of EUDRA GMP certificate no. NL/H 18/2008856A issued by competent Authority of Netherland on basis opf inspection conducted on 16—11-2018 for M/s Hainan Poly Pharm. Co., Ltd. Guilinyang Economic Development Area, Haikou, Hainan Province, China for the manufacturing operations including Lyophilisates sterile products.
	Details of letter of authorization / sole agency agreement	Firm has submitted notarized copy of "Supply Agreement" between M/s Hainan Poly Pharm. Co., Ltd. Guilinyang Economic Development Area, Haikou, Hainan Province, China & M/s Al-Habib Pharmaceuticals Plot No. 81, Block B, SMCHS, Karachi, Pakistan for the applied product

EVALUATION OF DATA	
Proposed Pack size	1's
Proposed unit price	--
The status in reference regulatory authorities	Approved by US FDA
For generic drugs (me-too status)	Leucofolate Injection 100mg of M/s CCL Pharmaceuticals
Indications	Indicated in the treatment of certain megaloblastic anemias resulting from folic acid deficiency
Module-II (Quality Overall Summary)	Firm has submitted QOS as per WHO QOS-PD template.
Name, address of drug substance manufacturer	M/s Cerbios Pharma S.A. Via Figino 6, Barbengo, 6917, Switzerland
Module-III Drug Substance:	Firm has submitted detailed drug substance data as per Module 3.2.S.
Module-III Drug Product:	Firm has submitted data of drug product as per Module 3.2.P.
Pharmaceutical Equivalence	Firm has submitted comparative analysis report against the reference product of Wesrt-Ward
Analytical method validation/verification of product	Firm has submitted analytical method verification studies for the applied product.
Container closure system of the drug product	Glass vial
Stability study data of drug product, shelf life and storage conditions	Firm has submitted long term stability data of 3 batches for 24 months at 30±2°C, 65±5%RH and 6 months at 40°C±75%RH for three batches.

Evaluation by PEC^{II}: The case was presented in 336th meeting of registration board wherein it was deferred for following observations, to which firm has replied as detailed against each:

Section no.	Observations	Firm's response
1.3	• Submit Original, Legalized and valid COPP for the applied product.	Firm has submitted original legalized COPP no. 20230158 issued by Hainan Provincial Medical Products Administration valid till 17-12-2025,, declaring the free sale status of the applied product in country of origin and GMP status of the manufacturer.
1.5.1	Submitted strength in submitted CPP and section1.5.2 is as "Each vial contains Leucovorin calcium 100mg" whereas the innovator drug product approved by US FDA contains Leucovorin calcium eq. 100mg base/vial. Justification shall be submitted for the variation in label claim and strength from the innovator drug product.	The applicant confirms that the strength of the proposed generic drug product is the same as that of the innovator drug product. For section 1.5.2, we acknowledge that the description of "Each vial contains Leucovorin calcium 100mg" is not accurately enough, which should be revised to "Each vial contains Leucovorin calcium (calculated on Leucovorin basis) l00mg"; For CPP, the strength information is the same as that of the innovator drug product, they are just difference in description, and no revision is necessary

Decision: Approved as per policy of inspection of manufacturer abroad with following label claim: "Each vial contains Leucovorin calcium (calculated on Leucovorin basis) l00mg".

Registration letter will be issued upon submission of following:

- **Analytical record for the submitted drug product stability data including chromatograms/spectrums etc.**
- **Fee for pre-registration variation as per SRO as per SRO1324 (I)/2024 dated 30-08-2024.**

112.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: **Dy.No 16611 dated 04-07-2023**
	Details of fee submitted	Rs.30,000/- dated 07-06-2023
	The proposed proprietary name / brand name	**Ondanz 8mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ondansetron as HCl Dihydrate…4mg
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / 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	MHRA Approved
	For generic drugs (me-too status)	Onset tablet by M/s Pharmedic (Pvt) Ltd.

Evaluation by PEC^{II}: The case was deferred in 340th meeting of Registration Board for following observations, to which firm has replied as detailed against each:

Section#	Observations	Firm's response
1.6.5	Copy of Valid GMP certificate/DML of the drug substance manufacturer shall be submitted.	Firm has submitted GMP certificate issued by Drugs Control Administration Government of Telangana dated valid till 18-12-2024.
3.2.S.4.3	Drug substance analytical method verification studies shall be submitted from the drug product manufacturer.	Submitted
3.2.P.2.2.1	• CDP studies have been submitted for 4mg strength instead of 8mg tablet.	Firm has submitted relevant CDP studies
3.2.P.3.5	• Submitted process validation protocol is for 8mg strength instead of 4mg tablet.	Firm has submitted revised protocol.
3.2.P.5.2	Test number of the dissolution test adopted for the drug product batch release, from the USP monograph, shall be specified.	Firm has referred to Test 1
3.2.P.8.3	Copy of commercial invoice attested by DRAP I&E office shall be submitted as evidence of import of drug substance.	Firm has submitted Form 6 (License to import) issued by RAP I&E office for 2 Kg of Ondansetron

Decision: Approved. Firm shall submit fee for pre-registration variation i.e. Rs. 9,000/- as per SRO as per SRO1324 (I)/2024 dated 30-08-2024.

113.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar**

	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: **Dy.No 16609 dated 04-07-2023**
	Details of fee submitted	Rs.30,000/- dated 07-06-2023
	The proposed proprietary name / brand name	**Ondanz 4mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ondansetron as HCl Dihydrate…4mg
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / 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	MHRA Approved
	For generic drugs (me-too status)	Onset tablet by M/s Pharmedic (Pvt) Ltd.

Evaluation by PEC^{II}: The case was deferred in 340th meeting of Registration Board for following observations, to which firm has replied as detailed against each:

Section#	Observations	Firm's response
1.6.5	Copy of Valid GMP certificate/DML of the drug substance manufacturer shall be submitted.	Submitted
3.2.S.4.3	Drug substance analytical method verification studies shall be submitted from the drug product manufacturer.	Submitted
3.2.P.2.2.1	• Details of the manufacturer of the competitor product used for performance of Pharmaceutical equivalence and CDP studies shall be submitted. • CDP studies have been submitted for 8mg strength instead of 4mg tablet.	Submitted. Firm has submitted CDP studies for 4 mg strength
3.2.P.3.5	• Submitted process validation protocol is for 8mg strength instead of 4mg tablet.	Firm has submitted revised protocol
3.2.P.5.2	Test number of the dissolution test adopted for the drug product batch release, from the USP monograph, shall be specified.	Firm has referred to Test 1
3.2.P.8.3	• Copy of commercial invoice attested by DRAP I&E office shall be submitted as evidence of import of drug substance.	Firm has submitted Form 6 (License to import) issued by RAP I&E office for 2 Kg of Ondansetron

Decision: Approved. Firm shall submit fee for pre-registration variation i.e. Rs. 9,000/- as per SRO as per SRO1324 (I)/2024 dated 30-08-2024.

114.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: **Dy.No 16612 dated 04-07-2023**
	Details of fee submitted	Rs.30,000/- dated 07-06-2023
	The proposed proprietary name / brand name	**Ondanz 4mg/2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml Ampoule Contains: Ondansetron as HCl dihydrate…4mg
	Pharmacotherapeutic Group of (API)	Serotonin 5HT3 antagonist / 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	MHRA Approved
	For generic drugs (me-too status)	Onset 4mg/2ml Injection by M/s Pharmedic (Pvt) Ltd.

Evaluation by PEC^{II}: The case was deferred in 340th meeting of Registration Board for following observations, to which firm has replied as detailed against each:

Section#	Observations	
1.5.2	Revised label claim shall be submitted declaring complete salt form of the drug substance along with applicable fee.	Firm has submitted following revised label claim: Each Ampoule (2mL) Contains: Ondansetron as Hydrochloride Dihydrate……4 mg
3.2.S.4.3	Drug substance analytical method verification studies shall be submitted from the drug product manufacturer.	Submitted
3.2.P.3.4	Submitted details are for the Phytonadione while the applied formulation is of Ondansetron Injection.	Firm has submitted revised documents
3.2.P.3.5	• Submitted process validation protocol does not include details of terminal sterilisation. Justification shall be submitted in this regard. • Submitted process validation protocol does not include any details of sampling plan and critical process parameters.	Firm has submitted revised protocol
3.2.P.8.3	• Copy of commercial invoice attested by DRAP I&E office shall be submitted as evidence of import of drug substance.	Firm has submitted Form 6 (License to import) issued by RAP I&E office for 2 Kg of Ondansetron

Decision: Approved. Firm shall submit fee for revision of label claim as per SRO as per SRO1324 (I)/2024 dated 30-08-2024.

115.	**Name and address of manufacturer / Applicant**	**M/s Wimits Pharmaceuticals (Pvt.) Ltd.** **Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore**
	Brand Name +Dosage Form + Strength	**Wascorel-S Tablet**

	Diary No. Date of R& I & fee	Dy. No. 2710; Dated 30-12-2014; Rs. 20,000/-
	Composition	Each film coated tablet contains: Clopidogrel Bisulfate…… 75 mg Aspirin …….. 150 mg
	Pharmacological Group	Thienopyridine class inhibitor of P2Y12 ADP platelet receptors/NSAID
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Not verifiable
	Me-too status	CLOPID ASP 75/150mg Tablets of M/s Ferozsons Labs
	GMP status	The firm is GMP compliant as per inspection conducted on 10-10-2016.
	Remarks of the Evaluator.	Evidence of approval for applied formulation by any reference regulatory authority as decided in 249th meeting of Registration Board is required
	Decision of 273rd meeting: Deferred for the evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 249th meeting.	
	Firm's response: Firm has requested to consider the product against the decision of 179th meeting of Authority while referring to the following me-too product: "Pidogrel 75/150 mg Tablet of "Highnoon Laboratories Limited " (Reg.# 038903)	
	Decision: Deferred for review of formulation with reference to the regulator status of applied formulation in reference regulatory authorities adopted by Registration Board in its 275th meeting.	
116.	**Name and address of manufacturer / Applicant**	**M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore**
	Brand Name +Dosage Form + Strength	Dexi Suspension
	Diary No. Date of R& I & fee	Dy. No. 2695;Dated 30.12.2014; Rs. 20,000/-
	Composition	Each 5 ml contains: Dexibuprofen…….. 100 mg
	Pharmacological Group	NSAID/ A Propionic acid Derivative
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	120 ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not verifable
	Me-too status	Dexipro 100mg Suspension of M/s WelMark Pharmaceutical (Reg.#076869)
	GMP status	The firm is GMP compliant as per inspection conducted on 10-10-2016.
	Remarks of the Evaluator.	Evidence of approval of applied formulation by reference regulatory authorities is required.
	Decision of 273rd meeting Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 249th meeting.	
	Firm's response: Firm has requested to consider the product against the decision of 179th meeting of Authority while referring to the following me-too product: "Dexy Suspension 100mg/5 of "TABROS PHARMA (Pvt) Ltd." (Reg.# 067494)	
	Decision: Deferred for review of formulation with reference to the regulator status of applied formulation in reference regulatory authorities adopted by Registration Board in its 275th meeting.	

117.	**Name and address of manufacturer / Applicant**	**M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore**
	Brand Name +Dosage Form + Strength	Sulo 0.2mg Capsules
	Diary No. Date of R& I & fee	Dy. No.2606 ; 20-06-2016; Rs.20,000/- (20-06-2016)
	Composition	Each capsule Contains: Tamsulosin hydrochloride…...0.2mg
	Pharmacological Group	Antagonist of alpha1A
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's;As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not verifiable
	Me-too status	Harnal 0.2mg Capsule of M/s Hilton Pharma, Karachi (Reg.#045084)
	GMP status	The firm is GMP compliant as per inspection conducted on 10-10-2016.
	Remarks of the Evaluator.	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 249th meeting, shall be submitted. • Source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets shall be submitted.
	Decision of 274th meeting: Deferred for following: i. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 249th meeting, shall be submitted. **ii.** Source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets shall be submitted.	
	Firm's response: Firm has requested to consider the product against the decision of 179th meeting of Authority while referring to the following me-too product: "Harnal 0.2mg Capsule of M/s Hilton Pharma, Karachi (Reg.#045084)"	
	Decision: Deferred for review of formulation with reference to the regulator status of applied formulation in reference regulatory authorities adopted by Registration Board in its 275th meeting.	
118.	**Name and address of manufacturer / Applicant**	**M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore**
	Brand Name +Dosage Form + Strength	Coline- S Tablet 500mg
	Diary No. Date of R& I & fee	Dy.No.7802; 01-03-2018; Rs.20,000 (01-03-2018)
	Composition	Each film- coated tablet contains: Citicoline as Sodium ……..... 500 mg
	Pharmacological Group	Psycho- stimulant
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specification
	Pack size & Demanded Price	10's, 20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Citolin 500mg tablet of M/s Global Pharma (Reg.#048336)
	GMP status	Last GMP inspection was conducted on 03-11-2017 and the report concludes satisfactory GMP compliance.

	Remarks of the Evaluator.	□□No official monograph is available for the applied formulation in USP or BP. □□International availability for the applied formulation could **not** be confirmed.
	Decision of 290th meeting: Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
	Firm's response: Firm has requested to consider the product against the decision of 179th meeting of Authority while referring to the following me-too product: "Citolin 500mg tablet of M/s Global Pharma (Reg.#048336)	
	Decision: Deferred for review of formulation with reference to the regulator status of applied formulation in reference regulatory authorities adopted by Registration Board in its 275th meeting.	
119.	**Name and address of manufacturer / Applicant**	**M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore**
	Brand Name +Dosage Form + Strength	Ferowim 150/0.5 mg Tablet
	Diary No. Date of R& I & fee	Dy.No 34701 dated 18-10-2018 Rs.20,000/-
	Composition	"Each Tablet Contains: Ferrous Fumarate…150mg Folic Acid…0.5mg
	Pharmacological Group	Haematinic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specification
	Pack size & Demanded Price	10"s, 30"s: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA(not confirmed)
	Me-too status	Lowrate Tablets of Lowitt Pharmaceutical
	GMP status	GMP Inspection conducted on 03-11-17 concluded that firm is operating at good level of GMP Compliance
	Remarks of the Evaluator.	Please explain whether applied formulation is coated or uncoated tablet as submitted master formulation does not contains ingredients of coating but Outline of method of manufacturing contains step of coating.
	Decision of 295th meeting: Deferred for following: □ Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. □ Clarification of applied formulation regarding coated or uncoated tablet is required as submitted master formulation does not contain ingredients of coating but Outline of method of manufacturing contains step of coating.	
	Firm's response: Firm has requested to consider the product against the decision of 179th meeting of Authority while referring to the following me-too product: "Fefan Tablet of "Amson Vaccines & Pharma (Pvt.) Ltd" (Reg.# 017372)	
	Decision: Deferred for further deliberation with reference to the decision of 179th meeting of Authority, against the previously registered drug product.	
120.	**Name and address of manufacturer / Applicant**	**M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore**
	Brand Name +Dosage Form + Strength	Hydronin 4% W/W Cream
	Diary No. Date of R& I & fee	Dy. No. 44276 dated 28-12-2018 Rs. 20,000 Dated 27-12-2018
	Composition	Each gm of Cream contains: Hydroquinone ……..40mg (4% w/w)
	Pharmacological Group	Ultraviolet Blocking agent
	Type of Form	Form-5
	Finished Product Specification	USP

	Pack size & Demanded Price	10g, 15g, 30g, 45g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed.
	Me-too status	Hyderquin Cream 4% of Atco Laboratories Pvt. Ltd
	GMP status	The firm has submitted renewal letter for DML no. F.1-10/2012-Lic dated07-06-202. The firm his granted Cream / Ointment / Lotion / Gel (General) NEW section.
	Remarks of the Evaluator.	The firm was asked for evidence of approval of required manufacturing facility vide shortcoming letter dated 06-03-2020. The firm has submitted renewal letter for DML no. F.1-10/2012-Lic dated07-06-202. The firm his granted Cream / Ointment / Lotion / Gel (General) NEW section.
	Decision of 324th meeting: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
	Firm's response: Firm has requested to consider the product against the decision of 179th meeting of Authority while referring to the following me-too product: "Hyderquin Cream 4% of Atco Laboratories Pvt. Ltd " (Reg.# 039193)	
	Decision: Deferred for review of formulation with reference to the regulator status of applied formulation in reference regulatory authorities adopted by Registration Board in its 275th meeting.	
121.	**Name and address of manufacturer / Applicant**	**M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore**
	Brand Name +Dosage Form + Strength	Covlor-P 200mg/5ml Injection
	Diary No. Date of R& I & fee	Dy.No. 5540 dated 06/04/2020 Rs. 20,000/- 06-04-2020
	Composition	Each 5ml Ampoule Contains: Chloroquine Phosphate…200mg
	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.	Not present in RRA
	Me-too status	
	GMP status	
	Remarks of the Evaluator.	
	Decision of 295th meeting: Registration Board deferred the case for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
	Firm's response: Firm has requested to consider the product against the decision of 179th meeting of Authority while referring to the following me-too product: "Chloroquine Injection 40mg/ml of "Lahore Chemical and Pharmaceutical Works Pvt. Ltd" (Reg.# 005798)	
	Decision: Deferred for review of formulation with reference to the regulator status of applied formulation in reference regulatory authorities adopted by Registration Board in its 275th meeting.	

122.	**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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 6026 dated 03-03-2023
	Details of fee submitted	Rs.30,000/- dated 16-02-2023
	The proposed proprietary name / brand name	**Sacupro 24/26 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Sacubitril…49mg Valsartan…51mg (As Sacubitril Valsartan sodium salt complex)
	Pharmacotherapeutic Group of (API)	Angiotensin receptor Neprilysin Inhibitor
	The status in reference regulatory authorities	Approved by U SFDA
	For generic drugs (me-too status)	Savesto tablet of M/s Getz Pharma
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	As per Innovator
123.	**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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 6027 dated 03-03-2023
	Details of fee submitted	Rs.30,000/- dated 16-02-2023
	The proposed proprietary name / brand name	**Sacupro 49/51 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Sacubitril…49mg Valsartan…51mg (As Sacubitril Valsartan sodium salt complex)
	Pharmacotherapeutic Group of (API)	Angiotensin receptor Neprilysin Inhibitor
	The status in reference regulatory authorities	Approved by U SFDA
	For generic drugs (me-too status)	Savesto tablet of M/s Getz Pharma
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	As per Innovator

Evaluation by PEC[II]: Above two cases were deferred in 339th meeting of Registration Board wherein these were deferred for following observations to which firm has replied as detailed against each:

Sr.#	Section#	Observation	Firm's response
1.	**3.2.S.4**	➢ Drug substance manufacturer has not included test of Sodium content in the drug substance	Drug substance specification and testing method has included test of Sodium content in the drug substance.

		specifications. Justification shall be submitted din this regard. ➢ Justification shall be submitted for not including the following tests in drug substance specifications as recommended by innovator product literature: • Assay of Co-crystal. • Calcium and Chloride content. ➢ Justification shall be submitted for variation in analytical method for Assay test from that proposed by the drug substance manufacturer. ➢ Analytical method for the Assay test of Co-crystal complex shall be submitted. ➢ Analytical method verification studies shall be submitted from M.s Pinnacle Biotech.	Sacubitril valsartan sodium salt complex is a non-compendial material, it's a manufacturer spec's grade material. 1. Assay of sacubitril valsartan sodium salt complex is tested as per manufacturer provided testing method. 2. No calcium & Chloride present in sacubitril valsartan sodium salt complex. Only sodium content exists. Sacubitril valsartan sodium salt complex is a non-compendial material, it's a manufacturer spec's grade material. We have tested this material as per manufacturer provided method of analysis.
2.	**3.2.S.5**	➢ Justification shall be submitted for applying Co-crystal complex as reference standard instead of the individual drug components.	Drug substance of our product is sacubitril valsartan sodium salt complex (combined form), that's why we are using combine reference standard of sacubitril valsartan sodium salt complex for testing.
3.	**3.2.P.2.2.1**	Justification shall be submitted for not performing Pharmaceutical equivalence and CDP studies against the innovator drug product.	Entresto 24mg/26mg & 49mg/51mg tablet is an innovator of sacubitril valsartan tablet. At the time of study innovator sample in local market is not available so we have performed Pharmaceutical Equivalence and CDP with market leader that is Sacvin 24mg/26mg & 49mg/51mg tablet manufactured by PharmEvo.
4.	**3.2.P.5.2**	Justification shall be submitted for variation in dissolution parameters i.e., apparatus, rpm and time limit from that recommended by innovator drug product literature.	We have adopted dissolution parameters of Sacupro tablet from "**US FDA Dissolution Method Database**". In **US FDA Dissolution Method Database** sacubitril valsartan tablet dissolution parameters updated on 24-10-2019. For Reference: Dissolution Methods (fda.gov) Furthermore, innovator drug product literature approval date in **US FDA Approved Drug** is 07-07-2015 Application Number. 207620
5.	**1.6.5**	• Valid DML/GMP certificate of the drug substance manufacturer of drug substance shall be submitted.	Submitted
6.	**3.2.P.8.3**	• Stability studies data of 6th month time point shall be submitted. • Justification shall be submitted for the potency of working standard applied for calculation of Assay	• Stability studies data of 6th month period is attached. • Potency on as is basis of working standard is used for calculation of Assay results

		results of drug substance during stability studies, considering the values of "Water content" and "Sodium content" reported in the COA of working standard. • Documents confirming procurement of drug substance shall be submitted.	of drug product during stability studies. • Working Standard Certificate and Procurement document is submitted
7.	**3.2.R.1**	• Complete batch manufacturing record of drug product stability batches shall be submitted.	Submitted

Decision: Registration Board approved the applications of Sacupro 24/26 mg Tablet and Sacupro 49/51 mg Tablet.

124.	**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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 14206 dated 07-06-2023
	Details of fee submitted	Rs.30,000/- dated 18-05-2023
	The proposed proprietary name / brand name	**Vonopro 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vonoprazan Fumarate Eq. to Vonoprazan…20mg
	Pharmacotherapeutic Group of (API)	**Proton pump inhibitor**
	The status in reference regulatory authorities	PMDA Japan Approved.
	For generic drugs (me-too status)	Vocinti tablet of M/s Searle
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications
125.	**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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 14206 dated 07-06-2023
	Details of fee submitted	Rs.30,000/- dated 18-05-2023
	The proposed proprietary name / brand name	**Vonopro 10mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vonoprazan Fumarate Eq. to Vonoprazan…10mg
	Pharmacotherapeutic Group of (API)	**Proton pump inhibitor**
	The status in reference regulatory authorities	PMDA Japan Approved.
	For generic drugs (me-too status)	Vocinti tablet of M/s Searle
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator specifications

Evaluation by PEC[II]: Above two cases were deferred in 339th meeting of Registration Board wherein these were deferred for following observations to which firm has replied as detailed against each:

Sr.#	Section#	Observation	Firm's response
1.	**1.6.5**	Valid DML/GMP certificate of the drug substance manufacturer issued by relevant regulatory authority of country of origin shall be submitted.	Submitted
2.	**3.2.S.1**	Submitted CAS number is not of Vonoprazan fumarate	It's a typographic error. Correct CAS No. is 881681-00-1. 7500 Fee is submitted for both the strength under Challan No.02739524 for Vonopro 10mg and Challan No 895806157509 for Vonopro 20mg.
3.	**3.2.S.4**	Justification shall be submitted for not including test of Fumaric acid content in drug substance specifications.	Vonoprazan fumarate is a non-compendial material, it's a manufacturer spec's grade material. Manufacturer neither provide us fumaric acid content test specification in Certificate of Analysis and Method of Analysis as well. Hence Fumaric acid test is not a mandatory test. Furthermore, For Reference, QUETIAPINE FUMARATE USP drug substance is a USP monograph which does not include fumaric acid testing
4	**3.2.P.5**	• Reference shall be submitted for the adopted dissolution parameters. • 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".	Firm has referred to US FDA Dissolution database. Firm has submitted performance of peak purity.
5.	**3.2.P.8.3**	Following shall be submitted: • Document confirming procurement of drug substance with approval of DRAP I&E Office shall be submitted • Complete raw data sheet for dissolution test, declaring details of standard and sample preparation.	Firm has submitted License to import drug substance issued by DRAP I&E office Karachi. Submitted

Decision: Registration Board approved the applications of Vonopro 20mg Tablet & Vonopro 10mg Tablet.

Firm shall submit fee for pre-registration variation i.e. Rs. 9,000/- for each strength as per SRO as per SRO1324 (I)/2024 dated 30-08-2024.		
126.	**Name, address of Applicant / Importer**	**M/s Skymed Healthcare Pvt. Ltd.** **1ST Floor House No 2, Near Chamba House, G.O.R. I, Lahore, Punjab**
	Details of Drug Sale License of importer	License No: 05-352-0063-038947D Address: 1ST Floor House No 2, Near Chamba House, G.O.R. I, Lahore, Punjab Validity: 14-01-2023 Status: Drug License by way of Whole sale
	Name and address of marketing authorization holder (abroad)	M/s Centurian Ilac San. Ve Ticaret A. S Gayrettepe MAH. Hossohbet Sok No: 6, Balmumcu Besiktas, Istanbul
	Name, address of manufacturer(s)	M/s Centurian Ilac San. Ve Ticaret A. S Malikoy, Baskent Organize Sanayi Bolgesi MAH. 19 CAD. No: 70/A Sincan /Ankara. **Solvent manufacturer:** Idol Ilac Dolum San, Ve Tic. A.S. Topkapi/Istanbul
	Name of exporting country	Turkey
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 18314 dated 20-07-2023
	Details of fee submitted	Rs.75,000/- dated 14-04-2023 & Rs.75,000/- dated 16-06-2023
	The proposed proprietary name / brand name	**Colitim 150mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium 315.25mg Eq. to Colistimethate Base……150mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	European Pharmacopoeia
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	CBA Injection 150mg of M/s Biocare
	Proposed Pack size	1's:As per SRO
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP (No. 2022/1570) issued by Turkish Medicine and Medical Devices Agency dated 31-05-2022. The certificate does confirm the free sale status of the product in country of Origin. **GMP:** Firm has submitted legalized copy of GMP certificate No. TR/GMP/2021/37 issued by Turkish Medicine and Medical Devices Agency, valid upto 07-2022.
	Details of letter of authorization / sole agency agreement	Firm has submitted legalized "Letter of Authorization" from M/s Deva holding A.S. Halkali Merkez MAH. Basin Ekspres CAD No. 134303, Kucukcekmece-Istanbul/Turkiye in name of M/s Deva holding A.S. Cerkezkoy Organize Sanayi Bolgesi, Karaagac MaH, Faith Bulvari No. 26 Kapakli-Tekirdag, Turkiey

Evaluation by PEC[II]: Above case were deferred in 340th meeting of Registration Board wherein these were deferred for following observations to which firm has replied as detailed against each:

Sr.#	Observation	Firm's response
1.	Valid copy of Drug Sale License of the applicant shall be submitted.	Submitted
2.	Section 1.5.6 refers to European Pharmacopoeia for the drug product specifications while section 3.2.P.5.1 declares drug product specifications as per USP. Clarification shall be submitted in this regard.	Firm has submitted declaration from M/s Centurian Ilac San. Ve Ticaret A. S Malikoy stating that there is a typing error in the 1.5.6 while the limit for our finished product specifications comply with USP monograph.

Decision: Approved as per policy of inspection of manufacturer abroad. Firm shall submit fee for pre-registration variation as per SRO as per SRO1324 (I)/2024 dated 30-08-2024. Registration letter will be issued upon submission of analytical record for the submitted drug product stability data including chromatograms/spectrums etc.

127.	**Name, address of Applicant / Importer**	**M/s Skymed Healthcare Pvt. Ltd.** **1ST Floor House No 2, Near Chamba House, G.O.R. I, Lahore, Punjab**
	Details of Drug Sale License of importer	License No: 05-352-0063-038947D Address: 1ST Floor House No 2, Near Chamba House, G.O.R. I, Lahore, Punjab Validity: 14-01-2023 Status: Drug License by way of Whole sale
	Name and address of marketing authorization holder (abroad)	M/s Centurian Ilac San. Ve Ticaret A. S Gayrettepe MAH. Hossohbet Sok No: 6, Balmumcu Besiktas, Istanbul
	Name, address of manufacturer(s)	M/s Centurian Ilac San. Ve Ticaret A. S Malikoy, Baskent Organize Sanayi Bolgesi MAH. 19 CAD. No: 70/A Sincan /Ankara. **Solvent manufacturer:** Idol Ilac Dolum San, Ve Tic. A.S. Topkapi/Istanbul
	Name of exporting country	Turkey
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 18315 dated 20-07-2023
	Details of fee submitted	Rs.75,000/- dated 14-04-2023 & Rs.75,000/- dated 16-06-2023
	The proposed proprietary name / brand name	**Planicid 200mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Unit Contains: Teicoplanin……200mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	European Pharmacopoeia
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Ticozid Injection 200mg of M/s Bosch
	Proposed Pack size	1's:As per SRO
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP (No. 2022/1551) issued by Turkish Medicine and Medical

		Devices Agency dated 27-05-2022. The certificate does confirm the free sale status of the product in country of Origin. **GMP:** Firm has submitted legalized copy of GMP certificate No. TR/GMP/2021/37 issued by Turkish Medicine and Medical Devices Agency, valid upto 07-2022.
	Details of letter of authorization / sole agency agreement	Firm has submitted legalized "Letter of Authorization" from M/s Deva holding A.S. Halkali Merkez MAH. Basin Ekspres CAD No. 134303, Kucukcekmece-Istanbul/Turkiye in name of M/s Deva holding A.S. Cerkezkoy Organize Sanayi Bolgesi, Karaagac MaH, Faith Bulvari No. 26 Kapakli-Tekirdag, Turkiey

Evaluation by PEC[II]: Above case were deferred in 340th meeting of Registration Board wherein these were deferred for following observations to which firm has replied as detailed against each:

Sr.#	Observation	Firm's response
1.	Valid copy of Drug Sale License of the applicant shall be submitted.	Submitted
2.	Section 1.5.6 refers to European Pharmacopoeia for the drug product specifications. Evidence of European Pharmacopoeia monograph for the applied formulation shall be submitted.	Firm has referred to the drug substance monograph of European pharmacopoeia along with EMA assessment report
3.	Pharmaceutical equivalence against the relevant strength of innovator/reference product shall be submitted.	Submitted against Tagrocid Injection 200mg

Decision: Approved with innovator's specifications as per policy of inspection of manufacturer abroad. Firm shall submit fee for pre-registration variation as per SRO as per SRO1324 (I)/2024 dated 30-08-2024.

Registration letter will be issued upon submission of analytical record for the submitted drug product stability data including chromatograms/spectrums etc.

128.	**Name, address of Applicant / Importer**	**M/s Skymed Healthcare Pvt. Ltd.** **1ST Floor House No 2, Near Chamba House, G.O.R. I, Lahore, Punjab**
	Details of Drug Sale License of importer	License No: 05-352-0063-038947D Address: 1ST Floor House No 2, Near Chamba House, G.O.R. I, Lahore, Punjab Validity: 14-01-2023 Status: Drug License by way of Whole sale
	Name and address of marketing authorization holder (abroad)	M/s Centurian Ilac San. Ve Ticaret A. S Gayrettepe MAH. Hossohbet Sok No: 6, Balmumcu Besiktas, Istanbul
	Name, address of manufacturer(s)	M/s Centurian Ilac San. Ve Ticaret A. S Malikoy, Baskent Organize Sanayi Bolgesi MAH. 19 CAD. No: 70/A Sincan /Ankara. **Solvent manufacturer:** Idol Ilac Dolum San, Ve Tic. A.S. Topkapi/Istanbul
	Name of exporting country	Turkey
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 18316 dated 20-07-2023

	Details of fee submitted	Rs.75,000/- dated 14-04-2023 & Rs.75,000/- dated 16-06-2023
	The proposed proprietary name / brand name	**Planicid 400mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Unit Contains: Teicoplanin……400mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	European Pharmacopoeia
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Ticozid Injection 200mg of M/s Bosch
	Proposed Pack size	1's:As per SRO
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP (No. 2022/1552) issued by Turkish Medicine and Medical Devices Agency dated 27-05-2022. The certificate does confirm the free sale status of the product in country of Origin. **GMP:** Firm has submitted legalized copy of GMP certificate No. TR/GMP/2021/37 issued by Turkish Medicine and Medical Devices Agency, valid upto 07-2022.
	Details of letter of authorization / sole agency agreement	Firm has submitted legalized "Letter of Authorization" from M/s Deva holding A.S. Halkali Merkez MAH. Basin Ekspres CAD No. 134303, Kucukcekmece-Istanbul/Turkiye in name of M/s Deva holding A.S. Cerkezkoy Organize Sanayi Bolgesi, Karaagac MaH, Faith Bulvari No. 26 Kapakli-Tekirdag, Turkiey

Evaluation by PEC^{II}: Above case were deferred in 340th meeting of Registration Board wherein these were deferred for following observations to which firm has replied as detailed against each:

Sr.#	Observation	Firm's response
1.	Valid copy of Drug Sale License of the applicant shall be submitted.	Submitted
2.	Section 1.5.6 refers to European Pharmacopoeia for the drug product specifications. Evidence of European Pharmacopoeia monograph for the applied formulation shall be submitted.	Firm has referred to the drug substance monograph of European pharmacopoeia along with EMA assessment report
3.	Pharmaceutical equivalence against the relevant strength of innovator/reference product shall be submitted.	Submitted against Tagrocid Injection 400mg

Decision: Approved with innovator's specifications as per policy of inspection of manufacturer abroad. Firm shall submit fee for pre-registration variation as per SRO as per SRO1324 (I)/2024 dated 30-08-2024.
Registration letter will be issued upon submission of analytical record for the submitted drug product stability data including chromatograms/spectrums etc.

129.	**Name, address of Applicant / Importer**	**M/s Skymed Healthcare Pvt. Ltd.** **1ST Floor House No 2, Near Chamba House, G.O.R. I, Lahore, Punjab**
	Details of Drug Sale License of importer	License No: 05-352-0063-038947D Address: 1ST Floor House No 2, Near Chamba House, G.O.R. I, Lahore, Punjab Validity: 14-01-2023 Status: Drug License by way of Whole sale

	Name and address of marketing authorization holder (abroad)	M/s Centurian Ilac San. Ve Ticaret A. S Gayrettepe Mah. Hossohbet Sok No: 6, Balmumcu Besiktas, Istanbul
	Name, address of manufacturer(s)	M/s Centurian Ilac San. Ve Ticaret A. S Malikoy, Baskent Organize Sanayi Bolgesi MAH. 19 CAD. No: 70/A Sincan /Ankara.
	Name of exporting country	Turkey
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 18313 dated 20-07-2023
	Details of fee submitted	Rs.75,000/- dated 14-04-2023 & Rs.75,000/- dated 16-06-2023
	The proposed proprietary name / brand name	**Omex 40mg Lyophillized Powder for IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Omeprazole Sodium Eq. to Omeprazole…40mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	European Pharmacopoeia
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Risek Injection of M/s Getz
	Proposed Pack size	As per SRO
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original legalized CoPP (No. 2022/1548) issued by Turkish Medicine and Medical Devices Agency dated 22-05-2022. The certificate does not confirm the free sale status of the product in country of Origin. **GMP:** Firm has submitted legalized copy of GMP certificate No. TR/GMP/2021/37 issued by Turkish Medicine and Medical Devices Agency, valid upto 07-2022. **Free Sale Certificate:** Firm has submitted "Certificate of Free Sale" no. 10587 valid upto 26-05-2024 issued by "Turkish Medicines And Medical Devices Agency" declaring that "Omex 40Mg Lyophilized Powder For IV Injection manufactured by M/s Centurian Ilac San. Ve Ticaret A. S Malikoy, Baskent Organize Sanayi Bolgesi MAH. 19 CAD. No: 70/A Sincan /Ankara has been authorised to be placed on the market for use in Turkey and I subject to our supervision as stipulated in Turkish Laws.
	Details of letter of authorization / sole agency agreement	Firm has submitted legalized "Letter of Authorization" from M/s Deva holding A.S. Halkali Merkez MAH. Basin Ekspres CAD No. 134303, Kucukcekmece-Istanbul/Turkiye in name of M/s Deva holding A.S. Cerkezkoy Organize Sanayi Bolgesi, Karaagac MaH, Faith Bulvari No. 26 Kapakli-Tekirdag, Turkiey

Evaluation by PEC^{II}: Above case were deferred in 340th meeting of Registration Board wherein these were deferred for following observations to which firm has replied as detailed against each:

Sr.#	Observation	Firm's response

1.	Valid copy of Drug Sale License of the applicant shall be submitted.	Submitted
2.	Submitted CoPP and free Sale certificate does not declare the status of availability of applied product in the market of country of origin. Clarification shall be submitted in this regard.	Firm has submitted original Legalized "Free Sale certificate" issued by Turkish medicines and Medical Devices Agency for the applied product.
3.	Section 1.5.6 refers to European Pharmacopoeia for the drug product specifications. Evidence of European Pharmacopoeia monograph for the applied formulation shall be submitted.	Firm has referred to the drug substance monographs of Omeprazole and Omeprazole magnesium
4.	Limits of pH test declared in section 3.2.P.5.1 are different form that recommend by BP monograph of applied formulation.	During the formulation development studies of the Omex 40 mg Lyophilized Powders for IV Injection it was shown that the product was stable at the mentioned pH range. The pH limit mentioned in the BP injection monograph is 9.0-11.0, the pH limit set in our specification is 10.0-12.0. It can be seen from the provided stability results of the drug product that the pH results meet the BP injection monograph requirement with. all the PH results obtained within 9.0-11.0 range.
5.	Accelerated stability studies shall be submitted for three commercial batches of the applied drug product in section 3.2.P.8.3	Submitted.

Decision: Approved with BP specifications as per policy of inspection of manufacturer abroad. Firm shall submit fee for pre-registration variation as per SRO as per SRO1324 (I)/2024 dated 30-08-2024. Registration letter will be issued upon submission of analytical record for the submitted drug product stability data including chromatograms/spectrums etc.

130.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Maxitech Pharma (Pvt) Ltd.** **Company Address: E-178, S.I.T.E., Super Highway Phase-II, Karachi**
	Name, address of Manufacturing site.	o M/s Maxitech Pharma (Pvt) Ltd. o Company Address: E-178, S.I.T.E., Super Highway Phase-II, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 37074: 20-12-2022
	Details of fee submitted	Slip No:646881642 PKR 30,000/-
	The proposed proprietary name / brand name	Oztela Tablet 30mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each film coated tablet contains:** **Apremilast…30mg**
	Pharmacotherapeutic Group of (API)	Selective immunosuppressants L04AA32
	Reference to Finished product specifications	Innovators Specification
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	(not provided)

	Proposed Pack size	(not provided)

Evaluation by PEC:

The case was deferred in 336th meeting for following observations to which firm has replied as detailed against each:

S. No	Sections	Observations/Deficiencies/ Short-comings	
1.	1.3.5	Submit valid GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.	GMP certificate issue don basis of inspection conducted on 30-04-2024 has been submitted
2.	1.5.5	Indicate Pharmacological class of the API (drug substance) with proper reference and WHO ATC code for each distinct therapeutic indication.	Immunosuppressants WHO ATC Code: L04AA32
3.	1.5.6	Mention the reference specifications of the finished product.	In-House specifications
4.	1.6	Submit miscellaneous information as per guidance document.	Submitted
5.	2.3.R.1	Submit production documentation.	Submitted
6.	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 Drug Product manufacturer.	Submitted
7.	3.2.S.4.3	Submit analytical Method Verification studies including specificity, accura and repeatability (method precision) performed by the Drug Product manufacturer.	Submitted
8.	3.2.S.4.4	a) Submit 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. b) A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer.	Submitted
9.	3.2.P.1.2	a) Justify the use of magnesium stearate as emulsifier in the drug product. b) The innovator mentions qty. of lactose as lactose monohydrate 171 mg whereas , your formulation contains 50mg.The average tablet weight of comparator product is 312mg whereas, your tablet weight as mentioned in specs. is 210mg.Jusification is required.	It was a typo-error, while the magnesium stearate was used as lubricant. We hereby confirms that the product in stability batches is stable on provided formulation and all excipients in the formulation is based on innovator product formulation
10	3.2.P.2.2.1	c) Submit batch number, DOM and DOE of innovator product.	Submitted.
11	3.2.P.3.5	The quantitative composition in process validation protocol is different than	Firm has submitted revised process validation protocol.

		composition as provided in section 3.2.P.1.2.	
12	3.2.P.5.1	a) The standard weight of tablet varies from weight as provided in 3.2.P.1. b) The innovator uses UPLC for the test whereas, you have used HPLC. c) The test of degradation products and microbial limits have not been included.	We hereby clarify that the UPLC is used when pressure is exceeding above normal limit while our method not shows any problem of exceeding pressure limit so we used HPLC for the test of finish product
13	3.2.P.5.2	Justify the injection volume 50ul w.r.t. column volume.	We hereby clarify that during use of 50ul injection volume in dissolution method, coloumn volume is not an issue because peak height and shape is good enough that coloumn shows not any problem regarding the peak shape.
14	3.2.P.5.3	a) The detection limit and quantitation limit has not been performed for assay validation. b) Submit method validation for dissolution.	We hereby confirm that the quantitation limit was found during Assay validation performance is 0.5ppm and detection limit as 0.2ppm Dissolution method validation report submitted.
15	3.2.P.8.3	a) Provide the API lot number in stability summary datasheets. b) The manufacturing date of TR-001 in stability summary data sheet is 08-2020 whereas, in COA as provided in 3.2.P.5.4 is 09-2020. c) The long term stability report mentions packing detail as ALU-ALU strip whereas, rest of the dossier mentions ALU-ALU blister. d) Submit supporting data of stability of initial analysis. e) Submit reference of previous approval of applications with stability study data of the firm (if any). f) Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. g) Submit documents for the procurement of API with approval from DRAP (in case of import). h) Submit compliance record of HPLC software 21CFR & audit trail reports on product testing. i) Submit record of digital data loggers.	Submitted The date on summary sheet was an error while the correct date is same a s that on COA i.e., 09-2020 Submitted

Decision: Deferred for clarification regarding the status of the other two strengths i.e., 10 mg & 20 mg, of applied formulation as required for the starter pack.

Case no.: 05 Miscellaneous cases

Following case was presented in 340th meeting of Registration Board and was approved but inadvertently decision could not be recorded in the final minutes. The case is re-produced here for information please.

131.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 19989 dated 11-08-2023
	Details of fee submitted	Rs.30,000/- dated 05-06-2023
	The proposed proprietary name / brand name	**Ertag 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ertugliflozin L-Pyroglutamic Acid Eq. to Ertugliflozin…5mg
	Pharmacotherapeutic Group of (API)	Drugs used in diabetes, Sodium glucose co-transporter 2 (SGLT2) inhibitors, ATC code: A10BK04.
	Reference to Finished product specifications	Manufacturer Specs
	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)	Ertuvia tablet of M/s Ferozsons

Evaluation by PEC[II]:

Sr.#	Observation	Firm's response
1.	Latest GMP inspection report of drug product manufacturer, conducted within last three years shall be submitted.	Submitted
2.	Valid DML/GMP certificate of the drug substance manufacturer issued by relevant regulatory authority of country of origin shall be submitted.	Submitted
3.	Details of characterisation studies performed to confirm the polymorphic form of the drug substance, shall be submitted.	Submitted
4.	Copies of the Drug substance analytical procedures used for routine testing of the Drug substance (API) by Drug Product manufacturer is required.	Submitted
5.	Drug substance specifications submitted by the Drug substance manufacturer include the assay test for the content of "Ertugliflozin-LPGA", while the assay test for the content of "Ertugliflozin" shall have been included as per the available literature of the innovator product.	The amount of Etrugliflozin L-PGA taken in Trial batches was taken based on theoretical Factor (1.2955) derived from the respective molecular weights. According to the data above the difference between quantity dispensed and the actual quantity that should have been dispensed, is nominal.

6.	Drug substance analytical method verification studies shall be submitted from drug product manufacturer.	Submitted
7.	COA of Ertugliflozin-LGA, does not declare results for the "Ertugliflozin potency". Justification shall be submitted in this regard.	Firm has submitted revised COA including results of LPGA content.
8.	Justify the quantity of "Ertugliflozin-LPGA" dispensed for formulation of each trial, with reference to the %age content of "Ertugliflozin" in the drug substance of "Ertugliflozin-LPGA".	The amount of Etrugliflozin L-PGA taken in Trial batches was taken based on theoretical Factor (1.2955) derived from the respective molecular weights. According to the data above the difference between quantity dispensed and the actual quantity that should have been dispensed, is nominal.
9.	Reference shall be submitted for the dissolution parameters applied for the performance of dissolution test in batch release of drug product.	Firm has referred to the US FDA Guidelines. Firm has referred to the AMV studies submitted from drug substance manufacturer.
10.	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".	Firm has referred to the AMV studies submitted from drug substance manufacturer.
11.	COA of reference/working standard used in the analysis of the drug product stability batches shall be submitted along with details of standardization, in case of working standard was used.	Submitted.
12.	Form 3 & Form 7 submitted for the clearance of imported drug substance shall be submitted since submitted commercial invoice does not declare the batch no. of the drug substance imported.	Copy of commercial invoice attested by I&E DRAP office has been submitted.

Decision: Registration Board noted the information and decided to record the decision for instant application as approved.

Agenda of Dr. Muhammad Haseeb Tariq

Case No. 01 Registration applications of CTD cases

a. New cases

132.	**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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26032: 27-10-2023
	Details of fee submitted	PKR 75,000/- : 18-10-2023
	The proposed proprietary name / brand name	**CAMZEE 2.5mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Mavacamten…2.5mg
	Pharmacotherapeutic Group of (API)	Other cardiac preparations
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	CAMZYOS Capsule **USFDA** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Mavacamten capsule is only available through a restricted program called the CAMZYOS REMS Program in USFDA because of the risk of heart failure due to systolic dysfunction, clarify how you will ensure risk management of the applied product.	Firm has submitted that they will follow its SOP for risk management system to ensure its safety for patients and also follow the guidelines of E-reporting manual of DRAP to counter any risk. Meanwhile we are also considering to take registration of DRAP e-reporting system for individual case safety reports (ICSRs). We will develop a special report card to monitor and report ADRs. We will also make sure to train healthcare professionals to access health conditions and continuous monitoring.
2.	Submit specifications and analytical method of API from API manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	Submitted.
3.	Submit details of the innovator' sproduct against which pharmaceutical equivalence and CDP study was conducted.	Submitted
4.	Submit 6 month's stability study data	Submitted.

Decision: Approved. Registration letter will be issued after confirmation from National PV Centre regarding availability of requirements and resources for RMP, ADR reporting and training of HCPs etc.

133.	**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)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26033: 27-10-2023
	Details of fee submitted	PKR 75,000/- : 18-10-2023
	The proposed proprietary name / brand name	**CAMZEE 5mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Mavacamten….5mg
	Pharmacotherapeutic Group of (API)	Other cardiac preparations
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	CAMZYOS Capsule **USFDA** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Mavacamten capsule is only available through a restricted program called the CAMZYOS REMS Program in USFDA because of the risk of heart failure due to systolic dysfunction, clarify how you will ensure risk management of the applied product.	Firm has submitted that they will follow its SOP for risk management system to ensure its safety for patients and also follow the guidelines of E-reporting manual of DRAP to counter any risk. Meanwhile we are also considering to take registration of DRAP e-reporting system for individual case safety reports (ICSRs). We will develop a special report card to monitor and report ADRs. We will also make sure to train healthcare professionals to access health conditions and continuous monitoring.
2.	Submit specifications and analytical method of API from API manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	Submitted.
3.	Submit details of the innovator' sproduct against which pharmaceutical equivalence and CDP study was conducted.	Submitted
4.	Submit 6 month's stability study data	Submitted.

Decision: Approved. Registration letter will be issued after confirmation from National PV Centre regarding availability of requirements and resources for RMP, ADR reporting and training of HCPs etc.

134.	**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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26034: 27-10-2023
	Details of fee submitted	PKR 75,000/- : 18-10-2023
	The proposed proprietary name / brand name	**CAMZEE 10mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Mavacamten….10mg
	Pharmacotherapeutic Group of (API)	Other cardiac preparations

	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	CAMZYOS Capsule **USFDA** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Mavacamten capsule is only available through a restricted program called the CAMZYOS REMS Program in USFDA because of the risk of heart failure due to systolic dysfunction, clarify how you will ensure risk management of the applied product.	Firm has submitted that they will follow its SOP for risk management system to ensure its safety for patients and also follow the guidelines of E-reporting manual of DRAP to counter any risk. Meanwhile we are also considering to take registration of DRAP e-reporting system for individual case safety reports (ICSRs). We will develop a special report card to monitor and report ADRs. We will also make sure to train healthcare professionals to access health conditions and continuous monitoring.
2.	Submit specifications and analytical method of API from API manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	Submitted.
3.	Submit details of the innovator' sproduct against which pharmaceutical equivalence and CDP study was conducted.	Submitted
4.	Submit 6 month's stability study data	Submitted.

Decision: Approved. Registration letter will be issued after confirmation from National PV Centre regarding availability of requirements and resources for RMP, ADR reporting and training of HCPs etc.

135.	**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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26034: 27-10-2023
	Details of fee submitted	PKR 75,000/- : 18-10-2023
	The proposed proprietary name / brand name	**CAMZEE 15mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Mavacamten….15mg
	Pharmacotherapeutic Group of (API)	Other cardiac preparations
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	CAMZYOS Capsule **USFDA** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm

1.	Mavacamten capsule is only available through a restricted program called the CAMZYOS REMS Program in USFDA because of the risk of heart failure due to systolic dysfunction, clarify how you will ensure risk management of the applied product.	Firm has submitted that they will follow its SOP for risk management system to ensure its safety for patients and also follow the guidelines of E-reporting manual of DRAP to counter any risk. Meanwhile we are also considering to take registration of DRAP e-reporting system for individual case safety reports (ICSRs). We will develop a special report card to monitor and report ADRs. We will also make sure to train healthcare professionals to access health conditions and continuous monitoring.
2.	Submit specifications and analytical method of API from API manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	Submitted.
3.	Submit details of the innovator' sproduct against which pharmaceutical equivalence and CDP study was conducted.	Submitted
4.	Submit 6 month's stability study data	Submitted.

Decision: Approved. Registration letter will be issued after confirmation from National PV Centre regarding availability of requirements and resources for RMP, ADR reporting and training of HCPs etc.

136.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s BJ Pharmaceuticals. 18 Km, Mandialli Stop, Lahore-Sheikhupura Road, Lahore**
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals. 18 Km, Mandialli Stop, Lahore-Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26013: 27-10-2023
	Details of fee submitted	PKR 30,000/- : 11-10-2023
	The proposed proprietary name / brand name	**I-ROSE Chewable Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Chewable Tablet Contains: Iron III Hydroxide Polymaltose Complex Eq. to Elemental Iron…100mg Folic Acid…0.35mg
	Pharmacotherapeutic Group of (API)	Iron preparation with folic acid
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	Not submitted.
	For generic drugs (me-too status)	Acefer F Tablet by Saffron Pharma
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	**Shortcomings communicated**	**Response by the firm**
1.	Submit evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting.	
2.	Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for both drug substances.	

3.	Submit verification studies of the analytical method of both drug substance, performed by drug product manufacturer in section 3.2.S.4.3.	
4.	As per TGA, Iron (III) hydroxide polymaltose complex 370mg is equivalent to 100mg elemental iron while you have used 308mg iron complex. Clarify how your formulaion will have similar elemental iron contents.	
5.	As per various reference regulatory authorities, iron and folic acid tablets are developed as bilayer tablets, while your formulation is developed as a single layer product. Clarify how will you ensure uniformity of folic acid throught each unit of the batch since the quantity of folic acid is very less as compared to the quantity of iron.	
6.	Justify why CDP studies are not performed.	
7.	Justify why content uniformity test is not included in drug product specification.	
8.	As per USP monograph as well as drug substance manufacturer, the assay method for folic acid is based on HPLC, while your drug product specification involves assay testing of folic acid through UV method. Clarify how the specificity as well as accuracy of the method will be ensured.	
9.	Submit evidence of procurement of API.	
10.	Submit valid GMP certificate of both API manufacturer.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings and for the restoration of production activities.

137.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26275: 31-10-2023
	Details of fee submitted	PKR 30,000/- : 05-09-2023
	The proposed proprietary name / brand name	**FERRINA 500mg/10ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 10ml Vial Contains: Iron as Ferric Carboxymaltose…500mg
	Pharmacotherapeutic Group of (API)	Iron preparation
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Ferinject Injection of RG
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	**Shortcomings communicated**	**Response by the firm**
1.	Submit evidence of approval of requisite manufacturing facility / section approval	Firm has submitted copy of inspection report for grant of GMP certificate which specifies that the firm has Liquid injectable general

	leter from Licensing Division which clarify the facility for filling 10ml vial.	section which further has semi-automatic vial filling machine in which they can fill vials of various volumes by placing vials manually under filling nozzles.
2.	Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3.	Submitted.
3.	Submit details of reference product against which PE studies are conducted.	Firm has submitted details of Ferinject Injection of Searle Pakistan.
4.	Submit evidence of procurement of API.	Firm has submitted copy of license to import dated 02-02-2022 along with copy of commercial invoice.
5.	Submit BMR of stability batches	Submitted.

Decision: Approved.

138.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Regal Pharmaceuticals Plot # 2A St.# S-5, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Regal Pharmaceuticals Plot # 2A St.# S-5, National Industrial Zone, Rawat, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26712: 07-11-2023
	Details of fee submitted	PKR 30,000/- : 01-11-2023
	The proposed proprietary name / brand name	**DEXLANO 30mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Hard Gelatin Capsule Contains: DDR Pellets of Dexlansoprazole Eq. to Dexlansoprazole…30mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Razodex Capsule by Getz
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Source of Pellets: M/s Vision Pharmaceutical, Islamabad.

Sr. No	**Shortcomings communicated**	**Response by the firm**
1.	Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	Firm has submitted specifications.
2.	Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3.	Firm has submitted verification report.
3.	Submit details of reference product against which PE and CDP studies are conducted.	Firm has submitted detail of Dextop Capsule of Searle
4.	Submit evidence of procurement of API.	Firm has submitted copy of commercial invoice from Vision pharma

5.	Submit BMR of stability batches	Submitted.
Decision: Approved.		
139.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Regal Pharmaceuticals Plot # 2A St.# S-5, National Industrial Zone, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Regal Pharmaceuticals Plot # 2A St.# S-5, National Industrial Zone, Rawat, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26713: 07-11-2023
	Details of fee submitted	PKR 30,000/- : 01-11-2023
	The proposed proprietary name / brand name	**DEXLANO 60mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Hard Gelatin Capsule Contains: DDR Pellets of Dexlansoprazole Eq. to Dexlansoprazole…60mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Razodex Capsule by Getz
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Source of Pellets: M/s Vision Pharmaceutical, Islamabad.

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	Firm has submitted specifications.
2.	Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3.	Firm has submitted verification report.
3.	Submit details of reference product against which PE and CDP studies are conducted.	Firm has submitted detail of Dextop Capsule of Searle
4.	Submit evidence of procurement of API.	Firm has submitted copy of commercial invoice from Vision pharma
5.	Submit BMR of stability batches	Submitted.

Decision: Approved.		
140.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27485: 23-11-2023
	Details of fee submitted	PKR 75,000/- : 03-11-2023
	The proposed proprietary name / brand name	**IBURAPID 342mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ibuprofen Lysine…. 342mg
	Pharmacotherapeutic Group of (API)	Anti-inflammatory and anti-rheumatic products
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	Ibuprofen Lysine 342mg tablet **MHRA** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

The formulation contains Ibuprofen Lysine 342mg equivalent to 200mg ibuprofen.

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit COA for reference standard / working standard.	Submitted.
2.	Submit details of reference product against which PE and CDP studies are conducted.	Submitted.
3.	Submit BMR of stability batches	Submitted.

Decision: Approved.

141.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27486: 23-11-2023
	Details of fee submitted	PKR 75,000/- : 03-11-2023
	The proposed proprietary name / brand name	**IBURAPID 684mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ibuprofen Lysine…. 684mg
	Pharmacotherapeutic Group of (API)	Anti-inflammatory and anti-rheumatic products
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	Ibuprofen Lysine 342mg tablet **MHRA** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

The formulation contains Ibuprofen Lysine 684mg equivalent to 400mg ibuprofen.

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit COA for reference standard / working standard.	Submitted.

2.	Submit details of reference product against which PE and CDP studies are conducted.	Submitted.
3.	Submit BMR of stability batches	Submitted.

Decision: Approved.

142.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27483: 23-11-2023
	Details of fee submitted	PKR 75,000/- : 03-11-2023
	The proposed proprietary name / brand name	**IBURAPID 20mg/ml Oral Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of Oral Suspension Contains: Ibuprofen Lysine Eq. to Ibuprofen…20mg
	Pharmacotherapeutic Group of (API)	Anti-inflammatory and anti-rheumatic products
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	Algidrin Pediatric 20 mg/ml oral suspension **Spain** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	**Shortcomings communicated**	**Response by the firm**
1.	Submit COA for reference standard / working standard.	Submitted.
2.	Submit details of reference product against which PE studies are conducted.	Firm has Submitted details of Spain approved reference product.
3.	Submit BMR of stability batches	Submitted.

Decision: Registration Board delibereated that other dosage forms of Ibuprofen lysate are approved in several reference regulatory authorities while oral suspension is only approved in Spain, hence Board advised to review the status of instant formulation in other reference regulatory authorities.

143.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27484: 23-11-2023

	Details of fee submitted	PKR 75,000/- : 03-11-2023
	The proposed proprietary name / brand name	**IBURAPID 40mg/ml Oral Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of Oral Suspension Contains: Ibuprofen Lysine Eq. to Ibuprofen…40mg
	Pharmacotherapeutic Group of (API)	Anti-inflammatory and anti-rheumatic products
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	Algidrin Pediatric 40 mg/ml oral suspension **Spain** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit COA for reference standard / working standard.	Submitted.
2.	Submit preservative effectiveness studies	Submitted.
3.	Submit details of reference product against which PE studies are conducted.	Firm has Submitted details of Spain approved reference product.
4.	Submit BMR of stability batches	Submitted.

Decision: Registration Board delibereated that other dosage forms of Ibuprofen lysate are approved in several reference regulatory authorities while oral suspension is only approved in Spain, hence Board advised to review the status of instant formulation in other reference regulatory authorities.

144.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27482: 23-11-2023
	Details of fee submitted	PKR 75,000/- : 03-11-2023
	The proposed proprietary name / brand name	**IBURAPID 10% Gel**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram of Gel Contains: Ibuprofen Lysine…100mg
	Pharmacotherapeutic Group of (API)	Anti-inflammatory and anti-rheumatic products
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	VEGETALLUMINA Antidolore 10% gel **AIFA Italy** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit COA for reference standard / working standard.	Submitted.

2.	Submit preservative effectiveness studies	Submitted.
3.	Submit details of reference product against which PE studies are conducted.	Firm has Submitted details of Italy approved reference product.
4.	Submit BMR of stability batches	Submitted.

Decision: Registration Board delibereated that other dosage forms of Ibuprofen lysate are approved in several reference regulatory authorities while topical gel is only approved in Spain, hence Board advised to review the status of instant formulation in other reference regulatory authorities.

145.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 24549: 09-10-2023
	Details of fee submitted	PKR 75,000/- : 14-07-2023
	The proposed proprietary name / brand name	**URIFLOW 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Bethanechol Chloride…10mg
	Pharmacotherapeutic Group of (API)	Choline esters / Parasympathomimetics
	Reference to Finished product specifications	JP
	The status in reference regulatory authorities	Duvoid Tablet **USFDA** Approved
	For generic drugs (me-too status)	Not available
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Clinical Indication: Indicated for the treatment of acute postoperative and postpartum nonobstructive (functional) urinary retention and for neurogenic atony of the urinary bladder with retention.

Decision: Approved.

146.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25001: 13-10-2023
	Details of fee submitted	PKR 75,000/- : 14-07-2023
	The proposed proprietary name / brand name	**URIFLOW 25mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Bethanechol Chloride…25mg

	Pharmacotherapeutic Group of (API)	Choline esters / Parasympathomimetics
	Reference to Finished product specifications	JP
	The status in reference regulatory authorities	Duvoid Tablet **USFDA** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Clinical Indication: Indicated for the treatment of acute postoperative and postpartum nonobstructive (functional) urinary retention and for neurogenic atony of the urinary bladder with retention.		
Decision: Approved.		
147.	**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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 24884: 12-10-2023
	Details of fee submitted	PKR 30,000/- : 02-08-2023
	The proposed proprietary name / brand name	**TERBINAFINE HCl 1% Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram Contains: Terbinafine HCl Eq. to Terbinafine…10mg (1%)
	Pharmacotherapeutic Group of (API)	Antifungal
	Reference to Finished product specifications	JP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
148.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R:2, Industrial Estate Gadoon, Swabi.**
	Name, address of Manufacturing site.	M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R:2, Industrial Estate Gadoon, Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26543: 03-11-2023
	Details of fee submitted	PKR 75,000/- : 01-11-2023
	The proposed proprietary name / brand name	**DEXIMED 30mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Dual Delayed Release Capsule Contains: Dexlansoprazole…30mg

	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Razodex Capsule by Getz
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Source of Pellets: M/s Vision Pharmaceutical, Islamabad.

Sr. No	Shortcomings communicated	Response by the firm
1.	Revise your label claim as per innovator's product along with submission of requisite fee.	
2.	Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	
3.	Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3.	
4.	Submit details of reference product against which PE and CDP studies are conducted.	
5.	Submit evidence of procurement of API.	
6.	Submit BMR of stability batches	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

149.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R:2, Industrial Estate Gadoon, Swabi.**
	Name, address of Manufacturing site.	M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R:2, Industrial Estate Gadoon, Swabi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26544: 03-11-2023
	Details of fee submitted	PKR 75,000/- : 01-11-2023
	The proposed proprietary name / brand name	**DEXIMED 60mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Dual Delayed Release Capsule Contains: Dexlansoprazole…60mg
	Pharmacotherapeutic Group of (API)	PPI
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Razodex Capsule by Getz
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Source of Pellets: M/s Vision Pharmaceutical, Islamabad.

Sr. No	Shortcomings communicated	Response by the firm
1.	Revise your label claim as per innovator's product along with submission of requisite fee.	

2.	Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.
3.	Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3.
4.	Submit details of reference product against which PE and CDP studies are conducted.
5.	Submit evidence of procurement of API.
6.	Submit BMR of stability batches

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

150.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25798: 25-10-2023
	Details of fee submitted	PKR 75,000/- : 16-10-2023
	The proposed proprietary name / brand name	**ZLIEF 10gm Cream**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram of Cream Contains: Trifarotene…50µg
	Pharmacotherapeutic Group of (API)	Retinoids for topical use in acne
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	Aklief Cream **USFDA** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Clinical Indication: Indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

Sr. No	**Shortcomings communicated**	**Response by the firm**
1.	Your formulation contains Copolymer of acrylamide and sodium acryloyldimethyltaurate along with 40% dispersion of isohexadecane for which no compendial monograph exists. Provide its detailed specifications along with other requirements as per the CTD guidance document.	Firm has submitted detailed specification for these excipients.
2.	The innovator's product has developed developed and validated an IVRT method using an in-vitro release Workstation automated system of cells diffusion. The innovator's product utilizes this test in its the first three commercial batches during both release and stability and also during drug product release testing. Clarify why the same test is not performed and not included in your drug product specification.	We have followed USP General guidelines for testing of semisolid drug products, <3> Topical and transdermal drug products-product quality tests in which it is stated under the section In vitro drug release test, for semi solid dosage forms in vitro drug release testing is currently not

		required for batch release. Moreover, the innovator's product utilizes this test in its first three commercial batches not in trials.
3.	Submit details of reference product against which PE studies are conducted.	Firm has submitted details of the innovator's product Aklief Cream
4.	Submit evidence of procurement of API including clearance documents.	Firm has submitted clearance certificate dated 12-06-2023 issued by AD I&E Islamabad
5.	Submit 6th month stability study data	Firm has submitted 6th month time point stability data along with analytical record.

Decision: Approved.

151.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26030: 27-10-2023
	Details of fee submitted	PKR 75,000/- : 16-10-2023
	The proposed proprietary name / brand name	**RUXOZEE 1.5% Cream**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram of Cream Contains: Ruxolitinib Phosphate Eq. to Ruxolitinib…15mg
	Pharmacotherapeutic Group of (API)	D11AH09: Agents for dermatitis, excluding corticosteroids L01EJ01: Protein Kinase Inhibitors
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	Opzelura 1.5% cream (**USFDA** Approved)
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Clinical Indication: • OPZELURA is indicated for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adult and pediatric patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

• OPZELURA is indicated for the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older.

Sr. No	**Shortcomings communicated**	**Response by the firm**
1.	Submit evidence of procurement of API including clearance documents.	Firm has submitted clearance certificate dated 05-07-2023

Decision: Approved. Manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of this drug.

152.	**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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 24690: 10-10-2023
	Details of fee submitted	PKR 75,000/- : 07-06-2023
	The proposed proprietary name / brand name	**MALFERIC 30mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Iron as Ferric Maltol…30mg
	Pharmacotherapeutic Group of (API)	Antianemic preparation
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	Accrufer Capsule (**USFDA** Approved)
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Clinical Indication: • Indicated for the treatment of iron deficiency in adults.

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit API stability study data till shelf life, since the submitted data is only for 3 months	API stability data till 24 months is submitted.

Decision: Approved.

153.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26133: 30-10-2023
	Details of fee submitted	PKR 75,000/- : 04-10-2023
	The proposed proprietary name / brand name	**SETRON 2.5mcg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ramosetron HCl…2.5mcg
	Pharmacotherapeutic Group of (API)	selective serotonin 5-HT3 receptor antagonist
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	Irribow Tablet **PMDA Japan** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	1x10's, 1x14's As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of API from drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	Submitted
2.	Submit details of reference product against which PE studies are conducted.	Submitted
3.	Submit copy of valid GMP certificate of API manufacturer	Submitted

Decision: Approved.

154.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26134: 30-10-2023
	Details of fee submitted	PKR 75,000/- : 03-10-2023
	The proposed proprietary name / brand name	**SETRON 5mcg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ramosetron HCl…5mcg
	Pharmacotherapeutic Group of (API)	selective serotonin 5-HT3 receptor antagonist
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	Irribow Tablet **PMDA Japan** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	1x10's, 1x14's As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of API from drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	Submitted
2.	Submit details of reference product against which PE studies are conducted.	Submitted
3.	Submit copy of valid GMP certificate of API manufacturer	Submitted

Decision: Approved.

155.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa**
	Name, address of Manufacturing site.	M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26380: 01-11-2023
	Details of fee submitted	PKR 30,000/- : 13-10-2023
	The proposed proprietary name / brand name	**VALIANT-M 50/500 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCl…500mg
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**TGA** Australia Approved
	For generic drugs (me-too status)	Vilget-M tablet by Getz
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
156.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, KPK, Pakistan**
	Name, address of Manufacturing site.	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, KPK, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27806: 29-11-2023
	Details of fee submitted	PKR 30,000/- : 01-09-2023
	The proposed proprietary name / brand name	**ALLER-HEEL 5mg Chewable Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Chewable Tablet Contains: Montelukast as Sodium…5mg
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonist
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Montiget chewable tablet by Getz
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		

Sr. No	**Shortcomings communicated**	**Response by the firm**
1.	Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3.	Submitted
2.	Submit evidence of procurement of API.	Submitted
3.	Submit BMR of stability batches	Submitted

Decision: Approved.		
157.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, KPK, Pakistan**

	Name, address of Manufacturing site.	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, KPK, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26684: 06-11-2023
	Details of fee submitted	PKR 30,000/- : 01-09-2023
	The proposed proprietary name / brand name	**ALLER-HEEL 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Montelukast as Sodium…10mg
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonist
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Montiget tablet by Getz
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3.	Submitted
2.	Submit evidence of procurement of API.	Submitted
3.	Submit BMR of stability batches	Submitted

Decision: Approved.

158.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, KPK, Pakistan**
	Name, address of Manufacturing site.	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, KPK, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26685: 06-11-2023
	Details of fee submitted	PKR 30,000/- : 01-09-2023
	The proposed proprietary name / brand name	**ALLER-HEEL 4mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Montelukast as Sodium…4mg
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonist
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Montiget tablet by Getz
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3.	Submitted
2.	Submit evidence of procurement of API.	Submitted
3.	Submit BMR of stability batches	Submitted

Decision: Approved.

159.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wahabsons Pharma Pvt Ltd. 4km, Bunir Road, Barikot, Sawat, Kpk**
	Name, address of Manufacturing site.	M/s Wahabsons Pharma Pvt Ltd. 4km, Bunir Road, Barikot, Sawat, Kpk
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 23983: 02-10-2023
	Details of fee submitted	PKR 30,000/- : 26-09-2023
	The proposed proprietary name / brand name	**DICLO 50mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Diclofenac Sodium Enteric Coated Pellets Eq. to Diclofenac Sodium…50mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**HPRA** Ireland Approved
	For generic drugs (me-too status)	Mobikare capsule by Barret Hodgson
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Source of pellets: M/s Vision Pharma, Islamabad.

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical method of API from both API manufacturer as well as drug product manufacturer	Submitted
2.	Submit COA of reference standard / working standard.	Submitted
3.	Submit details of reference product against which PE and CDP studies were conducted.	Submitted

Decision: Deferred for updated status of Drug Manufacturing License (DML) of the firm from Licensing Division.

160.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25890: 26-10-2023
	Details of fee submitted	PKR 30,000/- : 03-10-2023
	The proposed proprietary name / brand name	**VIT-K1 10mg/ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Phytomenadione…10mg
	Pharmacotherapeutic Group of (API)	Vitamin
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	K-Lot Injection by GT Pharma
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
161.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Platinum Pharmaceuticals Pvt Ltd. A-20, North western Industrial Zone, Bin Qasim Karachi**
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals Pvt Ltd. A-20, North western Industrial Zone, Bin Qasim Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25447: 20-10-2023
	Details of fee submitted	PKR 30,000/- : 27-09-2023
	The proposed proprietary name / brand name	**DYDROGESTERONE 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Dydrogesterone…10mg
	Pharmacotherapeutic Group of (API)	Progestogen
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	DUPHASTON 10 mg, film-coated tablet **ANSM France** Approved
	For generic drugs (me-too status)	Duphaston Tablet by Abbott
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		

Sr. No	**Shortcomings communicated**	**Response by the firm**
1.	Clarify whether the drug substance used in your formulation is cis or trans isomer.	Our drug substance complies with USP Specss, also CAS number and chemical name mentioned in USP monograph matches to that mentined in DMF and COA.
2.	Submit specifications and analytical method of API from drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	Submitted.
3.	As per the API specifications the specific optical rotation is between -469° and -485° while as per USP monograph the specific	In API specifications as well as COA the optical rotation mentioned is -442 and -462 which is as per USP.

	optical rotation is between -442° and -462°. Clarify how your API is as per USP.	
	4. Submit AD attested invoice.	Firm has submitted copy of license to import along with copy of invoice and Form 3.
Decision: Approved. Manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of this drug.		
162.	**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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26039: 27-10-2023
	Details of fee submitted	PKR 30,000/- : 20-09-2023
	The proposed proprietary name / brand name	**VISOMO 375/20 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Modified Release Tablet Contains: Naproxen (as enteric coated core)…375mg Esomeprazole as Magnesium Trihydrate (immediate release coat)…20mg
	Pharmacotherapeutic Group of (API)	NSAID with PPI
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Glomov Tablets by Global Pharma
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
163.	**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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25418: 19-10-2023
	Details of fee submitted	PKR 30,000/- : 20-09-2023
	The proposed proprietary name / brand name	**VISOMO 500/20 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Modified Release Tablet Contains: Naproxen (as enteric coated core)…500mg Esomeprazole as Magnesium Trihydrate (immediate release coat)…20mg
	Pharmacotherapeutic Group of (API)	NSAID with PPI

	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Glomov Tablets by Global Pharma
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
164.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Axis Pharmaceuticals. Value Addition City, 3-B, 1.5km, Khurrianwala-Sahianwala Road, Faisalabad**
	Name, address of Manufacturing site.	M/s Axis Pharmaceuticals. Value Addition City, 3-B, 1.5km, Khurrianwala-Sahianwala Road, Faisalabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 24126: 03-10-2023
	Details of fee submitted	PKR 30,000/- : 08-09-2023
	The proposed proprietary name / brand name	**NAPRIUM Plus 500/20 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Modified Release Tablet Contains: Naproxen (as enteric coated core)…500mg Esomeprazole as Magnesium Trihydrate (immediate release coat)…20mg
	Pharmacotherapeutic Group of (API)	NSAID with PPI
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Glomov Tablets by Global Pharma
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3.	Submitted
2.	Submit details of reference product against which PE and CDP studies were conducted.	Submitted
3.	Submit BMR of stability batches	Submitted

Decision: Approved.

165.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25425: 19-10-2023
	Details of fee submitted	PKR 30,000/- : 14-07-2023
	The proposed proprietary name / brand name	**ANEX-E 375/20 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Modified Release Tablet Contains: Naproxen (as enteric coated core)…375mg Esomeprazole as Magnesium Trihydrate (immediate release coat)…20mg
	Pharmacotherapeutic Group of (API)	NSAID with PPI
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Glomov Tablets by Global Pharma
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
166.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25426: 19-10-2023
	Details of fee submitted	PKR 30,000/- : 14-07-2023
	The proposed proprietary name / brand name	**ANEX-E 500/20 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Modified Release Tablet Contains: Naproxen (as enteric coated core)…500mg Esomeprazole as Magnesium Trihydrate (immediate release coat)…20mg
	Pharmacotherapeutic Group of (API)	NSAID with PPI
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Glomov Tablets by Global Pharma
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		

167.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan**
	Name, address of Manufacturing site.	M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25789: 25-10-2023
	Details of fee submitted	PKR 30,000/- : 11-10-2023
	The proposed proprietary name / brand name	**LAMICAL 1% Cutaneous Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram of topical solution Contains: Terbinafine (As HCl)…10mg
	Pharmacotherapeutic Group of (API)	Antifungal
	Reference to Finished product specifications	JP
	The status in reference regulatory authorities	Lamisil 1% cutaneous solution (**MHRA** Approved)
	For generic drugs (me-too status)	Terbisil Lotion by Saffron
	Proposed Pack size	20ml, As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit COA of reference standard / working standard used in analysis of drug substance.	Submitted
2.	Submit evidence of procurement of API.	Submitted
3.	Submit BMR of stability batches	Submitted

Decision: Approved.

168.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad**
	Name, address of Manufacturing site.	M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22463: 12-09-2023
	Details of fee submitted	PKR 75,000/- : 30-08-2023
	The proposed proprietary name / brand name	**PARACETAMOL 650mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Film Coated Tablet Contains: Paracetamol…650mg
	Pharmacotherapeutic Group of (API)	Analgesic and antipyretic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**Dailymed (USA)** Approved
	For generic drugs (me-too status)	Not available
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

The reference product is a bilayer caplet, the formulation of the firm also contains two layer containing 330mg and 320mg paracetamol.

Decision: Approved.

169.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad**

	Name, address of Manufacturing site.	M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22464: 12-09-2023
	Details of fee submitted	PKR 30,000/- : 30-08-2023
	The proposed proprietary name / brand name	**PARACETAMOL 665mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Film Coated Tablet Contains: Paracetamol…665mg
	Pharmacotherapeutic Group of (API)	Analgesic and antipyretic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	OSTEOMOL 665 PARACETAMOL **(TGA Approved)**
	For generic drugs (me-too status)	Panadol extend Tablet of GSK
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
The reference product is a bilayer caplet, the formulation of the firm also contains two layer containing 345mg and 320mg paracetamol.		
Decision: Approved. To mitigate the risk due to toxicity associated with overdose of Paracetamol Extended release Tablet 665mg, registration letter will be issued with following additional conditions/ statements: **"Following conditions should appear on label of the product in bold and conspicuous manner:** • **For adults, the highest recommended dose of Paracetamol Extended release Tablet 665mg 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).** • **Paracetamol Extended release Tablet 665mg should not be used as an alternative to Panadol/ Paracetamol Tablet 500mg without prior consultation with Physician/ Pharmacist."** • **Above-mentioned conditions will also be included in advertisement of the product and for this purpose, recommendation will be forwarded to Pharmacy Services Division, DRAP.** **To ensure compliance with the above-mentioned conditions, the applicant will be advised to conduct training programmes for the health care providers and submit biannual compliance reports to PE&R Division subsequent to issuance of registration.**		

170.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad**
	Name, address of Manufacturing site.	M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22613: 14-09-2023
	Details of fee submitted	PKR 30,000/- : 07-07-2023
	The proposed proprietary name / brand name	**COMFORTOL Plus 500/200 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Paracetamol…500mg Ibuprofen…200mg

	Pharmacotherapeutic Group of (API)	Analgesic and antipyretic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Provas Duo Tablet by Sami
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
171.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad**
	Name, address of Manufacturing site.	M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22612: 14-09-2023
	Details of fee submitted	PKR 75,000/- : 22-08-2023
	The proposed proprietary name / brand name	**DOPTOR 20mg/ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Doxaparm HCl…20mg
	Pharmacotherapeutic Group of (API)	Respiratory stimulants
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		

172.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 21979: 06-09-2023
	Details of fee submitted	PKR 30,000/- : 14-07-2023
	The proposed proprietary name / brand name	**TRIFLIX 5/1.25/5 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Perindopril Arginine…5mg Indapamide…1.25mg Amlodipine Besylate Eq. to Amlodipine…5mg
	Pharmacotherapeutic Group of (API)	Anti-hypertensive
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	Coverdine tablets **HPRA Ireland** Approved
	For generic drugs (me-too status)	Triplixam Tablet by Servier

	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
173.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 21980: 06-09-2023
	Details of fee submitted	PKR 30,000/- : 14-07-2023
	The proposed proprietary name / brand name	**TRIFLIX 5/1.25/10 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Perindopril Arginine…5mg Indapamide…1.25mg Amlodipine Besylate Eq. to Amlodipine…10mg
	Pharmacotherapeutic Group of (API)	Anti-hypertensive
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	Coverdine tablets **HPRA Ireland** Approved
	For generic drugs (me-too status)	Triplixam Tablet by Servier
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
174.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 21980: 06-09-2023
	Details of fee submitted	PKR 30,000/- : 14-07-2023
	The proposed proprietary name / brand name	**TRIFLIX 10/2.5/5 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Perindopril Arginine…10mg Indapamide….2.5mg Amlodipine Besylate Eq. to Amlodipine…5mg
	Pharmacotherapeutic Group of (API)	Anti-hypertensive
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	Coverdine tablets **HPRA Ireland** Approved
	For generic drugs (me-too status)	Triplixam Tablet by Servier
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		

Decision: Approved.		
175.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 21980: 06-09-2023
	Details of fee submitted	PKR 30,000/- : 14-07-2023
	The proposed proprietary name / brand name	**TRIFLIX 10/2.5/10 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Perindopril Arginine…10mg Indapamide….2.5mg Amlodipine Besylate Eq. to Amlodipine…10mg
	Pharmacotherapeutic Group of (API)	Anti-hypertensive
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	Coverdine tablets **HPRA Ireland** Approved
	For generic drugs (me-too status)	Triplixam Tablet by Servier
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		

176.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore**
	Name, address of Manufacturing site.	M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 23472: 22-09-2023
	Details of fee submitted	PKR 75,000/- : 06-09-2023
	The proposed proprietary name / brand name	**MEGLIN 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Imeglimin HCl…500mg
	Pharmacotherapeutic Group of (API)	Anti-diabetic
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**PMDA Japan** Approved
	For generic drugs (me-too status)	Glymeg Tablet 500mg of M/s Nabiqasim
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		

177.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Meditech Pharmaceuticals. Plot No. 83-A, 83-B, Industrial Estate, Hayatabad, Peshawar, Pakistan**

	Name, address of Manufacturing site.	M/s Meditech Pharmaceuticals. Plot No. 83-A, 83-B, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22010: 06-09-2023
	Details of fee submitted	PKR 30,000/- : 24-07-2023
	The proposed proprietary name / brand name	**AEROSAL 2mg/5ml Oral Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Salbutamol as Sulphate…2mg
	Pharmacotherapeutic Group of (API)	Selective beta-2-adrenoreceptor agonists
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Ventolin oral solution by GSK
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit API specifcations and analytical method from both API manufacturre as well as drug product manufacturer	Submitted
2.	Submit details of reference product against which PE studies were conducted..	Submitted
3.	Submit BMR of stability batches	Submitted

Decision: Approved.

178.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 21974: 06-09-2023
	Details of fee submitted	PKR 30,000/- : 02-08-2023
	The proposed proprietary name / brand name	**OTINIUM 40mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Otilonium Bromide…40mg
	Pharmacotherapeutic Group of (API)	Anticholinergic, quaternary ammonium compounds
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**Spain** Approved
	For generic drugs (me-too status)	Spasmomen tablet 40mg of Pharmatech
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Decision: Approved		
179.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22602: 14-09-2023
	Details of fee submitted	PKR 75,000/- : 15-08-2023
	The proposed proprietary name / brand name	**ROXASTAT 70mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Roxadustat…70mg
	Pharmacotherapeutic Group of (API)	Other antianemic preparations
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
180.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22455: 12-09-2023
	Details of fee submitted	PKR 75,000/- : 15-08-2023
	The proposed proprietary name / brand name	**ROXASTAT 150mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Roxadustat…150mg
	Pharmacotherapeutic Group of (API)	Other antianemic preparations
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		

181.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan**
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22153: 08-09-2023
	Details of fee submitted	PKR 75,000/- : 05-07-2023 + PKR 75,000/- : 23-08-2023
	The proposed proprietary name / brand name	**GATRAN 75mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Dabigatran Etexilate Mesylate Pellets eq. to Dabigatran Etexilate……75 mg
	Pharmacotherapeutic Group of (API)	Antithrombotic agents
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Dabiclo 75mg Capsule of M/s Ferozsons
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Source of pellets: M/s Lee Pharma Ltd, Plot No. V, Phase-II, VSEZ, Duvvada Sabbavaram Visakhapatnam Andhra Pradesh India.		
Decision: Approved.		
182.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan**
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22154: 08-09-2023
	Details of fee submitted	PKR 75,000/- : 05-07-2023 + PKR 75,000/- : 23-08-2023
	The proposed proprietary name / brand name	**GATRAN 110mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Dabigatran Etexilate Mesylate Pellets eq. to Dabigatran Etexilate…….110mg
	Pharmacotherapeutic Group of (API)	Antithrombotic agents
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Not available
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Source of pellets: M/s Lee Pharma Ltd, Plot No. V, Phase-II, VSEZ, Duvvada Sabbavaram Visakhapatnam Andhra Pradesh India.		
Decision: Approved.		

183.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan**
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22154: 08-09-2023
	Details of fee submitted	PKR 75,000/- : 05-07-2023 + PKR 75,000/- : 23-08-2023
	The proposed proprietary name / brand name	**GATRAN 150mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Dabigatran Etexilate Mesylate Pellets eq. to Dabigatran Etexilate…….150mg
	Pharmacotherapeutic Group of (API)	Antithrombotic agents
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Dabiclo 150mg Capsule of M/s Ferozsons
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Source of pellets: M/s Lee Pharma Ltd, Plot No. V, Phase-II, VSEZ, Duvvada Sabbavaram Visakhapatnam Andhra Pradesh India.		
Decision: Approved.		

184.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore**
	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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 23483: 22-09-2023
	Details of fee submitted	PKR 30,000/- : 13-09-2023
	The proposed proprietary name / brand name	**XYPEL ODT 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Orally Disintegrating Tablet Contains: Olanzapine…5mg
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Danlanza ODT Tablet by Daneen Pharma
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
185.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore**

	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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 23484: 22-09-2023
	Details of fee submitted	PKR 30,000/- : 13-09-2023
	The proposed proprietary name / brand name	**XYPEL ODT 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Orally Disintegrating Tablet Contains: Olanzapine…10mg
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Danlanza ODT Tablet by Daneen Pharma
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
186.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore**
	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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 23485: 22-09-2023
	Details of fee submitted	PKR 30,000/- : 13-09-2023
	The proposed proprietary name / brand name	**XYPEL ODT 15mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Orally Disintegrating Tablet Contains: Olanzapine…15mg
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Danlanza ODT Tablet by Daneen Pharma
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		
187.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore**
	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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 23486: 22-09-2023

	Details of fee submitted	PKR 30,000/- : 13-09-2023
	The proposed proprietary name / brand name	**XYPEL ODT 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Orally Disintegrating Tablet Contains: Olanzapine…20mg
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Danlanza ODT Tablet by Daneen Pharma
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		

188.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K**
	Name, address of Manufacturing site.	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22332: 11-09-2023
	Details of fee submitted	PKR 30,000/- : 19-07-2023
	The proposed proprietary name / brand name	**W-INJECT 10ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Ampoule Contains: Water for Injection…10ml
	Pharmacotherapeutic Group of (API)	Diluent
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	WFI by Surge
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		

189.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan**
	Name, address of Manufacturing site.	M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 23473: 22-09-2023
	Details of fee submitted	PKR 30,000/- : 29-08-2023
	The proposed proprietary name / brand name	**Sterile Water for Injection 10ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Ampoule Contains: Sterile Water for Injection…10ml
	Pharmacotherapeutic Group of (API)	Diluent

	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	WFI by Surge
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision: Approved.		

190.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore**
	Name, address of Manufacturing site.	M/s Winlet Pharmaceuticals. 30-km, Lahore Sargodha Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22952: 19-09-2023
	Details of fee submitted	PKR 30,000/- : 16-09-2023
	The proposed proprietary name / brand name	**CRUZ 90mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Etoricoxib…90mg
	Pharmacotherapeutic Group of (API)	Antiinflammatory and antirheumatic products, non-steroids
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Starcox Tablet by Getz
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit evidence of approval of requisite section approval from Licensing Division	Submitted
2.	Submit evidence of procurement of API.	Submitted
3.	Submit BMR of stability batches	Submitted
4.	Submit record of digital data logger of stability chambers	Submitted

Decision: Approved.

191.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, KPK**
	Name, address of Manufacturing site.	M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, KPK
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 23763: 27-09-2023
	Details of fee submitted	PKR 30,000/- : 11-08-2023
	The proposed proprietary name / brand name	**ATHNOX 60mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Etoricoxib…60mg

	Pharmacotherapeutic Group of (API)	Antiinflammatory and antirheumatic products, non-steroids
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Starcox Tablet by Getz
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit valid GMP certificate of API manufacturer	Submitted
2.	Submit evidence of procurement of API.	Submitted
3.	Submit complete report of validation studies of analytical method of drug product	Submitted

Decision: Approved.

b. Deferred cases

192.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ameer & Adnan Pharmaceutical Pvt Ltd. Plot No.47, Sundar Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Shawan Pharmaceuticals. Plot No. 37, Road: Ns-01, National Industrial Zone, Rawat, Rawalpindi
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 18075: 18-07-2023
	Details of fee submitted	PKR 75,000/- : 16-06-2023
	The proposed proprietary name / brand name	**AXON 250mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftriaxone as Sodium…250mg
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Oxidil Injection of Sami
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	
2.	Specify whether the application is for IM or IV use	
3.	Submit verification studies of the analytical method of drug substance in section 3.2.S.4.3.	
4.	Submit COA of relevant batch of API from the API manufacturer.	
5.	Justify why pharmaceutical equivalence studies are not conducted against the innovator / reference product.	
6.	Submit compatibility studies with the recommended diluent.	
7.	Submit complete analytical method of the drug product	

8.	Submit complete report of verification studies of the analytical method of drug product instead of submitting a 1 page summary without any protocols and results.	
9.	Submit in-use stability studies report	
10.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data	
11.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
12.	Documents for the procurement of API with approval from DRAP (in case of import).	

Decision of 340th RB meeting: Deferred for submission of reply to above cited shortcomings.

Submission by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	Submitted
2.	Specify whether the application is for IM or IV use	IV use only
3.	Submit verification studies of the analytical method of drug substance in section 3.2.S.4.3.	Submitted
4.	Submit COA of relevant batch of API from the API manufacturer.	Submitted
5.	Justify why pharmaceutical equivalence studies are not conducted against the innovator / reference product.	Submitted with oxidil injection
6.	Submit compatibility studies with the recommended diluent.	Submitted
7.	Submit complete analytical method of the drug product	Submitted
8.	Submit complete report of verification studies of the analytical method of drug product instead of submitting a 1 page summary without any protocols and results.	Submitted
9.	Submit in-use stability studies report	Submitted
10.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data	Submitted
11.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
12.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted

Decision: Approved.

193.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore**
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd. Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 4380: 15-02-2023
	Details of fee submitted	PKR 20,000/- : 23-04-2020 + PKR 10,000/- : 20-01-2023
	The proposed proprietary name / brand name	**NEUBROFEN 400mg/100ml Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 100ml Contains: Ibuprofen…400mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved

	For generic drugs (me-too status)	Aburid infusion by Vision pharma
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in its 275th meeting.	
2.	Submit evidence of requisite manufacturing facility / section approval.	
3.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	
4.	Submit report of verification studies of analytical method of drug substance.	
5.	Submit COA of reference standard / working standard actually used in the analysis of API.	
6.	Justify why your qualitative composition is different from innovator's product.	
7.	Submit pictorial evidence of the product against which pharmaceutical equivalence studies was conducted.	
8.	Provide details including batch number, manufacturer and country from where the product was procured for performing pharmaceutical equivalence studies.	
9.	Clarify why complete validation studies of the analytical method of the drug product was not conducted.	
10.	Submit evidence of import of API including clearance certificate.	
11.	Submit BMR of three stability batches.	

Decision of 336th RB meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Submission by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in its 275th meeting.	Ibuprofen 400 mg solution for infusion (MHRA Approved)
2.	Submit evidence of requisite manufacturing facility / section approval.	LVP section (blow, fill seal) & SVP Section (blow, fill seal)
3.	Submit specifications and analytical method of the drug substance from both API manufacturer as well as product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2.	Submitted
4.	Submit report of verification studies of analytical method of drug substance.	Submitted
5.	Submit COA of reference standard / working standard actually used in the analysis of API.	Submitted
6.	Justify why your qualitative composition is different from innovator's product.	Drug excipient compatability studies provided
7.	Submit pictorial evidence of the product against which pharmaceutical equivalence studies was conducted.	Due to staff turnover packs misplaced we really sorry for this
8.	Provide details including batch number, manufacturer and country from where the product was procured for performing pharmaceutical equivalence studies.	Due to staff turnover packs misplaced we really sorry for this

9.	Clarify why complete validation studies of the analytical method of the drug product was not conducted.	Submitted complete studies
10.	Submit evidence of import of API including clearance certificate.	Commercial invoice dated 20-03-2019 specifying 900g ibuprofen is submitted along with a FedEx receipt.
11.	Submit BMR of three stability batches.	Submitted.

Decision: Approved.

194.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Venus Pharma. 23 km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Venus Pharma. 23 km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 16711: 05-07-2023
	Details of fee submitted	PKR 30,000/- : 30-05-2023
	The proposed proprietary name / brand name	**VIOZONE 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vonoprazan Fumarate Eq. to Vonoprazan…10mg
	Pharmacotherapeutic Group of (API)	Anti Ulcer
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**PMDA** Japan Approved
	For generic drugs (me-too status)	Vonozan Tablet by Getz
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the polymorphic form of the drug substance used in the development of stability batches. Also clarify how the polymorphic form was identified by drug substance manufacturer and drug product manufacturer.	
2.	Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	
3.	Submit verification studies of the analytical method of API performed by drug product manufacturer in section 3.2.S.4.3.	
4.	Submit COA of relevant batch of API from API manufacturer as well as product manufacturer in section 3.2.S.4.4.	
5.	Submit COA of reference / working standard actually used in analysis of drug substance.	
6.	Justify your specificity test in the light of ICH Q2 guidelines, since you have only used diluent. Moreover also justify how placebo was used in the validation of drug substance and drug product.	
7.	Justify how the mixing time at all stages of mixing along with speed (rpm) of mixer will be validated, since your process validation protocols do not specify the mechanism of control/ validation of these parameters since they hold significant importance.	

Decision of 340th RB meeting: Deferred for submission of reply to above cited shortcomings.

Submission by the firm:

Sr. No	Shortcomings communicated	Response by the firm

1.	Specify the polymorphic form of the drug substance used in the development of stability batches. Also clarify how the polymorphic form was identified by drug substance manufacturer and drug product manufacturer.	Submitted, crystalline form
2.	Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	Submitted
3.	Submit verification studies of the analytical method of API performed by drug product manufacturer in section 3.2.S.4.3.	Submitted
4.	Submit COA of relevant batch of API from API manufacturer as well as product manufacturer in section 3.2.S.4.4.	Submitted
5.	Submit COA of reference / working standard actually used in analysis of drug substance.	Submitted
6.	Justify your specificity test in the light of ICH Q2 guidelines, since you have only used diluent. Moreover also justify how placebo was used in the validation of drug substance and drug product.	Submitted, spiking method was used in which spiking of placebo, and excipient was used.
7.	Justify how the mixing time at all stages of mixing along with speed (rpm) of mixer will be validated, since your process validation protocols do not specify the mechanism of control/ validation of these parameters since they hold significant importance.	Submitted. Only mixing time was validated, speed was kept constant

Decision: Approved.

195.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Venus Pharma. 23 km, Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Venus Pharma. 23 km, Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 16710: 05-07-2023
	Details of fee submitted	PKR 30,000/- : 30-05-2023
	The proposed proprietary name / brand name	**VIOZONE 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vonoprazan Fumarate Eq. to Vonoprazan…20mg
	Pharmacotherapeutic Group of (API)	Anti Ulcer
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**PMDA** Japan Approved
	For generic drugs (me-too status)	Vonozan Tablet by Getz
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	**Shortcomings communicated**	**Response by the firm**
1.	Specify the polymorphic form of the drug substance used in the development of stability batches. Also clarify how the polymorphic form was identified by drug substance manufacturer and drug product manufacturer.	
2.	Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	
3.	Submit verification studies of the analytical method of API performed by drug product manufacturer in section 3.2.S.4.3.	

4.	Submit COA of relevant batch of API from API manufacturer as well as product manufacturer in section 3.2.S.4.4.	
5.	Submit COA of reference / working standard actually used in analysis of drug substance.	
6.	Justify your specificity test in the light of ICH Q2 guidelines, since you have only used diluent. Moreover also justify how placebo was used in the validation of drug substance and drug product.	
7.	Justify how the mixing time at all stages of mixing along with speed (rpm) of mixer will be validated, since your process validation protocols do not specify the mechanism of control/ validation of these parameters since they hold significant importance.	
Decision of 340th RB meeting: Deferred for submission of reply to above cited shortcomings.		
Submission by the firm:		
Sr. No	**Shortcomings communicated**	**Response by the firm**
1.	Specify the polymorphic form of the drug substance used in the development of stability batches. Also clarify how the polymorphic form was identified by drug substance manufacturer and drug product manufacturer.	Submitted, crystalline form
2.	Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	Submitted
3.	Submit verification studies of the analytical method of API performed by drug product manufacturer in section 3.2.S.4.3.	Submitted
4.	Submit COA of relevant batch of API from API manufacturer as well as product manufacturer in section 3.2.S.4.4.	Submitted
5.	Submit COA of reference / working standard actually used in analysis of drug substance.	Submitted
6.	Justify your specificity test in the light of ICH Q2 guidelines, since you have only used diluent. Moreover also justify how placebo was used in the validation of drug substance and drug product.	Submitted, spiking method was used in which spiking of placebo, and excipient was used.
7.	Justify how the mixing time at all stages of mixing along with speed (rpm) of mixer will be validated, since your process validation protocols do not specify the mechanism of control/ validation of these parameters since they hold significant importance.	Submitted. Only mixing time was validated, speed was kept constant
Decision: Approved.		

196.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Meditech Pharmaceuticals. Plot No. 83-A, 83-B, Industrial Estate, Hayatabad, Peshawar, Pakistan**
	Name, address of Manufacturing site.	M/s Meditech Pharmaceuticals. Plot No. 83-A, 83-B, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 19529: 07-08-2023
	Details of fee submitted	PKR 30,000/- : 21-06-2023
	The proposed proprietary name / brand name	**AZIMED 250mg Capsule**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Azithromycin as dihydrate…250mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP / BP
	The status in reference regulatory authorities	**MHRA** Approved
	For generic drugs (me-too status)	Azomax by Novartis
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
Decision of 340th RB meeting: Deferred for clarification for the applied specifications whether BP or USP along with evidence of requisite testing equipment.		
Response by the firm: Firm has submitted that their finished product specifications complies with BP specs. Firm has also submitted analytical method along with verification study reports.		
Decision: Approved with BP specifications. Firm shall submit fee Rs. 9000/- for pre-approval correction in drug product specifications as per SRO 1324(I)/2024 dated 30-08-, before issuance of registration letter.		

197.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Meditech Pharmaceuticals. Plot No. 83-A, 83-B, Industrial Estate, Hayatabad, Peshawar, Pakistan**
	Name, address of Manufacturing site.	M/s Meditech Pharmaceuticals. Plot No. 83-A, 83-B, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 19530: 07-08-2023
	Details of fee submitted	PKR 30,000/- : 21-06-2023
	The proposed proprietary name / brand name	**AZIMED 500mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Azithromycin as dihydrate…500mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP / BP
	The status in reference regulatory authorities	RRA status could not be confirmed
	For generic drugs (me-too status)	Azibect 500mg Capsule by Bryon Pharm
	Proposed Pack size	As per SRO
Evaluation by PEC[3]:		
The applied formulation is not available in any reference regulatory authority, however this formulation is already registered in Pakistan.		
Decision of 340th RB meeting: Deferred for clarification for the applied specifications whether BP or USP along with evidence of requisite testing equipment.		
Response by the firm: Firm has submitted that their finished product specifications complies with BP specs. Firm has also submitted analytical method along with verification study reports.		
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.		

198.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s High-Q Pharmaceuticals. Plot No.224 & 225/1, Sector 23, Korangi Industrial Area, Karachi**

	Name, address of Manufacturing site.	M/s High-Q Pharmaceuticals. Plot No.224 & 225/1, Sector 23, Korangi Industrial Area, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 18299: 20-07-2023
	Details of fee submitted	PKR 30,000/- : 05-07-2023
	The proposed proprietary name / brand name	**RIVALXO 2.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Rivaroxaban…2.5mg
	Pharmacotherapeutic Group of (API)	Factor Xa Inhibitor
	Reference to Finished product specifications	Manufacturer's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Xcept Tablet Tablet by PharmEvo
	Proposed Pack size	10's, 14's, 28's, 30's: As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit module 1 as per CTD guidance document in which details of each section / sub section is provided in the relevant place instead of referring to annexures or enclosures etc.	
2.	Specify the polymorphic form of the drug substance used in the development of stability batches. Also clarify how the polymorphic form was identified by drug substance manufacturer and drug product manufacturer.	
3.	Provide details about impurities of drug substance in section 3.2.S.3.2.	
4.	The innovator's product reveals that the drug substance is slightly soluble in methylene chloride, while the API specifications of High Q pharma specifies that the API is very soluble in methylene chloride and is also included as test for API specification. Clarify how such significant difference in solubility can exist.	
5.	Justify why test for heavy metals is part of API specifications of M/s High Q Pharma, since the same test is recommended by API manufacturer and holds a significant importance in maintaining product specifications.	
6.	The API assay analytical method of M/s High Q Pharma is different from the method pf API manufacturer in terms of diluent composition, standard and sample solution preparation and concentration, column specifications, injection size, column temperature, detector wavelength and mobile phase. Moreover, the API manufacturer's method is based on gradient elution while High Q Pharma method is based on isocratic elution. Clarify how drug product manufacturer can adopt different analytical method from that specificed by API manufacturer.	
7.	The API analytical method of High Q Pharma mentioned in section 3.2.S.4.2 is different from the	
8.	The test for repeatability and accuracy in method verification studies involve measure of peak areas for particular test concentrations and its RSD values as also specified in your protocols. However, in the report, you have mentioned test results in terms of % assay and the sample values was in terms of weight of sample instead of concentration. Clarification is required in this regard.	
9.	API manufacturer have specified that the HPLC run time for API testing is 25 minutes while your analysis show that HPLC run time is 8 minutes. Clarification is required in ths regard.	

10. Clarify how you have used the API lot as working standard as well.
11. Provide complete trail for development of COA for working standard.
12. The review of innovator product reveals that the product belongs to BCS class II and to improve the bioavailability, drug substance was used in micronized form. However as per cOA of drug substance and module 3.2.S in your application it is evident that your drug substance is not micronized. Clarification is required that how the product developed without micronized API can be considered equivalent to the innovator's product.
13. Justify the use of betacyclodextrin as excipient in your formulation since the same excipient is not used by the innovator's product. Moreover clarification is also required that betacyclodextrin do not make in situ complexation with the API.
14. Justify why pharmaceutical equivalence is not performed against the innovator's product.
15. The review of innovator's product reveals that the product is practically insoluble in 0.1N HCl. Your CDP results show that the product release more than 65% in 10 minutes and more than 80% in 30 minutes without use of any surfactant etc. Clarification in required in this regard.
16. Justify how drug release of a single tablet at a later time can be less than the drug release at earlier time in 4.5 pH phosphate buffer. The results are tabulated below:

Sample No	10 Mins	15 mins
3	93.08	91.87
5	93.47	92.97
7	95.69	90.21

Scientific justification is required in this regard.

17. Justify how the mixing time at all stages of mixing along with speed (rpm) of mixer will be validated, since your process validation protocols do not specify the mechanism of control/ validation of these parameters and considering the poor water solubility of the product these parameters hold significant importance.
18. The drug product monograph was availabl in BP, while you have developed the product as per in house specs, justification is required in this regard.
19. The assay method of the drug product as per BP is based on gradient elution in HPLC. Similar method is also specified by API manufacturer as well. While your analytical method is based on isocratic elution. Clarification is required in this regard.
20. Justify your specificity test in the light of ICH Q2 guidelines, since you have only used diluent. Moreover also justify how placebo was used in the validation of drug substance and drug product.
21. The analytical method of drug prodct (section 3.2.P.5.2) specifies that sampling time for dissolution test is 45 minutes, while in the specifications you have mentioned 30 minutes. Clarification is required in this regard.
22. Submit valid GMP certificate of the API manufacturer issued by relevant regulatory authority of the country of origin. Since you have submitted GMP certificate issued by Shaoguan Pharmaceutical Association which is not a regulatory authority.

Decision of 340th RB meeting: Deferred for submission of reply to above cited shortcomings.

Submission by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit module 1 as per CTD guidance document in which details of each section / sub section is provided in the relevant place instead of referring to annexures or enclosures etc.	Submitted.
2.	Specify the polymorphic form of the drug substance used in the development of stability batches. Also clarify how the polymorphic form was identified by drug substance manufacturer and drug product manufacturer.	Modification I form

3.	Provide details about impurities of drug substance in section 3.2.S.3.2.	Submitted
4.	The innovator's product reveals that the drug substance is slightly soluble in methylene chloride, while the API specifications of High Q pharma specifies that the API is very soluble in methylene chloride and is also included as test for API specification. Clarify how such significant difference in solubility can exist.	In the High-Q specification of API, the solubility was **incompletely mentioned**; it should been as" soluble in methylene chloride and methanol mixture"
5.	Justify why test for heavy metals is part of API specifications of M/s High Q Pharma, since the same test is recommended by API manufacturer and holds a significant importance in maintaining product specifications.	In this case, by **mistake** the test for Heavy Metal was not Included and so in the COA. In order to comply with the requirement, we have performed this test following the procedure given in the DMF; the result found compliant with the requirement
6.	The API assay analytical method of M/s High Q Pharma is different from the method pf API manufacturer in terms of diluent composition, standard and sample solution preparation and concentration, column specifications, injection size, column temperature, detector wavelength and mobile phase. Moreover, the API manufacturer's method is based on gradient elution while High Q Pharma method is based on isocratic elution. Clarify how drug product manufacturer can adopt different analytical method from that specificed by API manufacturer.	While starting development work on this product, we explored various research journal/articles for the testing method and finally got one, as **complete DMF was not shared with us**. The identified HPLC method was then validated before adoption.
7.	The API analytical method of High Q Pharma mentioned in section 3.2.S.4.2 is different from the	
8.	The test for repeatability and accuracy in method verification studies involve measure of peak areas for particular test concentrations and its RSD values as also specified in your protocols. However, in the report, you have mentioned test results in terms of % assay and the sample values was in terms of weight of sample instead of concentration. Clarification is required in this regard.	Worksheet for clarificaaton is submitted.
9.	API manufacturer have specified that the HPLC run time for API testing is 25 minutes while your analysis show that HPLC run time is 8 minutes. Clarification is required in ths regard.	Kindly note that the change in run time is basically due to use of **different HPLC method**. We will follow BP method for the commercial product, after approval from DRAP
10.	Clarify how you have used the API lot as working standard as well.	Please note that due to consumption and availability of very low leftover quantity of Working Standard supplied by the API manufacturer, we had qualified the available in-use lot of Rivaroxaban against the above working standard
11.	Provide complete trail for development of COA for working standard.	Submitted.
12.	The review of innovator product reveals that the product belongs to BCS class II and to improve the bioavailability, drug substance was used in micronized form. However as per cOA of drug substance and module 3.2.S in your application it is evident that your drug substance is not micronized. Clarification is required that how the product	Powder is micronized to increase surface area that leads to improved dissolution rates, and enhanced bioavailability. Knowing that the **API used by us was not micronized**, we had used **betacyclodextrin, as dissolution & solubility enhancer** in the formulation

	developed without micronized API can be considered equivalent to the innovator's product.	
13.	Justify the use of betacyclodextrin as excipient in your formulation since the same excipient is not used by the innovator's product. Moreover clarification is also required that betacyclodextrin do not make in situ complexation with the API.	Betacyclodextrin is mainly been used as complexing agent to increase the aqueous solubility of API and dissolution. When cyclodextrins are used in solid dosage forms like tablets, they can also reduce the interaction of the drug with excipients. The solubility and dissolution rate of Rivaroxaban can be increased via **formation of inclusion complex with βCD**. Advance characterization of FTIR, SEM, XRD and DSC results of prepared **binary inclusion complexes** has confirmed the successful inclusion complexation of Rivaroxaban with cyclodextrin
14.	Justify why pharmaceutical equivalence is not performed against the innovator's product.	Since Xarelto 2.5mg Tablet (Innovator product) was not available in the market at that time hence, we performed the Pharmaceutical equivalence with Xcept 2.5mg tablet
15.	The review of innovator's product reveals that the product is practically insoluble in 0.1N HCl. Your CDP results show that the product release more than 65% in 10 minutes and more than 80% in 30 minutes without use of any surfactant etc. Clarification in required in this regard.	Betacyclodextrin used in the formulation as surfactant has enhanced the solubility and dissolution.
16.	Justify how drug release of a single tablet at a later time can be less than the drug release at earlier time in 4.5 pH phosphate buffer. The results are tabulated below: Sample No 10 Mins 15 mins 3 93.08 91.87 5 93.47 92.97 7 95.69 90.21 Scientific justification is required in this regard.	Kindly treat this as "**transcription error**" as the results, by mistake reported in the wrong column i.e., data of 10 mins entered in the column for 15 mins and vice versa.
17.	Justify how the mixing time at all stages of mixing along with speed (rpm) of mixer will be validated, since your process validation protocols do not specify the mechanism of control/ validation of these parameters and considering the poor water solubility of the product these parameters hold significant importance.	Firm has now submitted a table showing control variables for dry mixing and lubrication and final mixing.
18.	The drug product monograph was availabl in BP, while you have developed the product as per in house specs, justification is required in this regard.	We had started development work in 2020 while according to our knowledge this product (Rivaroxaban Tablet) was included in BP in 2021
19.	The assay method of the drug product as per BP is based on gradient elution in HPLC. Similar method is also specified by API manufacturer as well. While your analytical method is based on isocratic elution. Clarification is required in this regard.	Please note that while starting development work on this product, **we explored various research journal/articles** for the testing method and finally got one for tablets. The identified HPLC method was then validated before adoption.
20.	Justify your specificity test in the light of ICH Q2 guidelines, since you have only used diluent.	Justification for use of placebo in drug substance is **not** submitted.

	Moreover also justify how placebo was used in the validation of drug substance and drug product.	
21.	The analytical method of drug prodct (section 3.2.P.5.2) specifies that sampling time for dissolution test is 45 minutes, while in the specifications you have mentioned 30 minutes. Clarification is required in this regard.	Kindly treat this as **Typo error**, as correct sampling time (45 mins) is given under test conditions in same document
22.	Submit valid GMP certificate of the API manufacturer issued by relevant regulatory authority of the country of origin. Since you have submitted GMP certificate issued by Shaoguan Pharmaceutical Association which is not a regulatory authority.	DML is submitted.
Decision: Approved with Innovator's specifications. Firm shall use micrnozied API in their formulation for commercial manufacturing as per the reference product.		

199.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Well & Well Pharma Pvt Ltd. Plot 7, Street S-8, RCCI, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Well & Well Pharma Pvt Ltd. Plot 7, Street S-8, RCCI, Rawat, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 21207: 28-08-2023
	Details of fee submitted	PKR 30,000/- : 18-07-2023
	The proposed proprietary name / brand name	**ITRAWEL 100mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Itraconazole (as IR pellets)…100mg
	Pharmacotherapeutic Group of (API)	Antimycotics for systemic use.
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Rolac 100mg Capsules, Sami Pharmaceuticals
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Source of Pellets: M/s Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.

Sr. No	**Shortcomings communicated**	**Response by the firm**
1.	Specify the polymorphic form of the drug substance used in the development of stability batches. Also clarify how the polymorphic form was identified by drug substance manufacturer and drug product manufacturer.	
2.	Drug substance manufacturer as well as USP has specified a single HPLC based method for assay testing of pellets, while the drug product mnanufacturer has adopted an alternate in house method based on UV testing. Clarification is required in this regard.	
3.	Specify what is placebo in the specificity test of the pellets. Further specify how the specificity test was conducted.	
4.	Submit COA of reference / working standard actually used in analysis of drug substance.	
5.	Justify your comparative dissolution profile studies without calculation of %RSD and CV values at each time interval and determination of similarity factor using model independent approach.	

6.	Justify your process validation protocols without specifying the critical steps and intermediates.
7.	Provide details about the capsule shell in section 3.2.P.4 and also clarify the source of your capsule shell whether gelatinor HPMC whether manufactured using bovine source or otherwise. Moreover in case of natural source provide certification that the sheels are TSE and BSE free.
8.	Justify the analytical method for drug product in which alternate method for assay test is specified, while no such test is mentioned in USP.
9.	Submit evidence of procurement of drug substance.

Decision of 340th RB meting: Deferred for submission of reply to above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the polymorphic form of the drug substance used in the development of stability batches. Also clarify how the polymorphic form was identified by drug substance manufacturer and drug product manufacturer.	We have purchased ready to fill pellets from Vision pharma. They are also purchasing API from another source and do not have complete details of polymorphic form. They have asked API manufacturer to provide its detail. They will share as soon as it is available.
2.	Drug substance manufacturer as well as USP has specified a single HPLC based method for assay testing of pellets, while the drug product mnanufacturer has adopted an alternate in house method based on UV testing. Clarification is required in this regard.	All testing done as per USP. Alternate method only written as second line choice.
3.	Specify what is placebo in the specificity test of the pellets. Further specify how the specificity test was conducted.	Firm has submitted report of validation studies of Vision pharma. The clarification from drug product manufacturer is not provided, they have again provided specificity test result which say specificity was determined by spiking the blank sample with appropriate level of test sample and excipients.
4.	Submit COA of reference / working standard actually used in analysis of drug substance.	Submitted from Vision pharma
5.	Justify your comparative dissolution profile studies without calculation of %RSD and CV values at each time interval and determination of similarity factor using model independent approach.	Submitted
6.	Justify your process validation protocols without specifying the critical steps and intermediates.	Submitted
7.	Provide details about the capsule shell in section 3.2.P.4 and also clarify the source of your capsule shell whether gelatinor HPMC whether manufactured using bovine source or otherwise. Moreover in case of natural source provide certification that the sheels are TSE and BSE free.	Gelatin capsule from halal source supplied by Multicaps
8.	Justify the analytical method for drug product in which alternate method for assay test is specified, while no such test is mentioned in USP.	All testing done as per USP. Alternate method only written as second line choice.
9.	Submit evidence of procurement of drug substance.	Submitted.

Decision: Approved.

200.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Well & Well Pharma Pvt Ltd. Plot 7, Street S-8, RCCI, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Well & Well Pharma Pvt Ltd. Plot 7, Street S-8, RCCI, Rawat, Islamabad

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 21208: 28-08-2023
	Details of fee submitted	PKR 30,000/- : 18-07-2023
	The proposed proprietary name / brand name	**TERBIWEL 125mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Terbinafine HCl Eq. to Terbinafine…125mg
	Pharmacotherapeutic Group of (API)	Antifungal
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Terbiderm Tablet by Atco
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the polymorphic form of the drug substance used in the development of stability batches. Also clarify how the polymorphic form was identified by drug substance manufacturer and drug product manufacturer.	
2.	Justify how drug product manufacturer can adopt different analytical method for testing of drug substance, since your analytical method is different from that specified by pharmacopoeia and API manufacturer.	
3.	Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3.	
4.	Justify your comparative dissolution profile studies without calculation of %RSD and CV values at each time interval and determination of similarity factor using model independent approach.	
5.	Justify your process validation protocols without specifying the critical steps and intermediates.	
6.	Justify how the mixing time at all stages of mixing along with speed (rpm) of mixer will be validated, since your process validation protocols do not specify the mechanism of control/ validation of these parameters since they hold significant importance.	
7.	Justify the analytical method for drug product in which alternate method for assay test is specified, while no such test is mentioned in USP.	
8.	Specify what is placebo in the specificity test of the pellets. Further specify how the specificity test was conducted.	

Decision of 340th RB meeting: Deferred for submission of reply to above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the polymorphic form of the drug substance used in the development of stability batches. Also clarify how the polymorphic form was identified by drug substance manufacturer and drug product manufacturer.	There is no polymorphic form reported for the drug substance in literature. However API manufactured by this API manufacturer is crystalline form.
2.	Justify how drug product manufacturer can adopt different analytical method for testing of drug substance, since your analytical method is different from that specified by pharmacopoeia and API manufacturer.	All testing done as per USP. Alternate method only written as second line choice.
3.	Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3.	Submitted from API manufacturer only.

4.	Justify your comparative dissolution profile studies without calculation of %RSD and CV values at each time interval and determination of similarity factor using model independent approach.	Submitted
5.	Justify your process validation protocols without specifying the critical steps and intermediates.	Revised protocols are submitted
6.	Justify how the mixing time at all stages of mixing along with speed (rpm) of mixer will be validated, since your process validation protocols do not specify the mechanism of control/ validation of these parameters since they hold significant importance.	Revised protocols are submitted
7.	Justify the analytical method for drug product in which alternate method for assay test is specified, while no such test is mentioned in USP.	All testing done as per USP. Alternate method only written as second line choice.
8.	Specify what is placebo in the specificity test of the pellets. Further specify how the specificity test was conducted.	No pellets were used in this product.

Decision: Approved.

201.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Well & Well Pharma Pvt Ltd. Plot 7, Street S-8, RCCI, Rawat, Islamabad**
	Name, address of Manufacturing site.	M/s Well & Well Pharma Pvt Ltd. Plot 7, Street S-8, RCCI, Rawat, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 21209: 28-08-2023
	Details of fee submitted	PKR 30,000/- : 18-07-2023
	The proposed proprietary name / brand name	**TERBIWEL Forte 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Terbinafine HCl Eq. to Terbinafine…250mg
	Pharmacotherapeutic Group of (API)	Antifungal
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Terbiderm Tablet by Atco
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Sr. No	**Shortcomings communicated**	**Response by the firm**
1.	Specify the polymorphic form of the drug substance used in the development of stability batches. Also clarify how the polymorphic form was identified by drug substance manufacturer and drug product manufacturer.	
2.	Justify how drug product manufacturer can adopt different analytical method for testing of drug substance, since your analytical method is different from that specified by pharmacopoeia and API manufacturer.	
3.	Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3.	
4.	Justify your comparative dissolution profile studies without calculation of %RSD and CV values at each time interval and determination of similarity factor using model independent approach.	
5.	Justify your process validation protocols without specifying the critical steps and intermediates.	

6.	Justify how the mixing time at all stages of mixing along with speed (rpm) of mixer will be validated, since your process validation protocols do not specify the mechanism of control/ validation of these parameters since they hold significant importance.
7.	Justify the analytical method for drug product in which alternate method for assay test is specified, while no such test is mentioned in USP.
8.	Specify what is placebo in the specificity test of the pellets. Further specify how the specificity test was conducted.

Decision of 340th RB meeting: Deferred for submission of reply to above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the polymorphic form of the drug substance used in the development of stability batches. Also clarify how the polymorphic form was identified by drug substance manufacturer and drug product manufacturer.	There is no polymorphic form reported for the drug substance in literature. However API manufactured by this API manufacturer is crystalline form.
2.	Justify how drug product manufacturer can adopt different analytical method for testing of drug substance, since your analytical method is different from that specified by pharmacopoeia and API manufacturer.	All testing done as per USP. Alternate method only written as second line choice.
3.	Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3.	Submitted from API manufacturer only.
4.	Justify your comparative dissolution profile studies without calculation of %RSD and CV values at each time interval and determination of similarity factor using model independent approach.	Submitted
5.	Justify your process validation protocols without specifying the critical steps and intermediates.	Revised protocols are submitted
6.	Justify how the mixing time at all stages of mixing along with speed (rpm) of mixer will be validated, since your process validation protocols do not specify the mechanism of control/ validation of these parameters since they hold significant importance.	Revised protocols are submitted
7.	Justify the analytical method for drug product in which alternate method for assay test is specified, while no such test is mentioned in USP.	All testing done as per USP. Alternate method only written as second line choice.
8.	Specify what is placebo in the specificity test of the pellets. Further specify how the specificity test was conducted.	No pellets were used in this product.

Decision: Approved.

202.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Aptcure Pvt Ltd 8- Pharma City, 30 km Multan Road, Lahore**
	Name, address of Manufacturing site.	M/s Aptcure Pvt Ltd 8- Pharma City, 30 km Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 19521: 07-08-2023
	Details of fee submitted	PKR 30,000/- : 17-07-2023
	The proposed proprietary name / brand name	**APTRA 100mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Itraconazole (as IR pellets)…100mg
	Pharmacotherapeutic Group of (API)	Antimycotics for systemic use.

	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Rolac 100mg Capsules, Sami Pharmaceuticals
	Proposed Pack size	As per SRO

Evaluation by PEC[3]:

Source of Pellets: M/s Vision Pharmaceuticals (Pvt) Ltd Plot No. 22-23, Industrial Triangle Kahuta Road Islamabad.

Sr. No	Shortcomings communicated	Response by the firm
1.	Source of pellets specified in module 1 is M/s Vision Pharma, while source of pellets in module 3 is M/s Surge Pharma. Clarification is required along with submission of requisite fee for change of API manufacturer.	
2.	Specify the polymorphic form of the drug substance used in the development of stability batches. Also clarify how the polymorphic form was identified by drug substance manufacturer and drug product manufacturer.	
3.	Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	
4.	Submit report of verification studies of analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3.	
5.	Submit COA of reference / working standard actually used in analysis of drug substance. Since you have submitted USP reference standard certificate without providing its evidence of import.	
6.	Justify your comparative dissolution profile studies without calculation of %RSD values at each time interval and determination of similarity factor using model independent approach.	
7.	Identify the critical steps and intermediates in section 3.2.P.3.4, since you have only mentioned general statements instead of providing product specific controls.	
8.	Provide details about the capsule shell in section 3.2.P.4 and also clarify the source of your capsule shell whether gelatinor HPMC whether manufactured using bovine source or otherwise. Moreover in case of natural source provide certification that the sheels are TSE and BSE free.	
9.	Justify how the concentration of your standard solution is 0.06mg/ml since the concentration achieved using your method is 0.1mg/ml. Moreover USP also specify concentration different from 0.06mg/ml	
10.	Justify the test of repeatability in which you have performed all tests at 0.06mg/ml which is not the target concentration "A" Moreover also justify how will you interpret your results as per ICH Q2 guidelines since you have performed required statistical calculation.	
11.	Justify the test of accuracy using a single test run at each concentration.	
12.	Justify your specificity test in the light of ICH Q2 guidelines, since you have only used Mobile phase instead of placebo.	
13.	Submit stability study data in section 3.2.P.8.3 as per 6 points checklist as per the CTD guidance document since you have submitted data with multiple annexures without any sequence or checklist and the data is unorganized.	

Decision of 340th RB meeting: Deferred for submission of reply to above cited shortcomings.

Submission by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Source of pellets specified in module 1 is M/s Vision Pharma, while source of pellets in module 3 is M/s Surge Pharma. Clarification is required along with submission of requisite fee for change of API manufacturer.	It was a typo error, we purchased pellets from M/s Surge

2.	Specify the polymorphic form of the drug substance used in the development of stability batches. Also clarify how the polymorphic form was identified by drug substance manufacturer and drug product manufacturer.	Durimg staility polymorphic form was monitored using IR.
3.	Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	Submitted
4.	Submit report of verification studies of analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3.	Submitted
5.	Submit COA of reference / working standard actually used in analysis of drug substance. Since you have submitted USP reference standard certificate without providing its evidence of import.	Submitted
6.	Justify your comparative dissolution profile studies without calculation of %RSD values at each time interval and determination of similarity factor using model independent approach.	Submitted
7.	Identify the critical steps and intermediates in section 3.2.P.3.4, since you have only mentioned general statements instead of providing product specific controls.	Submitted
8.	Provide details about the capsule shell in section 3.2.P.4 and also clarify the source of your capsule shell whether gelatinor HPMC whether manufactured using bovine source or otherwise. Moreover in case of natural source provide certification that the sheels are TSE and BSE free.	Halal gelatin capsule by multicaps
9.	Justify how the concentration of your standard solution is 0.06mg/ml since the concentration achieved using your method is 0.1mg/ml. Moreover USP also specify concentration different from 0.06mg/ml	Analysis of drug substance in product part was performed as per USP at targrt concentration of 0.1mg/ml. No clarification submitted.
10.	Justify the test of repeatability in which you have performed all tests at 0.06mg/ml which is not the target concentration "A" Moreover also justify how will you interpret your results as per ICH Q2 guidelines since you have performed required statistical calculation.	No relevant clarification submitted.
11.	Justify the test of accuracy using a single test run at each concentration.	No relevant clarification submitted.
12.	Justify your specificity test in the light of ICH Q2 guidelines, since you have only used Mobile phase instead of placebo.	In the absence of excipients since it was ready to fill pellets mobile phase was utilized instead of placebo for testing.
13.	Submit stability study data in section 3.2.P.8.3 as per 6 points checklist as per the CTD guidance document since you have submitted data with multiple annexures without any sequence or checklist and the data is unorganized.	Evidence of purchase of API, record of digital data logger is not submitted.
Decision: Approved.		

203.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura**
	Name, address of Manufacturing site.	M/s Mcolson Research Laboratories Pvt Ltd. 26 km Lahore-Sheikhupura Road, Sheikhupura
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 18914: 27-07-2023
	Details of fee submitted	PKR 30,000/- : 21-06-2023
	The proposed proprietary name / brand name	**PROPYLTHIOURACIL 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Uncoated Tablet Contains: Propylthiouracil…50mg
	Pharmacotherapeutic Group of (API)	Antithyroid agent
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	Procarbizole Tablet by Pharmedic
	Proposed Pack size	10's, 20's, 100's: As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the polymorphic form of the drug substance used in the development of stability batches. Also clarify how the polymorphic form was identified by drug substance manufacturer and drug product manufacturer.	
2.	Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	
3.	Justify how specificity test was performed in the verification studies of analytical method of drug substance.	
4.	Submit COA of reference / working standard actually used in analysis of drug substance.	
5.	Justify your specificity test in the light of ICH Q2 guidelines, since you have only used diluent. Moreover also justify how placebo was used in the validation of drug substance and drug product.	
6.	Justify how the mixing time at all stages of mixing along with speed (rpm) of mixer will be validated, since your process validation protocols do not specify the mechanism of control/ validation of these parameters since they hold significant importance.	

Decision of 340th RB meeting: Deferred for submission of reply to above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the polymorphic form of the drug substance used in the development of stability batches. Also clarify how the polymorphic form was identified by drug substance manufacturer and drug product manufacturer.	We did structural characterization in comparison with working standard and USPand according to PXRD which inferred to be the same srydtal type.
2.	Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 for drug substances.	Submitted
3.	Justify how specificity test was performed in the verification studies of analytical method of drug substance.	Submitted
4.	Submit COA of reference / working standard actually used in analysis of drug substance.	Submitted
5.	Justify your specificity test in the light of ICH Q2 guidelines, since you have only used diluent. Moreover also justify how placebo was used in the validation of drug substance and drug product.	Submitted

6.	Justify how the mixing time at all stages of mixing along with speed (rpm) of mixer will be validated, since your process validation protocols do not specify the mechanism of control/ validation of these parameters since they hold significant importance.	Revised process validation protocols submitted.

Decision: Approved. Firm shall submit fee Rs. 9000/- for pre-approval variation as per SRO 1324(I)/2024 dated 30-08-, before issuance of registration letter.

204.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Next Pharmaceutical Products (Pvt) Ltd, Plot No. 44 A-B, Sundar Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Next Pharmaceutical Products (Pvt) Ltd, Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 18301: 20-07-2023
	Details of fee submitted	PKR 30,000/- : 13-07-2023
	The proposed proprietary name / brand name	**VONOPRAZAN 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vonoprazan Fumarate Eq. to Vonoprazan…10mg
	Pharmacotherapeutic Group of (API)	Anti Ulcer
	Reference to Finished product specifications	Manufacturer's
	The status in reference regulatory authorities	**PMDA** Japan Approved
	For generic drugs (me-too status)	Vonozan Tablet by Getz
	Proposed Pack size	7's, 14's, 28's, 30's: As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the polymorphic form of the drug substance used in the development of stability batches. Also clarify how the polymorphic form was identified by drug substance manufacturer and drug product manufacturer.	
2.	Submit APIstability study data till claimed shelf life since you have submitted long term stability data for 12 months only.	
3.	Justify why pharmaceutical equivalence studies are conducted against the innovator's product	
4.	Justify why dissolution test is not performed in pharmaceutical equivalence studies.	
5.	Justify how drug release of a single tablet reduces with time i.e. drug release of vessel 1 at 1.2pH stage at 15 minutes is 101.50 and the drug release of same vessel at 45 minutes is 94.10. Scientific justification is required how drug content of a single vessel can reduce and that you analytical procedure is not compromised.	
6.	Justify how the mixing time at all stages of mixing along with speed (rpm) of mixer will be validated, since your process validation protocols do not specify the mechanism of control/ validation of these parameters since they hold significant importance.	
7.	The innovator's product has recommended 15 minutes for dissolution test with 4.5pH acetate buffer as dissolution medium, while you have conducted dissolution test at 30 minutes with 6.8pH phosphate buffer.	

	Revise your specification and submit results as per the innovator's recommendation.	
8.	Justify the dissolution results consistently above 105% while the assay results are near 100% and no overage have been used.	
9.	Submit 6 month's stability study data.	

Decision of 340th RB meeting: Deferred for submission of reply to above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the polymorphic form of the drug substance used in the development of stability batches. Also clarify how the polymorphic form was identified by drug substance manufacturer and drug product manufacturer.	Crystalline Form-A
2.	Submit APIstability study data till claimed shelf life since you have submitted long term stability data for 12 months only.	Submitted
3.	Justify why pharmaceutical equivalence studies are conducted against the innovator's product	Innovator product is not available in Pakistan that's why CDP were conducted againt Vonozan tablet of Getz pharma
4.	Justify why dissolution test is not performed in pharmaceutical equivalence studies.	We relied on CDP results for dissolution test
5.	Justify how drug release of a single tablet reduces with time i.e. drug release of vessel 1 at 1.2pH stage at 15 minutes is 101.50 and the drug release of same vessel at 45 minutes is 94.10. Scientific justification is required how drug content of a single vessel can reduce and that you analytical procedure is not compromised.	During analysis when place in HPLC autosampler then it is possible then sample of same vessel vial position may be changed by analyst so result of single vessel vary but average is comparable.
6.	Justify how the mixing time at all stages of mixing along with speed (rpm) of mixer will be validated, since your process validation protocols do not specify the mechanism of control/ validation of these parameters since they hold significant importance.	Revised process validation protocols are submitted.
7.	The innovator's product has recommended 15 minutes for dissolution test with 4.5pH acetate buffer as dissolution medium, while you have conducted dissolution test at 30 minutes with 6.8pH phosphate buffer. Revise your specification and submit results as per the innovator's recommendation.	Revised specifications is submitted. Results observed in CDP already comply with specifications
8.	Justify the dissolution results consistently above 105% while the assay results are near 100% and no overage have been used.	Assay is erformed by weighing and crushing 20 tablets and become uniform but in dissolution in single sample is taken and due to trial batch and small quantity the API quantity may vary and cause higher results.
9.	Submit 6 month's stability study data.	Submitted.

Decision: Approved with Innovator's specifications. Firm shall submit fee Rs. 9000/- for pre-approval correction in drug product specifications as per SRO 1324(I)/2024 dated 30-08-, before issuance of registration letter.

205.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Next Pharmaceutical Products (Pvt) Ltd, Plot No. 44 A-B, Sundar Industrial Estate, Lahore**
	Name, address of Manufacturing site.	M/s Next Pharmaceutical Products (Pvt) Ltd, Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 18844: 26-07-2023
	Details of fee submitted	PKR 30,000/- : 13-07-2023
	The proposed proprietary name / brand name	**VONOPRAZAN 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vonoprazan Fumarate Eq. to Vonoprazan…20mg
	Pharmacotherapeutic Group of (API)	Anti Ulcer
	Reference to Finished product specifications	Manufacturer's
	The status in reference regulatory authorities	**PMDA** Japan Approved
	For generic drugs (me-too status)	Vonozan Tablet by Getz
	Proposed Pack size	7's, 14's, 28's, 30's: As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the polymorphic form of the drug substance used in the development of stability batches. Also clarify how the polymorphic form was identified by drug substance manufacturer and drug product manufacturer.	
2.	Submit APIstability study data till claimed shelf life since you have submitted long term stability data for 12 months only.	
3.	Justify why pharmaceutical equivalence studies are conducted against the innovator's product	
4.	Justify why dissolution test is not performed in pharmaceutical equivalence studies.	
5.	Justify how drug release of a single tablet reduces with time i.e. drug release of vessel 1 at 1.2pH stage at 15 minutes is 101.50 and the drug release of same vessel at 45 minutes is 94.10. Scientific justification is required how drug content of a single vessel can reduce and that you analytical procedure is not compromised.	
6.	Justify how the mixing time at all stages of mixing along with speed (rpm) of mixer will be validated, since your process validation protocols do not specify the mechanism of control/ validation of these parameters since they hold significant importance.	
7.	The innovator's product has recommended 15 minutes for dissolution test with 4.5pH acetate buffer as dissolution medium, while you have conducted dissolution test at 30 minutes with 6.8pH phosphate buffer. Revise your specification and submit results as per the innovator's recommendation.	
8.	Justify the dissolution results consistently above 105% while the assay results are near 100% and no overage have been used.	
9.	Submit 6 month's stability study data.	

Decision of 340th RB meeting: Deferred for submission of reply to above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	Specify the polymorphic form of the drug substance used in the development of stability batches. Also clarify how the polymorphic form was identified by drug substance manufacturer and drug product manufacturer.	Crystalline Form-A
2.	Submit APIstability study data till claimed shelf life since you have submitted long term stability data for 12 months only.	Submitted
3.	Justify why pharmaceutical equivalence studies are conducted against the innovator's product	Innovator product is not available in Pakistan that's why

		CDP were conducted againt Vonozan tablet of Getz pharma
4.	Justify why dissolution test is not performed in pharmaceutical equivalence studies.	We relied on CDP results for dissolution test
5.	Justify how drug release of a single tablet reduces with time i.e. drug release of vessel 1 at 1.2pH stage at 15 minutes is 101.50 and the drug release of same vessel at 45 minutes is 94.10. Scientific justification is required how drug content of a single vessel can reduce and that you analytical procedure is not compromised.	During analysis when place in HPLC autosampler then it is possible then sample of same vessel vial position may be changed by analyst so result of single vessel vary but average is comparable.
6.	Justify how the mixing time at all stages of mixing along with speed (rpm) of mixer will be validated, since your process validation protocols do not specify the mechanism of control/ validation of these parameters since they hold significant importance.	Revised process validation protocols are submitted.
7.	The innovator's product has recommended 15 minutes for dissolution test with 4.5pH acetate buffer as dissolution medium, while you have conducted dissolution test at 30 minutes with 6.8pH phosphate buffer. Revise your specification and submit results as per the innovator's recommendation.	Revised specifications is submitted. Results observed in CDP already comply with specifications
8.	Justify the dissolution results consistently above 105% while the assay results are near 100% and no overage have been used.	Assay is erformed by weighing and crushing 20 tablets and become uniform but in dissolution in single sample is taken and due to trial batch and small quantity the API quantity may vary and cause higher results.
9.	Submit 6 month's stability study data.	Submitted.
Decision: Approved with Innovator's specifications. Firm shall submit fee Rs. 9000/- for pre-approval correction in drug product specifications as per SRO 1324(I)/2024 dated 30-08-, before issuance of registration letter.		

206.	**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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 6028: 03-03-2023
	Details of fee submitted	PKR 75,000/- : 22-02-2023
	The proposed proprietary name / brand name	**ZOBLIN 120mg/4.8ml Oral Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Celecoxib……25mg
	Pharmacotherapeutic Group of (API)	COX 2 Inhibitor
	Reference to Finished product specifications	Innovator's
	The status in reference regulatory authorities	**USFDA** Approved
	For generic drugs (me-too status)	NA
	Proposed Pack size	10ml bottle (containing 4.8ml liquid), 6's pack size / Price As per SRO
Evaluation by PEC[3]:		

Sr. No	Shortcomings communicated	Response by the firm
1.	The innovator's product is a stable non-aquous microemulsion and available as viscous solution, while your formulation is a oral solution available as clear and colorless solution.	
2.	Justify why the test for viscosity, droplet size, and microbiological testing is not included in drug product specifications.	

Decision of 339th RB meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Sr. No	Shortcomings communicated	Response by the firm
1.	The innovator's product is a stable non-aquous microemulsion and available as viscous solution, while your formulation is a oral solution available as clear and colorless solution.	Our drug product is a stable, non-aqueous microemulsion and viscous solution. However, we have referenced the FDA-CDER description for ELYXYB (celecoxib) oral solution, which is described as a clear, colorless oral solution. The relevant reference has been attached.
2.	Justify why the test for viscosity, droplet size, and microbiological testing is not included in drug product specifications.	We conducted the quality tests for the Celecoxib oral solution as outlined in the United States Pharmacopeia section <2> on Oral Drug Products - Product Quality Tests. We performed both the Universal Tests for Oral Drug Products and the Specific Tests for liquids. While the microbiological enumeration tests were completed, the corresponding micro reports were inadvertently not attached. However, we have now attached the reports for the microbial enumeration tests.

Decision: Approved.

207.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Citi Pharma (Pvt) Ltd. (DML # 000512)** **3-Km Head Balloki Road Phool Nagar Kasur.**
	Name, address of Manufacturing site.	**M/s Citi Pharma (Pvt) Ltd. (DML # 000512)** **3-Km Head Balloki Road Phool Nagar Kasur.**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 33630: 22-11-2022
	Details of fee submitted	PKR 30,000/-: 17-10-2022 (Slip # 1714354721)
	The proposed proprietary name / brand name	**Askprol-JP Tablet 500 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Paracetamol …… 500 mg
	Pharmacotherapeutic Group of (API)	antipyretic
	Reference to Finished product specifications	BP Specification
	Proposed Pack size	1000's jar packing **Blister** in plastic jar
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved formulation
	For generic drugs (me-too status)	Paracetamol tablet 500 mg by Zafa

Evaluation by DD-PE&R:

Section	Observations

1.3.4	Please submit valid / fresh inspection report issued by DRAP for the confirmation of GMP status of the Tablet (General) Section. Please submit section approval letter for grant of Tablet (General) Section in Central Licensing Board, issued by Licensing Division DRAP.
3.2.P.1	Please submit the comparison of master formulation of your drug product vs innovator product in tabulated form. Please clarify whether your formulation film coated as mentioned in Section 1.5.2 of Module – I or otherwise?
3.2.P.5	Please clarify the specification either USP/BP/JP or others and submit prescribed fee of PKR 7500/- for correction
3.2.P.8	Please submit COA of API used in manufacturing of the stability batches.

Decision of 336th RB meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

Response by the firm:

Section	Observations	Response
1.3.4	Please submit valid / fresh inspection report issued by DRAP for the confirmation of GMP status of the Tablet (General) Section. Please submit section approval letter for grant of Tablet (General) Section in Central Licensing Board, issued by Licensing Division DRAP.	Firm has submitted GMP certificate dated 07-06-2022 which specifies Tablet general section
3.2.P.1	Please submit the comparison of master formulation of your drug product vs innovator product in tabulated form. Please clarify whether your formulation film coated as mentioned in Section 1.5.2 of Module – I or otherwise?	Firm has submitted tabulated comparison. Moreover ur product is not film coated (it was a typo error)
3.2.P.5	Please clarify the specification either USP/BP/JP or others and submit prescribed fee of PKR 7500/- for correction	BP specs
3.2.P.8	Please submit COA of API used in manufacturing of the stability batches.	Submitted

Decision: Approved.

Case No. 02 Cases of Import applications

a. Deferred cases

208.	**Name, address of Applicant / Importer**	**M/s Ghazali Brothers** **Address: : 1st Floor, Azzainab Court, Campbell Street, Karachi Pakistan**
	Details of Drug Sale License of importer	**License No: 143** **Address: 19-SR-7 Combell Street AzzainabCourt 1st floor Karachi.** **Address of Godown: 1.S.NO.14 G/Floor Karimji & others Plot WO7/15 N.Napier .** 2.2D, 2nd FloorKarimji & others Plot No W07/15, N.Napier Karachi. **Validity: 26-10-2023** **Status: Expired** *Applied for renewal on time*
	Name and address of marketing authorization holder (abroad)	**Jiangsu Huayang Pharmaceuticals Co. Ltd.** **Address:** No.21, Changjiamg Road, Si Yung County, China.
	Name, address of manufacturer(s)	**Jiangsu Huayang Pharmaceuticals Co. Ltd.** **Address:** No.21, Changjiamg Road, Si Yung County, China.
	Name of exporting country	**CHINA.**

	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**Date of Legalization:** not provided • CoPP: Firm has submitted CoPP certificate (No. 20230601002) dated 01-06-2023 issued by Anhui Drug Administration China. The CoPP specifies free sale status of the product in country of export along with its availability. CoPP Validity: 31-05-2028 • GMP: The firm has also submitted GMP certificate No. : JS20191088, Valid till invalidation of drug manufacturing license i.e. 31-12-2025
	Details of letter of authorization / sole agency agreement	Firm has submitted letter of authorization from **Jiangsu Huayang Pharmaceuticals Co. Ltd. Address:** No.21, Changjiamg Road, Si Yung County, China. The letter certifies that "M/s Ghazali Brothers, 1st Floor, Azzainab Court, Campbell Street, Karachi Pakistan" is their exclusive agent to promote, register, commercialize and distribute company's (Calcium Gluconate Injection 1g/10ml) product in the territory of Pakistan. The letter was issued on 25-10-2019.
	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. WY6-33U-BQVN Dated: 08-03-2024
	Details of fee submitted	PKR 300,000/-: PKR 150000 dated 01-09-2022 (Slip # 169634016). + PKR 150000 dated 01-03-2024 (Slip # 422119591)
	The proposed proprietary name / brand name	Calcium Gluconate Injection 1g/10ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 10 ml contains Calcium Gluconate …….. 980 mg
	Pharmaceutical form of applied drug	Sterile Liquid for injection
	Pharmacotherapeutic Group of (API)	Used in treatment of calcium deficiency
	Reference to Finished product specifications	USP Specification
	Proposed Pack size	Type I clear Glass Ampoule
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA & MHRA approved formulation
	For generic drugs (me-too status)	Locally registered

	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	Name: Jiangxi Xinganjiang Pharmaceutical Co., Ltd Address: No.36, Yunzhang Road, Jizhou District, Ji'an City, Jiangxi 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 40 ± 5°C / RH 75% for 06 months. Real time: 30 ± 5°C / RH 65% 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 done pharmaceutical equivalence with generics of Chenxin Pharmaceutical China and submitted comparison of Pharmaceutical equivalence as testing parameters of BP specifications.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	10 ampoules are packed in one box
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batches Accelerated Storage Conditions: Duration: 06 months Temperature: 40oC ±2oC Relative Humidity: 75% ± 5%. Long term Storage Conditions: Duration: 36 months Temperature: 30°C ±2oC Relative Humidity: 65% ± 5%.

Evaluation by PEC:

- Firm has to submit in hard copy, the legalized documents in original for CoPP, GMP Certificate of exporter & letter of authorization.

Section	Observations
3.2.P.1	• In the innovator product and other formulations approved in USFDA for FPP, each 10 ml of solution contains 940 or 950 mg of calcium gluconate, with an amount of calcium (equivalent to 94 mg or 95 mg of calcium gluconate) 4.5 mg of Calcium Saccharate, or other suitable calcium salts, for the purpose of stabilization. While in the formulation submitted by the manufacturer of applied drug product, each 10 ml of solution contains 980 mg of calcium gluconate. How will you justify the amount of calcium gluconate equivalent to 1g in the formulation and also mention the amount of total elemental calcium in the formulaiton? Please also provide reference of product with same formulation and composition approved in countries with stringent regulatory control declared by WHO.
3.2.P.2.7	• Please provide brand name of the medicinal product, formulation / composition and the address of manufacturer of the reference product used in Pharmaceutical equivalence studies.

Decision of 335th RB meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response by the firm:

Section	Observations	Response by the firm
3.2.P.1	In the innovator product and other formulations approved in USFDA for FPP, each 10 ml of solution contains 940 or 950 mg of calcium gluconate, with an amount of calcium (equivalent to 94 mg or 95 mg of calcium gluconate) 4.5 mg of Calcium Saccharate, or other suitable calcium salts, for the purpose of stabilization. While in the formulation submitted by the manufacturer of applied drug product, each 10 ml of solution contains 980 mg of calcium gluconate. How will you justify the amount of calcium gluconate equivalent to 1g in the formulation and also mention the amount of total elemental calcium in the formulaiton? Please also provide reference of product with same formulation and composition approved in countries with stringent regulatory control declared by WHO.	We have reviewed our formulation and can justify the amount of calcium gluconate used as follows: Calcium Gluconate is calcium D-gluconate(1:2)monohydrate.The molecular formula is C12H22CaO14.H2O. For our product calcium gluconate injection, each 10 ml of solution contains 980 mg of calcium gluconate is calcium D-gluconate(1:2)monohydrate. Calcium gluconate is calculated as calcium gluconate monohydrate (C12H22CaO14.H2O) , equivalent to 94mg of calcium gluconate （C12H22CaO14）, It means our calcium gluconate injection contains 94mg of calcium gluconate, 4.5 mg of Calcium Saccharate, consistent with the USFDA.
3.2.P.2.7	Please provide brand name of the medicinal product, formulation / composition and the address of manufacturer of the reference product used in Pharmaceutical equivalence studies.	The name of the reference listed drug manufacturer is FRESENIUS KABI USA LLC , and the manufacturer's address is Lake Zurich, IL 60047.The medicinal product formulation / composition is calcium gluconate,calcium saccharate, sodium hydroxide acid, hydrochloric acid, water for injection.

Decision of 340th RB meeting: Deferred for clarification of applied formulation, since the submitted CoPP specifies 1g/10ml while 980mg/10ml strength is mentioned in module 1 and module 3.

Response by the firm:

With regards to our product CALGUNATE INJECTION 10% (1g/10ml) that was discussed in the previous 340th meeting, our product brand name has been mentioned wrong in the 340th Meeting minutes. Kindly make the relevant correction, as brand name submitted is **CALGUNATE INJECTION 10% (1g/10ml).**

Moreover the manufacturer presented all relevant replies with regarding the clarification of the strength of the product.

We are hereby again attaching the relevant reply of the manufacturer for your kind reference, which clearly states that calcium gluconate 10%, 1g is equivalent to 980mg of calcium gluconate.

"For our product calcium gluconate injection, each 10ml of solution contains 980 mg of calcium gluconate is calcium D-gluconate(1:2)monohydrate. Calcium gluconate is calculated as calcium gluconate monohydrate ($C_{12}H_{22}CaO_{14}.H_2O$), equivalent to 94mg of calcium gluconate（$C_{12}H_{22}CaO_{14}$). It means our calcium gluconate injection contains 94mg of calcium gluconate, 4.5 mg of Calcium Saccharate , consistent with the USFDA" Unfortunately, our product again got deferred with the same query to clarify the strength again.
Decision: Deferred for following: • **Clarification of applied formulation, since the submitted CoPP specifies 1g/10ml while 980mg/10ml strength is mentioned in Module 1 and Module 3.** • **Analytical record for the submitted drug product stability data including chromatograms/spectrums etc.**

209.	**Name, address of Applicant / Importer**	**M/s Gene-Tech Laboratories B-246, Block 6, P.E.C.H.S, Karachi, Pakistan**
	Details of Drug Sale License of importer	**License No.: 0002** **Address:** 246-B, Block-6, PECHS, Karachi **Validity:** 15-08-2022 **Status:** License to sell drugs by way of Wholesale
	Name and address of marketing authorization holder (abroad)	M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea
	Name, address of manufacturer(s)	M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea
	Name of exporting country	South Korea
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted original, legalized **copy** of CoPP certificate (No. 2020-D1-3552) dated 23-10- 2020 issued by Ministry of Food and Drug Safety, South Korea for Hyal Forte Injection. 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.** **GMP:** Firm has submitted legalized **GMP** certificate(No. 2020-D1-3554) dated 23-10-2020 issued by Ministry of Food and Drug Safety, South Korea in name of M/s Shin Poong Pharmaceutical Co., Ltd. 7,Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea wherein pre-filled syringe dosageform has not been mentioned.
	Details of letter of authorization / sole agency agreement	Firm has submitted Legalized NOC from M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea which authorises **M/s Gene-TechLaboratories B-246, Block 6, P.E.C.H.S, Karachi,Pakistan** to register their products in Pakistan. The authorization letter is valid till 09-11-2022.
	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 exportpurpose only
	Dy. No. and date of submission	Dy. No 10553 dated 06-04-2021
	Details of fee submitted	Rs.100,000/- dated 24-03-2021
	The proposed proprietary name / brand name	**Hyal Forte Pre Filled Syringe**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each pre-filled syringe (2ml) Contains 20mg ofSodium Hyaluronate
	Pharmaceutical form of applied drug	Pre-filled syringe
	Pharmacotherapeutic Group of (API)	Hyaluronic acid
	Reference to Finished product specifications	Innovator specifications
	Proposed Pack size	1's;AS per SRO
	Proposed unit price	AS per SRO
	The status in reference regulatory authorities	Hyalgan PFS 20mg/2ml approved by ANSM ofFrance
	For generic drugs (me-too status)	Hyalgan PFS of M.s Matrix Pharma Reg.# 031340
	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 Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea
	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 drugsubstance.
	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 30 ℃±2.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 processand 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 equivalenceEuflexxa
	Analytical method validation/verification of product	Firm has submitted analytical method validationstudies for the applied product.
	Container closure system of the drug product	Pre-filled syringe
	Stability study data of drug product, shelf life and storage conditions	Firm has submitted stability study data of 3 batchesThe 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 at5°C ±3°C / 65% ± 5% RH. The real time stability study data for 3 batches is for 36 months only.

Evaluation by PEC:

- The submitted COPP does not clarify the description of applied product whether pre-filled syringe or otherwise. Also the strength is mentioned only as Each ml contains Sodium hyaluronate …. 10mg
- Valid authorisation letter from manufacturer s required since submitted NOC was valid till 09-11-2022.
- Firm has submitted legalized **GMP** certificate (No. 2020-D1-3554) dated 23-10-2020 issued by Ministryof Food and Drug Safety, South Korea in name of M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro,Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea wherein pre-filled syringe dosage form has not been mentioned.
- Justification shall be submitted for performing stability studies as per refrigerating conditions since the reference product Hyalgan approved by ANSM of France recommends storage condition of store below 25°C.

Decision of 333rd meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Submission by the firm:

Sr. No	Reason for deferment	Response by the firm
1.	The submitted COPP does not clarify the description of applied product whether pre-filled syringe or otherwise. Also the strength is mentioned only as Each ml contains Sodium hyaluronate …. 10mg	Firm has submitted copy of CoPP certificate (No. 2024-D1-0199) dated 08-02- 2024 issued by Ministry of Food and Drug Safety, South Korea for Hyal Forte Injection (pre-filled syringe). 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.
2.	Valid authorisation letter from manufacturer s required since submitted NOC was valid till 09-11-2022.	Firm has submitted copy of NOC from M/s Shin Poong Pharmaceutical Co., Ltd. which authorises M/s Gene-Tech Laboratories B-246, Block 6, P.E.C.H.S, Karachi,Pakistan to register their products in Pakistan. The authorization letter is issued on 29-01-2024.
3.	Firm has submitted legalized **GMP** certificate (No. 2020-D1-3554) dated 23-10-2020 issued by Ministryof Food and Drug Safety, South Korea in name of M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea wherein pre-filled syringe dosage form has not been mentioned.	Firm has submitted copy of GMP certificate (No. 2024-D1-0201) dated 08-02-2024 issued by Ministry of Food and Drug Safety, South Korea in name of M/s Shin Poong Pharmaceutical Co., Ltd. 7, Wonsi-ro,Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea wherein pre-filled syringe dosage form has been mentioned in injections.

4.	Justification shall be submitted for performing stability studies as per refrigerating conditions since the reference product Hyalgan approved by ANSM of France recommends storage condition of store below 25ºC.	Firm has **not** submitted any written justification instead a chart is submitted which does not specify any product.	

Decision of 336th RB meeting: Deferred for following:

- **Justification for performing stability studies as per refrigerating conditions since the reference product Hyalgan approved by ANSM of France recommends storage condition of store below 25ºC.**

Response by the firm:
We, Shin Poon Pharm. Co., Ltd., would like to justify the reason of performing stability studies as per refrigerating conditions since the reference product recommends storage condition of
store below 25°C.
While developing the product, our R&D team found a potential risk of viscosity reduction due to an increase in temperature. Therefore, we conducted stability studies as per refrigerating
conditions and set the storage condition as 2~8°C.

Decision of 339th RB meeting: Registration Board deferred for clarification as the product is not stable at/below 25^0 C, since the reference product recommends the storage condition below 25^0 C

Response by the firm:
Firm has submitted that innovator's product recommend storage condition at room temparture while our product is recommended at 2-8degree because:
Molecular weight of innovator hyalgan is: 500k – 730k Dalton
Molecular weight of our product: 2500 K Dalton.

A research study used highly purified hyaluronic acid with molecular weight 2000K Da obtained by fermentation and autoclaved at 118 degree for 5 mins. These are similar to preparation of our product. Degradation is one of the important properties required for visco supplementation. From this study when compared to hydrogels after 24 hours stored at 5 degree and 25 degree. Samples at 5 degree have no change while smples kept at 25 degree show a clear effect on rate of degradation. Hyal forte also show a decrease in viscosity under storage condition of 25 degree.

Decision: Deferred for clarification regarding regulatory status of the applied product whether regulated as drug product or medical device and relevant clinical data considered by relevant NRA.

Case No. 03 Deferred Cases of Form 5

210.	Name and address of manufacturer / Applicant	M/s Ambrosia Pharmaceuticals Plot # 18, Street # 09, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	Dexflam Suspension
	Composition	Each 5ml contains: Dexibuprofen ……. 100 mg
	Diary No. Date of R& I & fee	Dy.No 16022 dated 07/03/2019 Rs. 20,000/- (Slip # 1900238) dated 07/03/2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Manufacture Specifications
	Pack size & demanded price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Tercica by M/s Sami
	GMP status	Latest GMP status required
	Remarks of the Evaluator[3].	• Firm needs to submit inspection report conducted within last 03 years OR fresh / valid GMP certificate. • RRA status required.
	Decision of 330th RB meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.	
	Submission by the firm: Firm has submitted RRA reference of Seractil oral suspension in Austria. However the product	

	approved in Austria and Switzerland is oral suspension in sachet.
	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.

211.	**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	Clovix plus 75/75mg Tablet
	Diary No. Date of R& I & fee	Dy No. 8291:11-7-2017 PKR 20,000/-: 13-7-2017
	Composition	Each tablet contains: Clopidogrel (as bisulphate)…….75mg Aspirin (as enteric coated)……75mg
	Pharmacological Group	Antiplatelet
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	Not demanded by the firm
	Approval status of product in Reference Regulatory Authorities.	CoPlavix Tablet (**TGA** Approved)
	Me-too status	Clodril Plus Tablet M/s Macter International
	GMP status	Last GMP inspection conducted on 07-09-2017, and the report concludes that the firm was considered to be operating at satisfactory compliance with GMP guideline
	Remarks of the Evaluator.	• The applied formulation is of uncoated tablet containing clopidogrel as bisulphate and aspirin as enteric coated, while the reference product approved by TGA is film coated tablet containing aspirin without enteric coating.
	Decision of previous meeting of Registration Board	Registration Board deferred the case for further deliberation**. (M-284)**
	Evaluation by PEC	Firm has submitted revised master formulation with film coating without submission of fee for revision of formulation
	Decision of 286th RB meeting: Registration Board deferred the case for further deliberation on the TGA Australia approved formulation.	
	Response by the firm: Firm has submitted revised label claim along with 37000 fee. The revised label claim is as under: Each film-coated bilayer tablet contains: Clopidogrel (as bisulphate)….75mg Aspirin (as enteric coated)……75mg	
	Decision: Approved. Firm shall submit IP/OP/QP for bilayer tablet machine before issuance of Registration letter.	

Case No. 04 Miscellaneous case

The following application of M/s Hiranis was considered and deferred by Registration Board in its 243rd meeting. Now the firm has requested to consider their application.

212.	M/s Hiranis Pharmaceutical Pvt. Ltd. Plot.No. E-145- 149, North western Industrial Zone, Port Qasim,	Dilast Capsule 10mg Capsule Each capsule contains Ibudilast JP 10mg	Rs.500/ pack of 10's Rs 50/ capsule	1.Form-5 D 2.06-03-2014 Dy.No. 216 3.04-03-2014 Rs.50,000/- (The firm applied on form 5 D but in agenda the	1. Not present in reference drug agencies, however, Ibudilast capsule 10 mg is present in Japan while MHLW Japan does not show Ibudilast capsule 2. New drug 3. Firm was inspected on 17th & 23rd

	Karachi. **Capsule (General)**	(Phosphodiesterase inhibitor) Finished product specifications are Manufacturer.		form erroneously mentioned as form 5)	September 2013, for grant of DML by way of formulation
Decision of 243rd RB meeting: Deferred for confirmation of indication.					
Response by the firm: Firm has submitted that the applied product is available in PMDA Japan and requested to consider their application. However the application was submitted on Form 5D and no stability data has been submitted.					
Decision: Registration Board deferred for further deliberation regarding submission of stability study data of 3 batches of the drug product before the lapse of deadline decided by DRAP Authority i.e. till 30th June 2023.					

The following application of M/s Hiranis was considered and deferred by Registration Board in its 295th meeting. Now the firm has requested to consider their application.

213.	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan	Atizor 500mg Capsule	Each Capsule Contains: Azithromycin Dihydrate Eq. to Azithromycin …….500mg	Dy.No. 11354 dated 19/05/2020Rs. 20,000/- (2028876)dated 18-05-2020 Form 5	As per SRO	Inspection conducted on 07-09-2017: Satisfactory GMP compliance The applied strength of formulation could not be verified in RRA.
Decision of 295th RB meeting: Deferred for evidence of approval of applied formulation in reference regulatory authorities adopted by Registration Board in 275th meeting.						
Response by the firm: Firm has submitted that the above formulation is approved by European Country Bulgaria which is also PIC/s participating country. Moreover Acasia 500mg Capsule of CCL pharma is already registered in Pakistan.						
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.						

Agenda of Dr. Farhadullah

Case No. 01; Routine registration applications of Human Drugs on Form 5F

214.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories., Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, KPK
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories., Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, KPK
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 22427 dated 12-09-2023
	Details of fee submitted	Rs.30,000/- dated 02-09-2023 (Deposit slip#5096365980)

	The proposed proprietary name / brand name	**Amwin 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Uncoated Tablet Contains: Amlodipine as Besylate……10mg
	Pharmacotherapeutic Group of (API)	Calcium Channel Blockers
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Amlodipine 10mg tablets MHRA Approved.
	For generic drugs (me-too status)	Amdol 10mg Tablets by M/s Bio-Labs(Pvt) Ltd (Reg# 83517)
	Proposed Pack size & proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority. • Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate of the firm based on inspection dated 12-10-2022. The copy of cGMP certificate specifies Tablet (General/ Antibiotic) section.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required • The name and address of API manufacturer mentioned in this section is different than GMP certificate • M/s Cadila Pharmaceuticals Limited., 294, GIDC Estate, Ankleshwar – 393002, Gujarat India. • M/s Cadila Healthcare Limited., Unit-II, Plot No; 5/1-B, GIDC Estate, Ankleshwar – 393002, Gujarat India (GMP Certificate)	• Firm has submitted copy of cGMP M/s Cadila Pharmaceuticals Limited., 3203, GIDC Estate, Ankleshwar – 393002, Gujarat India issued by Food and Drugs Control Administration India valid upto 28-02-2025
3.2.S.4	• Copies of the Drug substance specifications and analytical procedure used for routine testing of the Drug substance by Drug Product manufacturer is required.	• Copies of the Drug substance specifications and analytical procedure used for routine testing of the Drug substance by Drug Product manufacturer is submitted.
3.2.P.2	• Clarification shall be submitted for performing dissolution test in pharmaceutical equivalence studies in three physiological medias.	• No clarification is submitted
3.2.P.5	• Justification shall be submitted for not mentioning the time of dissolution test in finish product specifications • Justification shall be submitted for not including the test for uniformity of dosage units in finish product specifications as per USP monograph • Detailed analytical procedures used for testing of the drug product shall be provided.	• The firm submitted that mistakenly it was not written. The firm has now submitted revised finish product specifications in which dissolution test and uniformity of dosage units has been included. • Analytical procedures used for testing of the drug product is submitted
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of secondary reference standard including source and lot number is submitted

3.2.P.8	• Submit copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP.	• Firm has submitted copy of form 6 issued dated 31-01-2022 specifying 03 kg Amlodipine Besylate. Form 6 is issued by AD (I&E) DRAP.

Decision: Approved. Registration Board further decided that registration letter will be issued after submission of following:

i. **Revision of address of API manufacturer in section 1.6.5 as per cGMP certificate.**
ii. **Submission of revised pharmaceutical equivalence report including dissolution test results in dissolution media adopted for batch release.**
iii. **Fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(l)2024 dated 30-08-2024**

215.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories., Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, KPK
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories., Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, KPK
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 22428 dated 12-09-2023
	Details of fee submitted	Rs.30,000/- dated 02-09-2023 (Deposit slip#81398754640)
	The proposed proprietary name / brand name	**Amwin 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Uncoated Tablet Contains: Amlodipine as Besylate……5mg
	Pharmacotherapeutic Group of (API)	Calcium Channel Blockers
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Amlodipine 5mg tablets MHRA Approved.
	For generic drugs (me-too status)	Amdol 5mg Tablets by M/s Bio-Labs(Pvt) Ltd (Reg# 83527)
	Proposed Pack size & proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority. • Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate of the firm based on inspection dated 12-10-2022. The copy of cGMP certificate specifies Tablet (General/ Antibiotic) section.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required • The name and address of API manufacturer mentioned in this section is different than GMP certificate	• Firm has submitted copy of cGMP M/s Cadila Pharmaceuticals Limited., 3203, GIDC Estate, Ankleshwar – 393002, Gujarat India issued by Food and Drugs Control Administration India valid upto 28-02-2025

	• M/s Cadila Pharmaceuticals Limited., 294, GIDC Estate, Ankleshwar – 393002, Gujarat India. • M/s Cadila Healthcare Limited., Unit-II, Plot No; 5/1-B, GIDC Estate, Ankleshwar – 393002, Gujarat India (GMP Certificate)	
3.2.S.4	• Copies of the Drug substance specifications and analytical procedure used for routine testing of the Drug substance by Drug Product manufacturer is required.	• Copies of the Drug substance specifications and analytical procedure used for routine testing of the Drug substance by Drug Product manufacturer is submitted.
3.2.P.2	• Clarification shall be submitted for performing dissolution test in pharmaceutical equivalence studies in three physiological medias.	• No clarification is submitted
3.2.P.5	• Justification shall be submitted for not mentioning the time of dissolution test in finish product specifications • Justification shall be submitted for not including the test for uniformity of dosage units in finish product specifications as per USP monograph • Detailed analytical procedures used for testing of the drug product shall be provided.	• The firm submitted that mistakenly it was not written. The firm has now submitted revised finish product specifications in which dissolution test and uniformity of dosage units has been included. • Analytical procedures used for testing of the drug product is submitted
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of secondary reference standard including source and lot number is submitted
3.2.P.8	• Submit copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP.	• Firm has submitted copy of form 6 issued dated 31-01-2022 specifying 03 kg Amlodipine Besylate. Form 6 is issued by AD (I&E) DRAP.

Decision: Approved.
Registration Board further decided that Registration letter will be issued after submission of following:

i. **Revision of address of API manufacturer in section 1.6.5 as per cGMP certificate.**
ii. **Submission of revised pharmaceutical equivalence report including dissolution test results in dissolution media of batch release.**
iii. **Fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(I)2024 dated 30-08-2024**

216.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories., Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, KPK
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories., Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, KPK
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 22434 dated 12-09-2023
	Details of fee submitted	Rs.30,000/- dated 02-09-2023 (Deposit slip#61403337759)

	The proposed proprietary name / brand name	**Zebra 45mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Mirtazipine……45mg
	Pharmacotherapeutic Group of (API)	Antidepressants
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Mirtazapine 45mg Film-coated Tablets MHRA Approved.
	For generic drugs (me-too status)	Remarta 45mg Tablets by M/s Crystolite Pharmaceuticals (Reg# 82318)
	Proposed Pack size & proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority. • Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate of the firm based on inspection dated 12-10-2022. The copy of cGMP certificate specifies Tablet (General/ Antibiotic) section.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of cGMP certificate of API manufacturer issued by Drugs Control Administration Government of Telangana India valid upto 28-06-2025
3.2.S.4	• Copies of the Drug substance specifications and analytical procedure used for routine testing of the Drug substance 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 shall be submitted. • Justification shall be submitted for not performing the test for water content and residue on ignition in batch analysis for drug substance by drug product manufacturer as per USP monograph	• Copies of the Drug substance specifications and analytical procedure used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance is submitted. • Firm submitted that mistakenly it was not written. Firm has submitted revised batch analysis report in which test for water content and residue on ignition in batch analysis for drug substance by drug product manufacturer has been performed
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided	• COA of secondary reference standard including source and lot number is submitted
3.2.S.7	• Stability study data of 3 batches of drug substance at real time conditions till claimed shelf life shall be submitted (only 18 months submitted)	• Stability study data of 3 batches of drug substance at real time conditions till 48months is submitted
3.2.P.2	• Clarification shall be submitted for performing dissolution test in pharmaceutical equivalence studies in three physiological medias. • Submit details of comparator product including manufacturer name against which Pharmaceutical equivalence and CDP studies has been performed	• No clarification is submitted • Firm has submitted details of comparator product against which pharmaceutical equivalence and CDP studies has been performed. Brand name: Mirtazep 45mg tablet, Manufacturer: Zafa Pharma, Batch No. 36, Mfg date; 03-2022, Exp. Date; 03-2026

3.2.P.5	• Justification shall be submitted for not including the test for uniformity of dosage units in finish product specifications as per USP monograph • Detailed analytical procedures used for testing of the drug product shall be provided.	• The firm submitted that mistakenly it was not written. The firm has submitted revised finished product specifications in which test for uniformity of dosage units has been included. • Analytical procedures used for testing of the drug product is submitted
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of secondary reference standard including source and lot number is submitted.
3.2.P.8	• Submit copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP.	• Firm has submitted copy of form 6 issued dated 28-01-2022 specifying 02 kg Mirtazapine. Form 6 is issued by AD (I&E) DRAP.

Decision: Approved. Registration Board further decided that Registration letter will be issued after submission of following:

i. **Submission of revised pharmaceutical equivalence report including dissolution test results in dissolution media of batch release.**

ii. **Fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(l)2024 dated 30-08-2024**

217.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories., Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, KPK
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories., Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, KPK
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 22433 dated 12-09-2023
	Details of fee submitted	Rs.30,000/- dated 02-09-2023 (Deposit slip#11847527513)
	The proposed proprietary name / brand name	**Zebra 30mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Mirtazipine……30mg
	Pharmacotherapeutic Group of (API)	Antidepressants
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Mirtazapine 30mg Film-coated Tablets MHRA Approved.
	For generic drugs (me-too status)	Remarta 30mg Tablets by M/s Crystolite Pharmaceuticals (Reg# 82317)
	Proposed Pack size & proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority.	• Firm has submitted copy of cGMP certificate of the firm based on inspection dated 12-10-2022. The copy of cGMP

	• Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	certificate specifies Tablet (General/ Antibiotic) section.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of cGMP certificate of API manufacturer issued by Drugs Control Administration Government of Telangana India valid upto 28-06-2025
3.2.S.4	• Copies of the Drug substance specifications and analytical procedure used for routine testing of the Drug substance 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 shall be submitted. • Justification shall be submitted for not performing the test for water content and residue on ignition in batch analysis for drug substance by drug product manufacturer as per USP monograph	• Copies of the Drug substance specifications and analytical procedure used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance is submitted. • Firm submitted that mistakenly it was not written. Firm has submitted revised batch analysis report in which test for water content and residue on ignition in batch analysis for drug substance by drug product manufacturer has been performed
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided	• COA of secondary reference standard including source and lot number is submitted
3.2.S.7	• Stability study data of 3 batches of drug substance at real time conditions till claimed shelf life shall be submitted (only 18 months submitted)	• Stability study data of 3 batches of drug substance at real time conditions till 48months is submitted
3.2.P.2	• Clarification shall be submitted for performing dissolution test in pharmaceutical equivalence studies in three physiological medias. • Submit details of comparator product including manufacturer name against which Pharmaceutical equivalence and CDP studies has been performed	• No clarification is submitted • Firm has submitted details of comparator product against which pharmaceutical equivalence and CDP studies has been performed. Brand name: Mirtazep 30mg tablet, Manufacturer: Zafa Pharma, Batch No. 24, Mfg date; 03-2022, Exp. Date; 03-2026
3.2.P.5	• Justification shall be submitted for not including the test for uniformity of dosage units in finish product specifications as per USP monograph • Detailed analytical procedures used for testing of the drug product shall be provided.	• The firm submitted that mistakenly it was not written. The firm has submitted revised finished product specifications in which test for uniformity of dosage units has been included. • Analytical procedures used for testing of the drug product is submitted
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of secondary reference standard including source and lot number is submitted.
3.2.P.8	• Submit copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP.	• Firm has submitted copy of form 6 issued dated 28-01-2022 specifying 02 kg Mirtazapine. Form 6 is issued by AD (I&E) DRAP.

Decision: Approved. Registration Board further decided that Registration letter will be issued after submission of following:

i. **Submission of revised pharmaceutical equivalence report including dissolution test results in dissolution media of batch release.**

ii. **Fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(I)2024 dated 30-08-2024**

218.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories., Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, KPK
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories., Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, KPK
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 22430 dated 12-09-2023
	Details of fee submitted	Rs.30,000/- dated 02-09-2023 (Deposit slip#2549614594)
	The proposed proprietary name / brand name	**Zebra 15mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Mirtazipine……15mg
	Pharmacotherapeutic Group of (API)	Antidepressants
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Mirtazapine 15mg Film-coated Tablets MHRA Approved.
	For generic drugs (me-too status)	Remarta 15mg Tablets by M/s Crystolite Pharmaceuticals (Reg# 82316)
	Proposed Pack size & proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority. • Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate of the firm based on inspection dated 12-10-2022. The copy of cGMP certificate specifies Tablet (General/ Antibiotic) section.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of cGMP certificate of API manufacturer issued by Drugs Control Administration Government of Telangana India valid upto 28-06-2025

3.2.S.4	• Copies of the Drug substance specifications and analytical procedure used for routine testing of the Drug substance 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 shall be submitted. • Justification shall be submitted for not performing the test for water content and residue on ignition in batch analysis for drug substance by drug product manufacturer as per USP monograph	• Copies of the Drug substance specifications and analytical procedure used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance is submitted. • Firm submitted that mistakenly it was not written. Firm has submitted revised batch analysis report in which test for water content and residue on ignition in batch analysis for drug substance by drug product manufacturer has been performed
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided	• COA of secondary reference standard including source and lot number is submitted
3.2.S.7	• Stability study data of 3 batches of drug substance at real time conditions till claimed shelf life shall be submitted (only 18 months submitted)	• Stability study data of 3 batches of drug substance at real time conditions till 48months is submitted
3.2.P.2	• Clarification shall be submitted for performing dissolution test in pharmaceutical equivalence studies in three physiological medias. • Submit details of comparator product including manufacturer name against which Pharmaceutical equivalence and CDP studies has been performed	• No clarification is submitted • Firm has submitted details of comparator product against which pharmaceutical equivalence and CDP studies has been performed. Brand name: Mirtazep 15mg tablet, Manufacturer: Zafa Pharma, Batch No. 52, Mfg date; 01-2022, Exp. Date; 01-2026
3.2.P.5	• Justification shall be submitted for not including the test for uniformity of dosage units in finish product specifications as per USP monograph • Detailed analytical procedures used for testing of the drug product shall be provided.	• The firm submitted that mistakenly it was not written. The firm has submitted revised finished product specifications in which test for uniformity of dosage units has been included. • Analytical procedures used for testing of the drug product is submitted
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of secondary reference standard including source and lot number is submitted.
3.2.P.8	• Submit copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP.	• Firm has submitted copy of form 6 issued dated 28-01-2022 specifying 02 kg Mirtazapine. Form 6 is issued by AD (I&E) DRAP.

Decision: Approved. Registration Board further decided that Registration letter will be issued after submission of following:

i. **Submission of revised pharmaceutical equivalence report including dissolution test results in dissolution media of batch release.**

ii. **Fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(l)2024 dated 30-08-2024**

219.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories., Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, KPK
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories., Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, KPK

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 22432 dated 12-09-2023
	Details of fee submitted	Rs.30,000/- dated 02-09-2023 (Deposit slip#638173792634)
	The proposed proprietary name / brand name	**Desbin 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Desloratadine……..…5mg
	Pharmacotherapeutic Group of (API)	Anti-Histamine
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Desloratadine 5mg Film-Coated Tablets MHRA Approved.
	For generic drugs (me-too status)	Mdisin 5mg Tablet by M/s Metro Pharmaceuticals (Reg# 81672)
	Proposed Pack size & proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority. • Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required
3.2.S.4	• Copies of the Drug substance specifications and analytical procedure used for routine testing of the Drug substance 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 shall be submitted.
3.2.P.2	• Clarification shall be submitted for performing dissolution test in pharmaceutical equivalence studies in three physiological medias. • Submit details of comparator product including manufacturer name against which Pharmaceutical equivalence and CDP studies has been performed
3.2.P.5	• Justification shall be submitted for not including the test for uniformity of dosage units in finish product specifications as per USP monograph • Detailed analytical procedures used for testing of the drug product shall be provided. • Justification shall be submitted for selectin limit of assay test in batch analysis of finished product as 90%-110% instead of 93%-105% as per submitted specifications and USP
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.P.8	• Submit copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings

220.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories., Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, KPK

	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories., Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, KPK
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 22438 dated 12-09-2023
	Details of fee submitted	Rs.30,000/- dated 02-09-2023 (Deposit slip#789331346958)
	The proposed proprietary name / brand name	**Desbin 5mg Dispersible Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Desloratadine……..…5mg Dispersible
	Pharmacotherapeutic Group of (API)	Anti-Histamine
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Desloratadine 5mg orodispersible tablets MHRA Approved.
	For generic drugs (me-too status)	Submitted evidence is not verifiable
	Proposed Pack size & proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority. • Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years
1.5.2	• The reference formulation is orodispersible tablet while you have applied for film-coated tablet. Revise the label claim as per refrence formulation along with submission of applicable fee.
1.5.8	• Provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required
3.2.S.4	• Copies of the Drug substance specifications and analytical procedure used for routine testing of the Drug substance 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 shall be submitted.
3.2.P.2	• Submit results of drug excipient compatibility study as the qualitative composition of applied product is not similar to reference product • Clarification shall be submitted for performing dissolution test in pharmaceutical equivalence studies in three physiological medias. • Submit details of comparator product including manufacturer name against which Pharmaceutical equivalence and CDP studies has been performed
3.2.P.5	• Justification shall be submitted for not including the test for uniformity of dosage units in finish product specifications as per USP monograph • Detailed analytical procedures used for testing of the drug product shall be provided. • Justification shall be submitted for selecting limit of assay test in batch analysis of finished product as 90%-110% instead of 95%-105% as per submitted specifications and USP

3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.P.8	• Submit copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings

221.	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)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 22957 dated 19-09-2023
	Details of fee submitted	Rs.75,000/- dated 23-08-2023 (Deposit slip#43877395106)
	The proposed proprietary name / brand name	**Asinap 5mg sublingual Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sublingual Tablet Contains: Asenapine Maleate eq. to Asenapine……5mg
	Pharmacotherapeutic Group of (API)	Antipsychotics
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	SAPHRIS (2.5mg, 5mg, 10mg) sublingual tablets USFDA Approved
	For generic drugs (me-too status)	N/A
	Proposed Pack size & proposed unit price	7's, 10's, 14's, 20's, 28's, 30's,: As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required • The name and address of API manufacturer mentioned in this section is different than GMP certificate, clarify? • M/s Alembic Pharmaceuticals Limited (API Unit-III)., Pot No. 842-843, Village-Karakhadi, Tal.-Parda, District-Vadodara-391450, Gujarat, India. • M/s Alembic Pharmaceuticals Limited (API Division Panelav) At-Panelav, Tal-Halol, City, Panelav, Dist.-Panchmahal Gujarat State India (GMP Cerificate)	• Firm has submitted copy of cGMP certificate of M/s Alembic Pharmaceuticals Limited (API Division Panelav) At-Panelav, Tal-Halol, City, Panelav, Dist.-Panchmahal Gujarat State India issued by Food & Drugs Control Administration, Gujarate State India valid upto 25-06-2027. • The name and address of API manufacturer mentioned in this section is different than GMP certificate

3.2.P.2	• Submit results of drug excipient compatibility study as the qualitative composition of applied product is not similar to reference product	• Firm has submitted results of drug excipient compatibility study.
3.2.P.5	• Justification shall be submitted for not including the test for water content in finished product specifications as per innovator's product review document	• The firm submitted that the finished product is manufactured using a dry granulation method, as opposed to innovator product which uses lyophilization. This difference in production techniques eliminates the need for a water content test in our product specifications. Additionally, Certificate of Analysis (CoA) of asenapine API indicates a neglible water content, not exceeding 0.5 %, which further supports the omission of water content testing for our finished product

Decision: Approved. Registration Board further decided that Registration letter will be issued after submission of cGMP certificate of relevant manufacturing site of drug substance manufacturer or revision of address of drug substance manufacturer as per section 1.6.5

222.	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)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 22958 dated 19-09-2023
	Details of fee submitted	Rs.75,000/- dated 23-08-2023 (Deposit slip#468095722985)
	The proposed proprietary name / brand name	**Asinap 10mg sublingual Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sublingual Tablet Contains: Asenapine Maleate eq. to Asenapine……10mg
	Pharmacotherapeutic Group of (API)	Antipsychotics
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	SAPHRIS (2.5mg, 5mg, 10mg) sublingual tablets USFDA Approved
	For generic drugs (me-too status)	N/A
	Proposed Pack size & proposed unit price	7's, 10's, 14's, 20's, 28's, 30's,: As per SRO

Evaluation by PEC[XI]:

Section	Observations	Response
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required • The name and address of API manufacturer mentioned in this section	• Firm has submitted copy of cGMP certificate of M/s Alembic Pharmaceuticals Limited (API Division Panelav) At-Panelav, Tal-Halol, City, Panelav, Dist.-Panchmahal Gujarat State India issued by Food & Drugs Control Administration, Gujarate State India valid upto 25-06-2027.

	is different than GMP certificate, clarify? • M/s Alembic Pharmaceuticals Limited (API Unit-III)., Pot No. 842-843, Village-Karakhadi, Tal.-Parda, District-Vadodara-391450, Gujarat, India. • M/s Alembic Pharmaceuticals Limited (API Division Panelav) At-Panelav, Tal-Halol, City, Panelav, Dist.-Panchmahal Gujarat State India (GMP Cerificate)	• The name and address of API manufacturer mentioned in this section is different than GMP certificate
3.2.S	• Drug substance data in module 3 is not submitted. Submit complete drug substance data without referring to other application	• Complete drug substance data in module 3 is submitted
3.2.P.2	• Submit results of drug excipient compatibility study as the qualitative composition of applied product is not similar to reference product	• Firm has submitted results of drug excipient compatibility study.
3.2.P.5	• Justification shall be submitted for not including the test for water content in finished product specifications as per innovator's product review document	• The firm submitted that the finished product is manufactured using a dry granulation method, as opposed to innovator product which uses lyophilization. This difference in production techniques eliminates the need for a water content test in our product specifications. Additionally, Certificate of Analysis (CoA) of asenapine API indicates a negligible water content, not exceeding 0.5 %, which further supports the omission of water content testing for our finished product

Decision: Approved. Registration Board further decided that Registration letter will be issued after submission of of cGMP certificate of relevant manufacturing site of drug substance manufacturer or revision of address of drug substance manufacturer as per section 1.6.5

223.	Name, address of Applicant / Marketing Authorization Holder	M/s Wnsfeild Pharmaceuticals., Plot # 122, Block A, Phase-V, Industrial Estate, Hattar, Haripur, KPK
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals., Plot # 122, Block A, Phase-V, Industrial Estate, Hattar, Haripur, KPK
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 22789 dated 25-09-2023
	Details of fee submitted	Rs.30,000/- dated 06-09-2023 (Deposit slip# 1482471504)
	The proposed proprietary name / brand name	**Phyto-K 10mg/ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml Ampoule Contains: Phytonadione……10mg
	Pharmacotherapeutic Group of (API)	Fat soluble vitamin

	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Vitamin K1 10mg/ml by M/s Hospira USFDA Approved.
	For generic drugs (me-too status)	Vit-K 10mg/ml Injectable Emulsion by M/s Genix Pharma (Reg# 82260)
	Proposed Pack size & proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.1	• Submit copy of submitted fee challan	• Copy of submitted fee challan is submitted
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority.	• Firm has submitted copy of renewal of DML dated 11-06-2024 specifying General Liquid injection section.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of DML (License No#20160262) of API manufacturer issued by Anhui food and Drug Administration China valid upto 31-12-2025.
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>	• 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> is provided
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Complete analytical procedure for all the tests by drug substance manufacturer for submitted specifications shall be submitted • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Justification shall be submitted for not performing the test for Z-Isomer Content in batch analysis of drug substance by drug product manufacturer as per drug substance manufacturer	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • Analytical procedure for drug substance by drug substance manufacturer is submitted • Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance is submitted. • Firm has submitted revised batch analysis report of drug substance by drug product manufacturer
3.2.S.5	• COA of primary / secondary reference standard including source and lot number shall be provided	• COA of secondary reference standard including source and lot number is submitted
3.2.P.2	• Submit details of comparator product including batch number, manufacturing date and expiry date against which Pharmaceutical equivalence studies has been performed	• Firm has submitted details of comparator product. Manufacturer; GT Pharma, Batch No; KKL011, Mfg date; 05-2022, Exp date; 05-2022
3.2.P.3	• Justify the process of sterile filtration in manufacturing method as the applied product is Injectable Emulsion	• The firm submitted that, as the product is aqueous colloidal solution free from foreign particles and filled in sterile pre-printed

		ampoules. Formulation of the product is submitted.
3.2.P.5	• Analytical procedure for all the tests given in finished product specifications shall be submitted • Submit numerical results for bacterial endotoxin test in batch analysis of finished product instead of passed	• Analytical procedure for all the tests given in finished product specifications is submitted.Results for bacterial endotoxin test in batch analysis of finished product is submitted
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of secondary reference standard including source and lot number is provided.
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of intimation letter of previously obtained loan material to additional director (PE&R) DRAP Islamabad from M/s Weatherfolds Pharmnaceuticals. • Firm has submitted copy of form 6 from M/s Weather folds Pharmaceuticals issued dated 26-05-2022 specifying 0.2 kg Vitamin K1. Form 6 is issued by AD (I&E) DRAP.

Decision: Approved.

224.	Name, address of Applicant / Marketing Authorization Holder	M/s Wnsfeild Pharmaceuticals., Plot # 122, Block A, Phase-V, Industrial Estate, Hattar, Haripur, KPK
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals., Plot # 122, Block A, Phase-V, Industrial Estate, Hattar, Haripur, KPK
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 23408 dated 21-09-2023
	Details of fee submitted	Rs.30,000/- dated 04-08-2023 (Deposit slip#661215149)
	The proposed proprietary name / brand name	**Cefbact 2.5gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftazidime as Pentahydrate…..…2000mg Avibactam as Sodium Salt…….500mg
	Pharmacotherapeutic Group of (API)	Cephalosporine antibiotics
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	Zavicefta 2g/0.5g powder for concentrate for solution for infusion MHRA Approved AVYCAZ (ceftazidime/avibactam) 2g/0.5g for injection USFDA Approved
	For generic drugs (me-too status)	Zavicefta Injection 2g/0.5g (Powder for Concentrate for Solution for Infusion) by M/s Pfizer Pakistan (Reg# 106848)
	Proposed Pack size & proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response

1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority.	• Firm has submitted copy of renewal of DML dated 11-06-2024 specifying Dry Powder injection (cephalosporin) section.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of DML (License#20160262) of API manufacturer issued by Guangdong Drug Administration, China valid upto 28-10-2025
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>	• 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> is submitted
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance 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 shall be submitted. • Justification shall be submitted for not performing the test for sterility, bacterial endotoxin and pyridine content in batch analysis of drug substance by drug product manufacturer as per drug substance manufacturer • Certificate of Analysis (COA) of relevant batch of drug substance used during product development and stability study by drug substance manufacturer shall be submitted	• Copies of the Drug substance specifications by Drug Product manufacturer is submitted. However, analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is not submitted. • Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance is submitted. • The firm has submitted revised batch analysis report of drug substance containing test results for pyridine content, BET and sterility. Certificate of Analysis (COA) of relevant batch of drug substance used during product development and stability study by drug substance manufacturer is submitted
3.2.S.7	• Stability study data of 3 batches of drug substance at real time conditions till claimed shelf life shall be submitted (only 06 months submitted)	• Stability study data of 3 batches of drug substance at real time conditions is submitted till 02 years.
3.2.P.1	• Provide information including type of diluent, its composition, quantity or volume, specifications and regulatory status in Pakistan for the diluent which is to be provided along with the applied drug.	• The firm submitted that water for injection brand name Winwater injection 10ml will be provided with our product. The registration No. of the product is 118195.
3.2.P.2	• Submit details of comparator product including batch number, manufacturing date and expiry date against which Pharmaceutical equivalence studies has been performed • Justification shall be submitted for not reporting results of assay test of both the APIs individually in pharmaceutical equivalence studies	• The firm submitted that pharmaceutical equivalence was performed against Zavicefta powder for injection by M/s Pfizer. Details of comparator product not submitted • Firm has submitted revised pharmaceutical equivalence studies in which results of assay test of both the APIs are reported.
3.2.P.3	• Justification shall be submitted as the content of sodium bicarbonate in premixed drug substance (236mg/vial)	• The firm submitted that sodium carbonate content in premixed drug substance (236mg/vial) is typographic mistake. The sodium bicarbonate content of the mixture

	are different than that recommended by innovator product	is 239.6 mg/vial. The total sodium content of the mixture is approximately 146 mg/vial
3.2.P.5	• Justification is required for not including the test for reconstitution time, pH, pyridine content, uniformity of dosage unit, water content and bacterial endotoxins in finished product specification by drug product manufacturer as recommended by innovator product review document • Analytical procedure for all the tests given in finished product specifications by drug product manufacturer shall be submitted • Justification is required for not performing the test for reconstitutions time, uniformity of dosage units, particulate matter and pyridine content in batch analysis by drug product manufacturer as recommended by innovator product review document	• Firm has submitted revised finished product specifications in which test for pH, pyridine content, uniformity of dosage unit, water content and bacterial endotoxins in finished product specification. • Analytical procedure for tests given in finished product specifications by drug product manufacturer is submitted. • • Firm has submitted revised batch analysis report in which test for pH, pyridine content, uniformity of dosage unit, water content and bacterial endotoxins in batch analysis by drug product manufacturer has been performed.
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of secondary reference standard including source and lot number is provided
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import). • Justify the batch size of trial batches against the number of units required for complete testing of drug product during stability study including real time stability study till claimed shelf life • Clarify the batch size of trial batches as you have mentioned 1200 vials in batch analysis while 250 vials in stability summary sheets • Stability study data of drug product at 6th month time point shall be submitted	• Firm has submitted copy of intimation letter of previously obtained loan material to additional director (PE&R) DRAP Islamabad from M/s Welwrd Pharmaceuticals. • Firm has submitted copy of form 6 from M/s Welwrd Pharmaceuticals issued dated 20-12-2022 specifying 02 kg Ceftazidime with Avibactam Sodium. Form 6 is issued by AD (I&E) DRAP. • The firm submitted that trial batch size is selected to cover the whole testing (chemical/physical/microbial) required in each (three time) testing interval for real time and accelerated stability study • The firm submitted that 1200 vials in trial batches is typographic mistake, the actual batch size is 250 vials which is mentioned in stability summary sheets • Stability study data of drug product at 6th month time point is submitted

Decision: Approved. Registration Board further decided that Registration letter will be issued after submission of fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(l)2024 dated 30-08-2024

225.	Name, address of Applicant / Marketing Authorization Holder	M/s Welwrd Pharmaceuticals., Plot # 3, Block A, Phase I-II, Industrial Estate Hattar
	Name, address of Manufacturing site.	M/s Welwrd Pharmaceuticals., Plot # 3, Block A, Phase I-II, Industrial Estate Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 22783 dated 15-09-2023
	Details of fee submitted	Rs.30,000/- dated 19-07-2023 (Deposit slip#121369066)
	The proposed proprietary name / brand name	**Avecefta 2/0.5gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Ceftazidime as Pentahydrate……2gm Avibactam as Sodium……..…0.5gm
	Pharmacotherapeutic Group of (API)	Cephalosporine antibiotics
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	Zavicefta 2g/0.5g powder for concentrate for solution for infusion MHRA Approved AVYCAZ (ceftazidime/avibactam) 2g/0.5g for injection USFDA Approved
	For generic drugs (me-too status)	Zavicefta Injection 2g/0.5g (Powder for Concentrate for Solution for Infusion) by M/s Pfizer Pakistan (Reg# 106848)
	Proposed Pack size & proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance 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 shall be submitted. • Justification shall be submitted for not performing the test for pyridine content in batch analysis of drug substance by drug product manufacturer as per drug substance manufacturer	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted • Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance is submitted. • The firm submitted that it was a typographical mistake. The firm has submitted revised batch analysis report of drug substance containing test results for pyridine content
3.2.S.7	• Stability study data of 3 batches of drug substance at real time conditions till claimed shelf life shall be submitted (only 06 months submitted)	• Stability study data of 3 batches of drug substance at real time conditions is submitted till 02 years.
3.2.P.1	• Provide information including type of diluent, its composition, quantity or volume, specifications and regulatory status in Pakistan for the diluent which is to be provided along with the applied drug.	• The firm submitted that water for injection brand name welwater 10cc will be provided by our company welwrd pharmaceuticals hattar. The registration No. of the product is 040347.
3.2.P.2	• Submit details of comparator product including marketing authorization holder against which Pharmaceutical equivalence studies has been performed	• The firm submitted that pharmaceutical equivalence was performed against Zavicefta powder for injection by M/s Pfizer.

3.2.P.5	• Justification is required for not including the test for reconstitution time and pyridine content in finished product specification by drug product manufacturer as recommended by innovator product review document • Justification is required for not performing the test for reconstitutions time, particulate matter and pyridine content in batch analysis by drug product manufacturer as recommended by innovator product review document	• Firm has submitted revised finished product specifications in which test for pyridine content is included in finished product specification. • Firm has submitted revised batch analysis report in which test for particulate matter and pyridine content in batch analysis by drug product manufacturer has been performed.
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of secondary reference standard including source and lot number is provided
3.2.P.8	• Justify the batch size of trial batches against the number of units required for complete testing of drug product during stability study including real time stability study till claimed shelf life • Submit data of stability batches supported by attested respective documents like chromatograms, Raw data sheets and COA,.	• The firm submitted complete breakdown of vial utilization; Batch size; 200 vials • Filled vial testing; 26 vials • Finished product testing; 16 vials • Accelerated stability testing; 48 vials,, • Real time stability testing; 96 Bottles, • Total required; 186 vials • Data of stability batches supported by attested respective documents like chromatograms, Raw data sheets and COA is submitted

Decision: Approved. Registration Board further decided that Registration letter will be issued after submission of fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(l)2024 dated 30-08-2024

226.	Name, address of Applicant / Marketing Authorization Holder	M/s Wenovo Pharmaceuticals., Plot # 31, 32 Punjab Small Industrial Estate, Taxila, Rawalpindi.
	Name, address of Manufacturing site.	M/s Wenovo Pharmaceuticals., Plot # 31, 32 Punjab Small Industrial Estate, Taxila, Rawalpindi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 25297 dated 18-10-2023
	Details of fee submitted	Rs.30,000/- dated 25-09-2023 (Deposit slip#897341598576)
	The proposed proprietary name / brand name	**Mirtavo 15mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Mirtazapine……15mg
	Pharmacotherapeutic Group of (API)	Antidepressants
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Mirtazapine 15mg film coated tablets MHRA Approved

	For generic drugs (me-too status)	Mirtasat tablet 15mg by M/s Himont Pharmaceuticals (Reg# 93756)
	Proposed Pack size & proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Complete analytical procedure for all the tests by drug substance manufacturer for submitted specifications shall be submitted • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Results of assay test is not reported in batch analysis of drug substance by drug substance manufacturer, clarify
3.2.S.7	• Stability study data of 3 batches of drug substance at real time conditions till claimed shelf life shall be submitted (only 18 months data submitted)
3.2.P.2	• Clarification shall be submitted for performing dissolution test in pharmaceutical equivalence studies in three physiological medias. • Clarification is required for not reporting results of assay test in pharmaceutical equivalence studies • Submit details of comparator product including manufacturer name against which Pharmaceutical equivalence and CDP studies has been performed
3.2.P.5	• Justification is required for not including the test for uniformity of dosage units and time of dissolution test in finished product specification as per USP monograph • Detailed analytical procedures used for testing of the drug product by drug product manufacturer shall be provided. • The copies of complete batch analysis of at least two batches shall be provided.
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings

227.	Name, address of Applicant / Marketing Authorization Holder	M/s Wenovo Pharmaceuticals., Plot # 31, 32 Punjab Small Industrial Estate, Taxila, Rawalpindi.
	Name, address of Manufacturing site.	M/s Wenovo Pharmaceuticals., Plot # 31, 32 Punjab Small Industrial Estate, Taxila, Rawalpindi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 25298 dated 18-10-2023
	Details of fee submitted	Rs.30,000/- dated 25-09-2023 (Deposit slip#67810125851)
	The proposed proprietary name / brand name	**Mirtavo 30mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Mirtazapine……30mg
	Pharmacotherapeutic Group of (API)	Antidepressants
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Mirtazapine 30mg film coated tablets MHRA Approved
	For generic drugs (me-too status)	Mirtasat tablet 30mg by M/s Himont Pharmaceuticals (Reg# 93757)
	Proposed Pack size & proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is required. • Complete analytical procedure for all the tests by drug substance manufacturer for submitted specifications shall be submitted • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Results of assay test is not reported in batch analysis of drug substance by drug substance manufacturer, clarify
3.2.S.7	• Stability study data of 3 batches of drug substance at real time conditions till claimed shelf life shall be submitted (only 18 months data submitted)
3.2.P.2	• Clarification shall be submitted for performing dissolution test in pharmaceutical equivalence studies in three physiological medias. • Submit details of comparator product including manufacturer name against which Pharmaceutical equivalence and CDP studies has been performed
3.2.P.5	• Justification is required for not including the test for uniformity of dosage units and time of dissolution test in finished product specification as per USP monograph • Detailed analytical procedures used for testing of the drug product by drug product manufacturer shall be provided. • The copies of complete batch analysis of at least two batches shall be provided.
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings

228.	Name, address of Applicant / Marketing Authorization Holder	M/s AGP Limited., B-23-C, S.I.T.E. Karachi
	Name, address of Manufacturing site.	M/s AGP Limited., B-23-C, S.I.T.E. Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 24348 dated 05-10-2023
	Details of fee submitted	Rs.30,000/- dated 18-09-2023

		(Deposit slip#648328567)
	The proposed proprietary name / brand name	**Bricetam 10mg/ml Oral Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml Contains: Brivaracetam…….10mg
	Pharmacotherapeutic Group of (API)	Antiepileptics, other antiepileptics.
	Reference to Finished product specifications	AGP specifications
	The status in reference regulatory authorities	BRIVIACT (brivaracetam) oral solution 10mg/ml USFDA Approved
	For generic drugs (me-too status)	Brilep Oral Solution 10mg/ml by M/s Hiranis Pharmaceuticals (Reg#123236)
	Proposed Pack size & proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
3.2.P.8	• Stability study data of applied product at 6th month time point shall be submitted. • Justify the batch size of trial batches against the number of units required for complete testing of drug product during stability study including real time stability study till claimed shelf life • Submit copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP.	• Stability study data of applied product at 6th month time point is submitted. • The firm submitted that the batch size of trial batches is justified against the number of units required for complete testing. The firm submitted that 2 packs are required for one time analysis. Batch size; 40 Bottles • Accelerated; 05 Bottles,, • Real time; 18 Bottles, • Packs required for other testing; 01 • Total required; 24 Bottles • Firm has again submitted copy of form 6 issued dated 01-09-2022 specifying 05kg Brivaracetam. Form 6 is issued by AD (I&E) DRAP.

Decision: Approved with innovator's specifications. Registration Board further decided that Registration letter will be issued after submission of fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(l)2024 dated 30-08-2024

229.	Name, address of Applicant / Marketing Authorization Holder	M/s AGP Limited., B-23-C, S.I.T.E. Karachi
	Name, address of Manufacturing site.	M/s AGP Limited., B-23-C, S.I.T.E. Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 24774 dated 11-10-2023
	Details of fee submitted	Rs.30,000/- dated 18-09-2023 (Deposit slip#01273907)
	The proposed proprietary name / brand name	**Bricetam 50mg/5ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Brivaracetam……..…10mg

	Pharmacotherapeutic Group of (API)	Antiepileptics, other antiepileptics.
	Reference to Finished product specifications	AGP specifications
	The status in reference regulatory authorities	BRIVIACT (brivaracetam) injection, for intravenous use, 50 mg/5 mL, USFDA Approved
	For generic drugs (me-too status)	Brivera 50mg/5ml Injection by M/s Helix Pharma
	Proposed Pack size & proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
3.2.P.5	• Justification shall be submitted for not including the test for sterility, bacterial endotoxins, sub-visible particles and microbiological quality in finished product specifications as per innovator product review document	• The firm has submitted revised finished product specifications in which the test for sterility, bacterial endotoxins and sub-visible particles has been included
3.2.P.8	• Stability study data of applied product at 6th month time point shall be submitted. • Stability study data at 3rd month time point for Bricetam 10mg/ml Oral Solution is submitted intead of Bricetam 50mg/5ml Injection for all the batches • Submit copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP.	• Stability study data of applied product at 6th month time point is submitted. • Stability study data for Bricetam 50mg/5ml Injection at 3rd month time point is submitted • Firm has again submitted copy of form 6 issued dated 01-09-2022 specifying 05kg Brivaracetam. Form 6 is issued by AD (I&E) DRAP.

Decision: Approved with innovator's specifications. Registration Board further decided that Registration letter will be issued after submission of fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(l)2024 dated 30-08-2024

230.	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)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 24777 dated 11-10-2023
	Details of fee submitted	Rs.30,000/- dated 22-09-2023 (Deposit slip#7202488722)
	The proposed proprietary name / brand name	**Bacetam 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Brivaracetam…….10mg
	Pharmacotherapeutic Group of (API)	Antiepileptics.
	Reference to Finished product specifications	Innovator's specifications

	The status in reference regulatory authorities	BRIVIACT (10mg, 25mg, 50mg, 75mg, 100mg) film coated tablets USFDA Approved
	For generic drugs (me-too status)	Brivatam 10mg tablet by M/s CCL Pharmaceuticals (Reg#109737)
	Proposed Pack size & proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.6.5	• Submit valid copy of cGMP certificate / Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	• Firm has submitted copy of DML (License# Zhe 20100526) of API manufacturer issued by Zhejiang Medical Product Administration valid upto 07-06-2025
3.2.S.4	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted. • Certificate of Analysis (COA) of relevant batch of drug substance used during product development and stability study by drug product manufacturer shall be submitted	• Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance is submitted. • Certificate of Analysis (COA) of relevant batch of drug substance (batch No# NP1713-1908003) used during product development and stability study by drug product is submitted
3.2.S.7	• Stability study data of 3 batches of drug substance at real time conditions till claimed shelf life shall be submitted (only 09 months data submitted)	• Stability study data of 3 batches of drug substance at real time conditions till claimed shelf life is submitted (upto 36 months)
3.2.P.8	• Justification shall be submitted for initiation of stability study (12-2021) after almost four months of manufacturing of trial batches (08-2021).	• The firm submitted that we the Searle company informed you that initial testing for stability testing for stability testing for stability batches was carried out at the time of manufacturing. • New tool was fabricated for bacetam 10mg tablet, trial was done. • However, at the time of blistering of stability batch leakage was observed. Upon further investigation, it reveleaed that new fabricated tool need some re-engineering to rectify the leakage problem. Tool was sent back to fabricator and said problem was rectified, which took comparatively more time to rectify it. • As per SOP, if there is difference in initial testing date and stability kept date for more than one month than re-analysis of that product will be performed, and its re-analysis results will be considered as initial results for that batch

Decision: Approved.

231.	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)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 25420 dated 19-10-2023
	Details of fee submitted	Rs.30,000/- dated 08-09-2023 (Deposit slip#152554890622)
	The proposed proprietary name / brand name	**Nabivara 75mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Brivaracetam……75mg
	Pharmacotherapeutic Group of (API)	Antiepileptics, Other antiepileptics
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	BRIVIACT (10mg, 25mg, 50mg, 75mg, 100mg) film coated tablets USFDA Approved
	For generic drugs (me-too status)	Brivatam 25mg tablet by M/s CCL Pharmaceuticals (Reg#109738)
	Proposed Pack size & proposed unit price	14's; As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.3.4	• Valid copy of DML or receiving of application submitted in Licensing Division for renewal of DML shall be submitted	• Acknowledgement for renewal of DML dated 09-04-2024 is submtted
1.6.5	• Submit valid copy of cGMP certificate / Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin	• Firm has submitted copy of cGMP and GLP certificate of API manufacturer issued by Drugs Control Administration Government of Andhra Pradesh India valid upto 19-01-2025
3.2.S.4	• Drug substance data in module 3 is not submitted. Submit complete drug substance data without referring to other application	• Complete drug substance data in module 3 is submitted
3.2.P.5	• Justification shall be submitted for not including the test for water content in finished product specifications as per innovator's product review document	• Firm submitted that in reference to innovator's product review document we have incorporated water content test in finished product specifications and also conducted water content test on retention samples and submitted the results.

Decision: Approved. Registration Board further decided that Registration letter will be issued after submission of fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(l)2024 dated 30-08-2024

232.	Name, address of Applicant / Marketing Authorization Holder	M/s Genetics Pharmaceuticals (Pvt.) Ltd., 539-A, Sundar Industrial Estate, Raiwind Road, Lahore
	Name, address of Manufacturing site.	M/s Genetics Pharmaceuticals (Pvt.) Ltd., 539-A, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 24315 dated 04-10-2023
	Details of fee submitted	Rs.30,000/- dated 18-08-2023 (Deposit slip#08001892)
	The proposed proprietary name / brand name	**Neolepra ODT 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Orally Disintegrating Tablet Contains: Olanzapine……..…10mg
	Pharmacotherapeutic Group of (API)	Antipsychotics
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	Olanzapine 10mg Orodispersible Tablets MHRA Approved
	For generic drugs (me-too status)	Zyprexa zydis Tablet 10mg by M/s Eli-Lilly Pakistan (Reg# 69571)
	Proposed Pack size & proposed unit price	10's; As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of retention of license certificate of API manufacturer issued by Food & Drugs Control Administration, Gujarate State India valid upto 21-03-2026. • Firm has also submitted copy of application applied for renewal of cGMP certificate of API manufacturer dated 12-08-2024.
3.2.S.4	• Drug substance data in module 3 is not submitted. Submit complete drug substance data without referring to other application	• Complete drug substance data in module 3 is submitted.
3.2.P.2	• Submit results of drug excipient compatibility study as the qualitative composition of applied product is not similar to reference product	• The firm submitted that qualitative composition of applied product is same as reference product i.e. Apo-olanzapine ODT by Apotex Inc. (Approved by Health Canada). Firm has submitted details of reference formulation and applied formulation
3.2.P.5	• Justification shall be submitted for not including the test for uniformity of dosage units in finish product specifications as per USP monograph	• Firm has submitted revised finished product specifications in which test for content uniformity has been included
3.2.P.8	• Submit documents for procurement of API with approval from DRAP	• Firm has submitted copy of commercial invoice cleared dated 10-11-2021 specifying 10kg Olanzapine. The invoice is cleared by AD (I&E) DRAP.

Decision: Approved. Registration Board further decided that Registration letter will be issued after submission of fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(I)2024 dated 30-08-2024

233.	Name, address of Applicant / Marketing Authorization Holder	M/s Kaizen Pharmaceuticals (Pvt.) Ltd., E-127-E-129, North Western Industrial Zone, Port Qasim Authority, Karachi
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals (Pvt.) Ltd., E-127-E-129, North Western Industrial Zone, Port Qasim Authority, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 24512 dated 06-10-2023
	Details of fee submitted	Rs.75,000/- dated 05-09-2023 (Deposit slip#697323682)
	The proposed proprietary name / brand name	**Vilazo 40mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vilazodone HCl……..…40mg
	Pharmacotherapeutic Group of (API)	Selective serotonin reuptake inhibitor and Serotonin 5-HT1A receptor partial agonist; Serotonin modulator
	Reference to Finished product specifications	Innovator's specification
	The status in reference regulatory authorities	VIIBRYD (10mg, 20mg, 40mg) film-coated tablets USFDA Approved
	For generic drugs (me-too status)	N/A
	Proposed Pack size and unit price	3x10's: As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.6.5	• Clarification shall be submitted since the address of manufacturing site mentioned in the submitted GMP, COA and stability summary sheet of drug substance manufacturer is different than that mentioned in section 1.6.5 and section 3.2.S.2.1 of form 5F	• The firm submitted that M/s Symed Labs ltd., situated at address Plot No. 25/B, Phase-III, IDA, Jeedimetla, Hyderabad, Jeedimetla village, Qutbullapur mandal, Medchal-Malkajgiri District, Telangana state, India is in agreement with seemed Research center located at plot No 89/A, phase-I, IDA, Jeedimetla, Hyderabad Andhra Pradesh India. • Symed Labs Limited and Symed Research Center is in relationship for the development and manufacture of active pharmaceutical ingredients. Seemed Research Center develops the API at their technology development center and transfers the technology to Symed Labs for manufacturing. Symed Labs upscales the APIs after receiving the technology from Symed Research Center. • Firm has revised the details of API manufacturer in section 1.6.5; • M/s Symed Labs Limited (Unit-I) Plot No. 25/B, Phase-III, IDA, Jeedimetla, Hyderabad, Jeedimetla (V), Qutbullapur (M), Medchal-Malkajgiri District, India

3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of secondary reference standard including source and lot number is provided.
3.2.P.8	• Submit copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP.	• Firm has again submitted copy of form 6 issued dated 07-10-2022 specifying 400gm Vilazodone hydrochloride. The form 6 is issued by AD (I&E) DRAP. • Firm has also submitted courier Fedex details

Decision: Approved.

234.	Name, address of Applicant / Marketing Authorization Holder	M/s Kaizen Pharmaceuticals (Pvt.) Ltd., E-127-E-129, North Western Industrial Zone, Port Qasim Authority, Karachi
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals (Pvt.) Ltd., E-127-E-129, North Western Industrial Zone, Port Qasim Authority, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 24511 dated 06-10-2023
	Details of fee submitted	Rs.75,000/- dated 05-09-2023 (Deposit slip#4564563886)
	The proposed proprietary name / brand name	**Vilazo 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vilazodone HCl……..…20mg
	Pharmacotherapeutic Group of (API)	Selective serotonin reuptake inhibitor and Serotonin 5-HT1A receptor partial agonist; Serotonin modulator
	Reference to Finished product specifications	Innovator's specification
	The status in reference regulatory authorities	VIIBRYD (10mg, 20mg, 40mg) film-coated tablets USFDA Approved
	For generic drugs (me-too status)	N/A
	Proposed Pack size and unit price	3x10's: As per SRO

Evaluation by PEC[XI]:

The firm has submitted request to Incharge PEC dated 31-10-2024 for withdrawal of previous applications and proceeding of new registration application for Ilazo 10mg tablet and Ilazo 20mg tablet (Vilazodone). The letter stated that registration application of their product Ilazo 10mg tablet tablet (R&I dated 15-09-2021) and Ilazo 20mg tablet (R&I dated 15-09-2021) was discussed in 322nd meeting of Registration Board held on 08th-10th November, 2022 and *deferred the case for submission of reply to the above cited shortcomings within six months.* The firm informed that due to technical reasons, we were unable to submit the required documents within the six months time frame. Therefore we kindly request the withdrawal of previous applications. The firm further submitted to consider the newly submitted application.

Section	**Observations**	**Firm's Response**
1.6.5	• Clarification shall be submitted since the address of manufacturing site mentioned in the submitted GMP, COA and stability summary sheet of drug substance manufacturer is different than that mentioned in	• The firm submitted that M/s Symed Labs ltd., situated at address Plot No. 25/B, Phase-III, IDA, Jeedimetla, Hyderabad, Jeedimetla village, Qutbullapur mandal, Medchal-Malkajgiri District, Telangana state, India is in agreement with seemed Research center located at plot No 89/A, phase-I, IDA,

	section 1.6.5 and section 3.2.S.2.1 of form 5F	Jeedimetla, Hyderabad Andhra Pradesh India. • Symed Labs Limited and Symed Research Center is in relaship for the development and manufacture of active pharmaceutical ingredients. Seemed Research Center develops the API at their technology development center and transfers the technology to Symed Labs for manufacturing. Symed Labs upscales the APIs after receiving the technology from Symed Research Center. • Firm has revised the details of API manufacturer in section 1.6.5; • M/s Symed Labs Limited (Unit-I) Plot No. 25/B, Phase-III, IDA, Jeedimetla, Hyderabad, Jeedimetla (V), Qutbullapur (M), Medchal-Malkajgiri District, India
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of secondary reference standard including source and lot number is provided.
3.2.P.8	• Submit copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP.	• Firm has again submitted copy of form 6 issued dated 07-10-2022 specifying 400gm Vilazodone hydrochloride. The form 6 is issued by AD (I&E) DRAP. • Firm has also submitted courier Fedex details

Decision: Registration Board decided to approve the instant application of the firm.
Registration Board further decided to dispose of the previous application of the firm which was deferred in 322nd meeting of Registration Board. The details of the application is given below;

Name, address of Applicant / Marketing Authorization Holder	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. 25694 dated 15/09/2021
Details of fee submitted	PKR 75,000/-: dated 02/07/2021
The proposed proprietary name / brand name	Ilazo 20mg tablet
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains Vilazodone HCl……...20mg
Pharmaceutical form of applied drug	Film coated tablet
Pharmacotherapeutic Group of (API)	Antidepressant Agent
Reference to Finished product specifications	Manufacturer's specification

	Proposed Pack size	10's, 20's, 30's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	VIIBRYD (10mg, 20mg, 40mg) film-coated tablets USFDA Approved
	For generic drugs (me-too status)	N/A
	GMP status of the Finished product manufacturer	The firm was inspected on 11-08-2020 and conclusion of inspection was: The overall cGMP compliance of the firm with respect to building, facilities and procedures demonstrated was satisfactory at the time of inspection.
	Name and address of API manufacturer.	***Section 1.6.5:*** M/s Symed Labs Limited Sy.No.744, 745, ***750, 751, 752*** & 751. Mandollagudem Village, Choutuppal Mandal, Yadadri District, Telangana India***. (expired 24-04-2018)*** ***3.2.S.2:*** Symed Labs Limited (Unit-I) Survey No.353, Domadugu (Village), Jinnaram (Mandal), Medak (Dist) – 502 313. 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)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, 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:(VLH Ex No: 001, VLH Ex No: 002, VLH Ex No: 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 that is Viibryd 20mg tablet performing quality tests (Identification, Assay, Dissolution). CDP has been performed against the same brand that is Viibryd 20mg Tablet in Acid media (pH 0.1N HCl), 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 have submitted including linearity, accuracy, precision, specificity, LOD, LOQ)

STABILITY STUDY DATA

Manufacturer of API	Symed Labs Limited (Unit I), Survey No.353, Domadugu (Village), Jinnaram (Mandal), Medak (Dist.) - 502 313. Telangana, India ***(Applied)***		
API Lot No.	VLH0060616		
Description of Pack (Container closure system)	PVC/ aluminum 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: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24(Months)		
Batch No.	TF-01	TF-02	TF-03
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	13-09-2017	19-12-2017	19-12-2017
Date of Initiation	28-09-2017	04-01-2018	04-01-2018
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 previous inspection report of Rofair 500 mcg Tablet which is conducted on 25-06-2019 and considered in 290th meeting of Registration Board. The report confirms that: • HPLC system is 21 CFR part II compliant and Audit trail reports were 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.	The firm submitted certificate No. L.Dis.No.6592/A3/2017 of M/s Symed Labs Limited Sy.No.744, 745 & 751. Mandollagudem Village, Choutuppal Mandal, Yadadri District, Telangana India issued by Drugs Control Administration Govt. of Telangana. ***(valid upto 24-04-2018)***
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted FedEx receipt dated 28-March-2017. However, the contents of receipt are not readable

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, 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)	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	• Valid GMP certificate / DML of drug substance manufacturer issued by relevant regulatory authority of country of origin is required • Clarification shall be submitted since the submitted GMP, COA, stability summary sheet of drug substance and section 1.6.5 and section 3.2.S.2.1 of form 5F reflects different manufacturing site	
3.2.S.4	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	
3.2.S.6	• Description of the container closure system(s) for the shipment and storage of the API including materials of construction of each primary packaging component.	
3.2.P.2.2.1	• A brief description of formulation development shall be given.	
3.2.P.5.1.	• Justify the acceptance criteria of dissolution test NLT Q in 45min in product specifications since FDA review documents specifies that dissolution criteria shall be NLT Q in 30 min for the applied product	
3.2.P.5.3	• No chromatographic conditions are mentioned in analytical method validation	
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	
3.2.P.8	• The quantity of imported drug substance as per submitted COA is 40gm (DS COA) / 0.039KG (Drug product COA) and three batches of 10mg & 20mg Ilazo tablets each of 1500 tablets were manufactured from it. Justification is required as how the imported drug substance was sufficient enough to manufacture three batches of each strength. *(drug substance required for three batches of 10mg tab 45.33 gm and 20mg tab is 90.54gm)* • COAs of performed stability study are not submitted • Compliance Record of HPLC software 21CFR & audit trail reports on product testing is not submitted • Submit readable copy of documents for the procurement of API with approval from DRAP. • Sampling and testing date of API by drug product manufacturer is 13-11-2017 while manufacturing date of the drug product batch No. TF-01 is 13-09-2017 which is prior to sampling and testing date of API, clarify?	

Decision of 322nd meeting of RB: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

235.	Name, address of Applicant / Marketing Authorization Holder	M/s Kaizen Pharmaceuticals (Pvt.) Ltd., E-127-E-129, North Western Industrial Zone, Port Qasim Authority, Karachi

	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals (Pvt.) Ltd., E-127-E-129, North Western Industrial Zone, Port Qasim Authority, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 24510 dated 06-10-2023
	Details of fee submitted	Rs.75,000/- dated 05-09-2023 (Deposit slip#7518815068)
	The proposed proprietary name / brand name	**Vilazo 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vilazodone HCl……..…10mg
	Pharmacotherapeutic Group of (API)	Selective serotonin reuptake inhibitor and Serotonin 5-HT1A receptor partial agonist; Serotonin modulator
	Reference to Finished product specifications	Innovator's specification
	The status in reference regulatory authorities	VIIBRYD (10mg, 20mg, 40mg) film-coated tablets USFDA Approved
	For generic drugs (me-too status)	N/A
	Proposed Pack size and unit price	3x10's: As per SRO

Evaluation by PEC[XI]:

The firm has submitted request to Incharge PEC dated 31-10-2024 for withdrawal of previous applications and proceeding of new registration application for Ilazo 10mg tablet and Ilazo 20mg tablet (Vilazodone). The letter stated that registration application of their product Ilazo 10mg tablet tablet (R&I dated 15-09-2021) and Ilazo 20mg tablet (R&I dated 15-09-2021) was discussed in 322nd meeting of Registration Board held on 08th-10th November, 2022 and *deferred the case for submission of reply to the above cited shortcomings within six months.* The firm informed that due to technical reasons, we were unable to submit the required documents within the six months time fram. Therefore we kindly request the withdrawal of previous applications. The firm further submitted to consider the newly submitted application.

Section	Observations	Firm's Response
1.6.5	• Clarification shall be submitted since the address of manufacturing site mentioned in the submitted GMP, COA and stability summary sheet of drug substance manufacturer is different than that mentioned in section 1.6.5 and section 3.2.S.2.1 of form 5F	• The firm submitted that M/s Symed Labs ltd., situated at address Plot No. 25/B, Phase-III, IDA, Jeedimetla, Hyderabad, Jeedimetla village, Qutbullapur mandal, Medchal-Malkajgiri District, Telangana state, India is in agreement with seemed Research center located at plot No 89/A, phase-I, IDA, Jeedimetla, Hyderabad Andhra Pradesh India. • Symed Labs Limited and Symed Research Center is in relaship for the development and manufacture of active pharmaceutical ingredients. Seemed Research Center develops the API at their technology development center and transfers the technology to Symed Labs for manufacturing. Symed Labs upscales the APIs after receiving the technology from Symed Research Center. • Firm has revised the details of API manufacturer in section 1.6.5; • M/s Symed Labs Limited (Unit-I) Plot No. 25/B, Phase-III, IDA, Jeedimetla, Hyderabad,

		Jeedimetla (V), Qutbullapur (M), Medchal-Malkajgiri District, India
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of secondary reference standard including source and lot number is provided.
3.2.P.8	• Submit copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP.	• Firm has again submitted copy of form 6 issued dated 07-10-2022 specifying 400gm Vilazodone hydrochloride. The form 6 is issued by AD (I&E) DRAP. • Firm has also submitted courier Fedex details

Decision: Registration Board decided to approve the instant application of the firm. Registration Board further decided to dispose of the previous application of the firm which were deferred in 322nd meeting of Registration Board. The details of the application is given below;

Name, address of Applicant / Marketing Authorization Holder	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. 25693 dated 15/09/2021
Details of fee submitted	PKR 75,000/-: dated 02/07/2021
The proposed proprietary name / brand name	Ilazo 10mg tablet
Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains Vilazodone HCl……...10mg
Pharmaceutical form of applied drug	Film coated tablet
Pharmacotherapeutic Group of (API)	***Angiotensin II receptor blocker***
Reference to Finished product specifications	Manufacturer's specification
Proposed Pack size	10's, 20's, 30's
Proposed unit price	As per SRO
The status in reference regulatory authorities	VIIBRYD (10mg, 20mg, 40mg) film-coated tablets USFDA Approved
For generic drugs (me-too status)	N/A
GMP status of the Finished product manufacturer	The firm was inspected on 11-08-2020 and conclusion of inspection was: The overall cGMP compliance of the firm with respect to building, facilities and procedures demonstrated was satisfactory at the time of inspection.
Name and address of API manufacturer.	***Section 1.6.5:*** M/s Symed Labs Limited Sy.No.744, 745, ***750, 751, 752*** & 751.

		Mandollagudem Village, Choutuppal Mandal, Yadadri District, Telangana India***. (expired 24-04-2018)*** ***3.2.S.2:*** Symed Labs Limited (Unit-I) Survey No.353, Domadugu (Village), Jinnaram (Mandal), Medak (Dist) – 502 313. 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)	The firm as submitted detail of nomenclature, structure, general properties, solubilities, 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:(VLH Ex No: 001, VLH Ex No: 002, VLH Ex No: 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 that is Viibryd 10mg tablet performing quality tests (Identification, Assay, Dissolution). CDP has been performed against the same brand that is Viibryd 10mg Tablet in Acid media (pH 0.1N HCl), 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 have submitted including linearity, accuracy, precision, specificity, LOD, LOQ)
STABILITY STUDY DATA		

Manufacturer of API	Symed Labs Limited (Unit I), Survey No.353, Domadugu (Village), Jinnaram (Mandal), Medak (Dist.) - 502 313. Telangana, India ***(Applied)***		
API Lot No.	VLH0060616		
Description of Pack (Container closure system)	PVC/ aluminum 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: 24 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6, 9, 12, 18, 24(Months)		
Batch No.	TF-01	TF-02	TF-03
Batch Size	1500 tab	1500 tab	1500 tab
Manufacturing Date	13-09-2017	19-12-2017	19-12-2017
Date of Initiation	28-09-2017	18-01-2018	18-01-2018
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 previous inspection report of Rofair 500 mcg Tablet which is conducted on 25-06-2019 and considered in 290th meeting of Registration Board. The report confirms that: • HPLC system is 21 CFR part II compliant and Audit trail reports were 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.	The firm submitted certificate No. L.Dis.No.6592/A3/2017 of M/s Symed Labs Limited Sy.No.744, 745 & 751. Mandollagudem Village, Choutuppal Mandal, Yadadri District, Telangana India issued by Drugs Control Administration Govt. of Telangana. ***(valid upto 24-04-2018)***
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted FedEx receipt dated 28-March-2017. However, the contents of receipt are not readable
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, 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)	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

1.5.5.	• Mention correct Pharmacological class of the API (drug substance) along with WHO ATC code for each distinct therapeutic indication.	
1.6.5	• Valid GMP certificate / DML of drug substance manufacturer issued by relevant regulatory authority of country of origin is required • Clarification shall be submitted since the submitted GMP, COA, stability summary sheet of drug substance and section 3.2.S.2.1 of form 5F reflects different manufacturing site	
3.2.S.4	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	
3.2.S.6	• Description of the container closure system(s) for the shipment and storage of the API including materials of construction of each primary packaging component.	
3.2.P.2.2.1	• A brief description of formulation development shall be given.	
3.2.P.5.1.	• Justify the acceptance criteria of dissolution test NLT Q in 45min in product specifications since FDA review documents specifies that dissolution criteria shall be NLT Q in 30 min for the applied product	
3.2.P.5.3	• No chromatographic conditions are mentioned in analytical method validation	
3.2.P.5.4	• Identification test as mentioned in specification is by HPLC while in Batch analysis performed by IR, clarify?	
3.2.P.6	• COA of Reference Standards or Materials is not submitted, instead COA of Drug substance is submitted. COA of primary / secondary reference standard including source and lot number shall be provided.	
3.2.P.8	• The quantity of imported drug substance as per submitted COA is 40gm (DS COA) / 0.039KG (Drug product COA) and three batches of 10mg & 20mg Ilazo tablets each of 1500 tablets were manufactured from it. Justification is required as how the imported drug substance was sufficient enough to manufacture three batches of each strength. ***(drug substance required for three batches of 10mg tab 45.33 gm and 20mg tab is 90.54gm)*** • COAs of performed stability study are not submitted • Compliance Record of HPLC software 21CFR & audit trail reports on product testing is not submitted • Submit readable copy of documents for the procurement of API with approval from DRAP. • Sampling and testing date of API by drug product manufacturer is 13-11-2017 while manufacturing date of the drug product batch No. TF-01 is 13-09-2017 which is prior to sampling and testing date of API, clarify?	

Decision of 322nd meeting of RB: Registration Board deferred the case for submission of reply to the above cited shortcomings within six months.

236.	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)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 25419 dated 19-10-2023
	Details of fee submitted	Rs.30,000/- dated 14-09-2023 (Deposit slip#642126461493)

	The proposed proprietary name / brand name	**Itoque 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Itopride HCl……50mg
	Pharmacotherapeutic Group of (API)	Drugs for functional gastrointestinal disorders, Propulsives
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	Progit 50mg Film-Coated Tablets MHRA Approved Reflad 50mg film-coated tablets HPRA Approved
	For generic drugs (me-too status)	Itomit 50mg Tablet by M/s Wimits Pharmaceuticals (Reg#99735)
	Proposed Pack size & proposed unit price	7's, 10's, 20's, 30's; As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.3.4	• Valid copy of DML or receiving of application submitted in Licensing Division for renewal of DML shall be submitted	• Acknowledgement for renewal of DML dated 09-04-2024 is submitted
3.2.P.8	• Submit copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP.	• Firm has submitted copy of commercial invoice dated 26-09-2022 specifying 0.65kg Itopride Hydrochloride. However, the commercial invoice is not cleared by AD (I&E) DRAP. • Firm has submitted copy of form 6 issued dated 03-10-2022 specifying 0.65kg Itopride hydrochloride. The form 6 is issued by AD (I&E) DRAP. • Firm has also submitted GD copy and Airway bill specifying Itopride Hydrochloride.

Decision: Approved.

237.	Name, address of Applicant / Marketing Authorization Holder	M/s Crystolite Pharmaceuticals., Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad.
	Name, address of Manufacturing site.	M/s Crystolite Pharmaceuticals., Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 24687 dated 10-10-2023
	Details of fee submitted	Rs.75,000/- dated 24-07-2023 (Deposit slip#45687798476)
	The proposed proprietary name / brand name	**Lizole 1% Cream**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram Contains: Luliconazole……..…10mg
	Pharmacotherapeutic Group of (API)	Antifungals for topical use
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	LUZU (luliconazole) Cream, 1% for topical use USFDA Approved.
	For generic drugs (me-too status)	N/A
	Proposed Pack size & proposed unit price	5gm; As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.3.4	• Valid copy of DML or receiving of application submitted in Licensing Division for renewal of DML shall be submitted	• Firm has submitted valid copy of DML renewed w.e.f. 30-08-2023
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority.	• Firm has submitted copy of renewal of DML dated 06-03-2019 specifying Cream/Ointment (General) section.
1.6.5	• Valid copy of cGMP certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of cGMP certificate of API manufacturer issued by Tengzhou Food and Drug Administration, China valid upto 22-09-2027.
3.2.S.4	• Copies of the Drug substance specifications used for routine testing of the Drug substance by Drug Product manufacturer is required.	• Copies of the Drug substance specifications by Drug Product manufacturer is not submitted.
3.2.P.2	• Submit details of comparator product including marketing authorization holder against which Pharmaceutical equivalence studies has been performed	• Firm has submitted details of comparator product against which Pharmaceutical equivalence studies has been performed Brand Name: Luliconazole cream 1% Manufacturer: Bausch Health company, Canada Distributor; Oceanside Pharmaceuticals a division of Bausch Health, USA. Batch No; 8147161; Exp date; 07-2025

Decision: Approved. Registration Board further decided that Registration letter will be issued after submission of copies of the Drug substance specifications of the Drug substance by Drug Product manufacturer.

238.	Name, address of Applicant / Marketing Authorization Holder	M/s Ferozsons Laboratories Ltd., P.O. Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa
	Name, address of Manufacturing site.	M/s Ferozsons Laboratories Ltd., P.O. Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 26381 dated 01-11-2023

	Details of fee submitted	Rs.30,000/- dated 20-09-2023 (Deposit slip#84819708161)
	The proposed proprietary name / brand name	**Linagen 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Linagliptin…….5mg
	Pharmacotherapeutic Group of (API)	Dipeptidyl peptidase-4 (DPP-4) inhibitor (antidiabetic)
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	Tradjenta 5mg film coated tablets USFDA Approved.
	For generic drugs (me-too status)	Linvesta 5mg Tablet by M/s Wilshire Laboratories (Reg#110608)
	Proposed Pack size & proposed unit price	7's, 10's, 14's, 20's, 28's, 30's; As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.6.5	• Valid copy of cGMP certificate / Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of DML (License#Yue20160622) of API manufacturer issued by Guangdon Food and Drug Administration China valid upto 07-10-2026.
3.2.P.5	• Justification is required for not including the test for loss on drying in finished product specification as per innovator product review document. • Justification is required since dissolution apparatus mentioned in dissolution method (Apparatus II) for applied drug product is different than that recommended by innovator product review document (Apparatus I (Basket)	• Firm has submitted revised finished product specifications in which the test for loss on drying has been incorporated. • The firm submitted that we have followed dissolution method (apparatus II) for linagen 5mg tablet as per FDA dissolution guidance 2018 recommended by FDA Dissolution database. • However, the product is also tested by adopting the recommendations of innovator's product i.e. Apparatus I (basket) and found complies. The results of test are submitted

Decision: Approved.Registration Board further decided that Registration letter will be issued after submission of fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(l)2024 dated 30-08-2024

239.	Name, address of Applicant / Marketing Authorization Holder	M/s Wnsfeild Pharmaceuticals., Plot # 122, Block A, Phase-V, Industrial Estate, Hattar, Haripur, KPK
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals., Plot # 122, Block A, Phase-V, Industrial Estate, Hattar, Haripur, KPK
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 26512 dated 02-11-2023
	Details of fee submitted	Rs 30,000/- dated 04-05-2023 (Deposit slip#763295553574)

	The proposed proprietary name / brand name	**Tamsofin 6mg/0.4mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Solifenacin Succinate……...6mg Tamsulosin HCl……0.4mg
	Pharmacotherapeutic Group of (API)	Tamsolusin Alpha-adrenoreceptor antagonists Solifenacin succinate Antimuscarinic
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	Vecit 6mg/0.4mg Modified-release Tablets MHRA Approved Solifenacin succinate/Tamsulosin hydrochloride Milpharm 6mg/0.4mg modified release tablets MHRA Approved
	For generic drugs (me-too status)	Tamsol-S 0.4mg/6mg Tablet by M/s Global Pharmaceuticals (Reg# 96667)
	Proposed Pack size & proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations
1.1	• Submit differential fee of Rs. 270000/- for imported source of pellets
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority. • Provide evidence of double layer tablet compression machine for applied product
1.5.2	• The reference formulation is bilayer, film coated modified release tablet while you have applied for film coated tablet. Revised the label claim as per reference formulation along with submission of applicable • Modified release layer of tamsolusine ??? pellets? Fee.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer for drug substance Tamsulosin HCl and Solefenacin succinate issued by relevant regulatory authority of country of origin 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 solifenacin succinate and Tamsulosin HCl by Drug Product manufacturer is required. • Copies of the complete analytical procedures used for routine testing of the Drug substance solifenacin succinate and Tamsulosin HCl by Drug substance manufacturer is required. • Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance solifenacin succinate and Tamsulosin HCl shall be submitted. • Justification shall be submitted for not performing the test for sulphated ash/residue on ignition in batch analysis of drug substance solifenacin succinate and Tamsulosin HCl by drug product manufacturer as per drug substance manufacturer • Certificate of Analysis (COA) of relevant batch of drug substance used during product development and stability study by both drug substance manufacturer and drug product manufacturer for solifenacin succinate shall be submitted
3.2.S.5	• COA of primary / secondary reference standard solifenacin succinate including source and lot number shall be provided.
3.2.P.1	• The reference formulation is bilayer, film coated modified release tablet containing modified releas layer of Tamsulosin HCl and immediate release layer of solifenacin succinate while the applied formulation does not contain modified release component, clarify?

3.2.P.2	• Submit details of comparator product including batch number, manufacturing date and expiry date against which Pharmaceutical equivalence studies has been performed • Submit complete results of CDP studies of applied product against the reference product • Submit results of drug excipient compatibility study as the qualitative composition of applied product is not similar to reference product
3.2.P.5	• Justification is required for not mentioning the dissolution limits of both solifenacin succinate and tamsolucin hydrochloride sepearately in finished product specifications as solifenacine is available in immediate layer and tamsulosin hydrochloride is available in modifies release layer • Analytical procedure for all the tests given in finished product specifications shall be submitted
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.
3.2.P.8	• Submit copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP. • Stability study data of drug product at 6th month time point shall be submitted

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings

240.	Name, address of Applicant / Marketing Authorization Holder	M/s Macter International Ltd., F-216, S.I.T.E, Karachi, Pakistan
	Name, address of Manufacturing site.	M/s Macter International Ltd., F-216, S.I.T.E, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 27430 dated 22-11-2023
	Details of fee submitted	Rs 30,000/- dated 06-11-2023 (Deposit slip#22699807)
	The proposed proprietary name / brand name	**Esonap 500mg/20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Modified Release Tablet Contains: Naproxen (Enteric Coated Core)…500mg Esomeprazole (Immediate Release Coat)……..…20mg
	Pharmacotherapeutic Group of (API)	NSAID and proton pump inhibitor
	Reference to Finished product specifications	Not submitted
	The status in reference regulatory authorities	VIMOVO 500mg/20mg modified-release tablets MHRA Approved
	For generic drugs (me-too status)	Glomov 500/20mg Tablet by M/s Global Pharmaceuticals (Pvt.) Ltd (Reg#109338)
	Proposed Pack size & proposed unit price	14's, 28's; As per SRO

Evaluation by PEC[XI]:

Section	Observations
1.5.6	• Mention the reference specifications of the finished product
1.6.5	• Valid copy of cGMP certificate / Drug Manufacturing License of the Drug Substance manufacturer for naproxen issued by relevant regulatory authority of country of origin is required

3.2.S.4	• Justification shall be submitted for selecting different limit of assay test in drug substance specification for esomeprazole magnesium by drug product manufacturer (98-102.05%) than USP monograph • Justification shall be submitted for selecting different composition of mobile phase ratio (35;35 v/v) in assay test for esomeprazole by drug product manufacturer than USP method (35;65 v/v)
3.2.P.2	• Submit results of drug excipient compatibility study as the qualitative composition of applied product is not similar to reference product
3.2.P.5	• Justification is required for not including the time for dissolution test for naproxen in finished product specification as per innovator product review document.
3.2.P.8	• Submit copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings

241.	Name, address of Applicant / Marketing Authorization Holder	M/s DeMont Research Laboratories (Pvt.) Ltd., 20-km, Lahore-Sharikpur Road, Sheikhupura.
	Name, address of Manufacturing site.	M/s DeMont Research Laboratories (Pvt.) Ltd., 20-km, Lahore-Sharikpur Road, Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 26542 dated 03-11-2023
	Details of fee submitted	Rs.30,000/- dated 26-09-2023 (Deposit slip#0944035543)
	The proposed proprietary name / brand name	**Nif-La 30mg Extended Release Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Tablet Contains: Nifedipine……30mg
	Pharmacotherapeutic Group of (API)	Calcium antagonist
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Nidef 30mg Prolonged Release Tablets MHRA Approved
	For generic drugs (me-too status)	Ifedip PR Tablet 30mg Tablet by M/s Genix Pharma (Reg# 108623)
	Proposed Pack size & proposed unit price	20's; As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.5.5	• Indicate correct Pharmacological class of the API (drug substance) with proper reference.	• The firm submitted that Nifedipine is a calcium channel blocker in dihydropyridine subclass. It is primarily used as an antihypertensive and used as an anti-anginal medication. FDA approved indications include chronic stable angina, hypertension.
2.3.R.1	• The reference formulation contains a series of three coating layers (seal coating, cellulose acetate coating, film coating) while you have applied a single coating layer clarify	• The firm has referred to Adalat LA 30mg tablets in which different coating layers are not mentioned

3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug substance manufacturer is required.	• Copies of the Drug substance specifications by Drug substance manufacturer is submitted. However, analytical procedures of the Drug substance by Drug substance manufacturer is not submitted.
3.2.S.7	• Stability study data of 3 batches of drug substance at real time conditions till claimed shelf life shall be submitted	• Stability study data of 3 batches of drug substance at real time conditions till 60 months is submitted
3.2.P.2	• Submit results of drug excipient compatibility study as the qualitative composition of applied product is not similar to reference product • The results of comparative dissolution profile conducted in three BCS media across the physiological pH range shall be submitted	• Results of drug excipient compatibility study of applied product is submitted • Firm has submitted dissolution results of applied product against Adalat LA 30mg tablet by M/s Bayer Pakistan and Maspidine 30mg SR tablet by M/s Mass Pharma on gastric fluid without enzyme containing 0.5 SLS.
3.2.P.8	• Submit copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP.	• Firm has submitted copy of commercial invoice cleared dated 29-09-2020 specifying 10kg Nifedipine USP. The commercial invoice is attested AD (I&E) DRAP.

Decision: Approved. Registration Board further decided that Registration letter will be issued after submission of following documents:

i. **Analytical procedures of the Drug substance by Drug substance manufacturer**
ii. **Results of comparative dissolution profile conducted in three BCS media across the physiological pH range**

Case No. 02; Deferred Registration application on Form 5F

242.	Name, address of Applicant / Marketing Authorization Holder	M/s Kaizen Pharmaceuticals (Pvt.) Ltd., E-127-129, North Western Industrial Zone, Port Qasim Authority, Karachi
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals (Pvt.) Ltd., E-127-129, North Western Industrial Zone, Port Qasim Authority, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 18535 dated 24-07-2023
	Details of fee submitted	Rs.75,000/- dated 07-06-2023 (Deposit slip#3045015647)
	The proposed proprietary name / brand name	**Rupaler 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Rupatadine (as Fumarate)……10mg
	Pharmacotherapeutic Group of (API)	Antihistamines
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Rupatadine 10mg Tablets MHRA Approved
	For generic drugs (me-too status)	N/A
	Proposed Pack size and unit price	20's, 50's, 100's,: As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.3.4	• Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate of the firm based on inspection dated 03-01-2023.
3.2.S.4	• Copies of the Drug substance specifications and analytical procedure used for routine testing of the Drug substance by Drug Product manufacturer is required. • Justification shall be submitted for not performing fumaric acid content and pH test in batch analysis of drug substance by drug product manufacturer	• Copies of the Drug substance specifications and analytical procedure used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • The firm submitted we have prepared rupatadine fumarate specifications and method of analysis from available monograph of BP. • BP does not have any test for fumaric acid content and pH. That's why we did not perform the said test.
3.2.P.2	• Justification is required for selecting only two time point (10 and 15min) of dissolution in CDP studies instead of a minimum of three time-points (zero excluded) for both reference and test product as per applicable guideline.	• The firm submitted that the dissolution results at all the three time points are above 85% at 10 minutes interval. As per international guidelines of comparative dissolution profile for e.g. FDA, "only one measurement should be considered after 85% dissolution of both the products." That is why only two points are included in data. FDA reference is submitted. • However, these guidance suggests that this method is most suitable for dissolution profile comparison when three to four or more dissolution time points are available.
3.2.P.8	• Clarify the batch size of applied product as in batch analysis and stability summary sheets it is 1000 tablets while in executed BMR it is 700 tablets.	• The firm submitted that 700 tablets are mentioned in BMR, which is correct. In the batch analysis and stability summary sheets, 1000 tablets are mentioned which is incorrectly written by mistake. We are submitting the corrected batch analysis report and summary sheets.

Previous Decision (340th-DRB): Deferred for submission of results of comparative dissolution profile of applied product against innovator/reference/comparator product conducted in three BCS media across the physiological pH range as per the guidance document.

Firms Response:
Firm has submitted CDP results of their product against the product Rupatadine AL 10mg by M/s Aliud Pharma in three BCS media considering three time points of sampling for dissolution

Decision: Approved.

243.	Name, address of Applicant / Marketing Authorization Holder	M/s Arsons Pharmaceutical Industries (Pvt.) Ltd., 2.5km Defence Road, off Multan Road, Lahore
	Name, address of Manufacturing site.	M/s Arsons Pharmaceutical Industries (Pvt.) Ltd., 2.5km Defence Road, off Multan Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 6410 dated 07-03-2023

	Details of fee submitted	Rs.30,000/- dated 18-10-2022 (Deposit slip#00907444)
	The proposed proprietary name / brand name	**Voltrex 2% Gel**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram of Gel Contains: Diclofenac Diethylamine Eq. to Diclofenac Sodium……20mg
	Pharmacotherapeutic Group of (API)	NSAID
	Reference to Finished product specifications	BP
	The status in reference regulatory authorities	Diclofenac Diethylamine 2.32% w/w Gel, MHRA approved
	For generic drugs (me-too status)	Swiso 2% Gel by M/s Swiss Pharmaceuticals (Reg.No# 66888)
	Proposed Pack size and unit price	1's; As per SRO

Evaluation by PEC[XI]:

Section	Observations	Firm's Response
1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)	• Firm has submitted copy of DML and letter submitted for renewal of DML dated 03-05-2023
1.3.5	• Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of cGMP certificate of the firm based on inspection dated 05-10-2023.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Firm has submitted copy of cGMP certificate of API manufacturer issued by Food and Drugs Control Adminstration Gujarat State India valid upto 22-11-2025
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>	• 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> is submitted
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance 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 shall be submitted.	• Not submitted • Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance is submitted. However, results specificity and accuracy test is not submitted
3.2.S.7	• Stability study data of drug substance from M/s Cubic analytical solution is submitted instead of API manufacturer. Stability study data of drug substance at zone VI-A conditions till claimed shelf life shall be submitted	• Stability study data of drug substance from M/s Cubic analytical solution is submitted again instead of API manufacturer.
3.2.P.2	• Submit results of drug excipient compatibility study as the qualitative composition of applied product is not similar to reference product	• Not submitted

3.2.P.5	• Results of accuracy tests in analytical method verification study is not submitted	• Results of accuracy tests in analytical method verification study is submitted
3.2.P.6	• COA of primary / secondary reference standard including source and lot number shall be provided.	• COA of primary / secondary reference standard including source and lot number is submitted.
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of clearance certificate dated 03-08-2022 specifying 100Kg Diclofenac Diethylamine. The invoice is cleared by AD (I&E) DRAP.

Previous Decision (339th-DRB):: Deferred for submission of following:

i. Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer
ii. Results of specificity and accuracy in analytical method verification studies performed by the Drug Product manufacturer for drug substance
iii. Stability study data of drug substance from API manufacturer at zone VI-A conditions till claimed shelf life
iv. Results of drug excipient compatibility study

Firm's Response:

S No.	Deferment Reasons	Firm's Response
1	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer	• Analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. However, specifications for drug substance is still not submitted
2	• Results of specificity and accuracy in analytical method verification studies performed by the Drug Product manufacturer for drug substance	• The firm submitted that specificity and accuracy test are not required due to assay performed by potentiometric method
3	• Stability study data of drug substance from API manufacturer at zone VI-A conditions till claimed shelf life	• Stability study data of drug substance from M/s Cubic analytical solution is submitted again instead of API manufacturer.
4	• Results of drug excipient compatibility study	• Results of drug excipient compatibility study is submitted

Decision: Approved. Registration Board further decided that Registration letter will be issued after submission of following documents:

i. Copies of the Drug substance specifications by Drug product manufacturer
ii. Results of specificity and accuracy in analytical method verification studies performed by the Drug Product manufacturer for drug substance
iii. Stability study data of drug substance from API manufacturer at zone VI-A conditions till claimed shelf life

244.	Name, address of Applicant / Marketing Authorization Holder	M/s Wnsfeild Pharmaceuticals., Plot # 122, Block A, Phase-V, Industrial Estate, Hattar, Haripur, KPK
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals., Plot # 122, Block A, Phase-V, Industrial Estate, Hattar, Haripur, KPK
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 3663 dated 08-02-2023
	Details of fee submitted	Rs.30,000/- dated 31-01-2023 (Deposit slip#58109440758)

	The proposed proprietary name / brand name	**Sofovel 400/100 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Sofosbuvir…….400mg Velpatasvir……100mg
	Pharmacotherapeutic Group of (API)	Nucleotide polymerase inhibitors / HCV NS5A replication complex inhibitors.
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	EPCLUSA (400mg/100mg) film-coated tablets USFDA Approved
	For generic drugs (me-too status)	Hilvel 400mg/100mg Tablet by M/s Hilton Pharma (Reg# 86973)
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations
1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority. • Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin 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 Sofosbuvir and Velpatasvir 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 Sofosbuvir and Velpatasvir shall be submitted. • Justification shall be submitted for not performing the test for residue on ignition, and chiral purity in batch analysis of drug substance sofosbuvir by drug product manufacturer as per drug substance manufacturer • Copies of the Drug substance specifications of the Drug substance velpatasvir by Drug substance manufacturer is required. • Justification shall be submitted for not performing the test for residue on ignition, in batch analysis of drug substance velpatasvir by drug product manufacturer as per drug substance manufacturer
3.2.S.7	• Stability study data of velpatasvir at real time conditions till claimed shelf life shall be submitted
3.2.P.1	• Description and Composition of the applied Drug Product shall be submitted
3.2.P.2	• CDP studies of the applied drug with the innovator / reference / comparator product shall be submitted
3.2.P.3.2	• Batch formula for proposed commercial batch size shall be provided that includes a list of all components of the drug product to be used in the manufacturing process
3.2.P.5	• Justification shall be submitted for not including the test for content uniformity in finished product specifications as per innovator's product review document • Justification shall be submitted for not mentioning the time of dissolution test in finish product specifications • Analytical procedure for all the tests given in finished product specifications shall be submitted • Justification shall be submitted for selection of the assay method of drug product via UV-Vis spectrophotometer instead of HPLC method

	• Justification shall be submitted as you have submitted analytical method validation studies by HPLC method while analytical method for assay test for sofosbuvir by UV method.
3.2.P.6	• COA of primary / secondary reference standard of sofosbuvir and velpatasvir including source and lot number shall be provided
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import). • Clarification of applying HPLC method for Assay analysis of applied formulation in stability study while submitted for assay is UV Spectrophotometric. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required

Previous Decision (M-336th-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Firm's Response:

S No.	Deferment Reason	Firm's Response
1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)	• Firm has submitted valid copy of DML
1.3.5	• Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority. • Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of letter of renewal of DML date 11th June, 2024 specifying Tablet (General) Section • Firm has submitted copy of cGMP certificate of the firm based on inspection dated 03-04-2024.
1.6.5	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	• Not submitted
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>	• 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> is submitted
3.2.S.4	• Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance Sofosbuvir and Velpatasvir 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 Sofosbuvir and Velpatasvir shall be submitted. • Justification shall be submitted for not performing the test for residue on ignition, and chiral purity in batch analysis of drug substance sofosbuvir by drug product manufacturer as per drug substance manufacturer • Copies of the Drug substance specifications of the Drug substance velpatasvir by Drug substance manufacturer is required. • Justification shall be submitted for not performing the test for residue on ignition, in batch analysis of drug substance velpatasvir by drug product	• Copies of the Drug substance specifications Sofosbuvir and Velpatasvir by Drug Product manufacturer is submitted. However, Copies of analytical procedures used for routine testing of Sofosbuvir and Velpatasvir by Drug Product manufacturer is not submitted. • Analytical Method Verification studies performed by the Drug Product for Sofosbuvir and Velpatasvir is submitted. However, results of accuracy and specificity test of Sofosbuvir is not submitted in analytical method verification studies • Drug substance specifications of the Drug substance velpatasvir by Drug substance manufacturer is submitted • Not submitted

	manufacturer as per drug substance manufacturer	
3.2.S.7	• Stability study data of velpatasvir at real time conditions till claimed shelf life shall be submitted	• Submitted
3.2.P.1	• Description and Composition of the applied Drug Product shall be submitted	• Composition of the applied Drug Product is submitted
3.2.P.2	• CDP studies of the applied drug with the innovator / reference / comparator product shall be submitted	• CDP studies of the applied drug with the innovator / reference / comparator product is not submitted
3.2.P.3.2	• Batch formula for proposed commercial batch size shall be provided that includes a list of all components of the drug product to be used in the manufacturing process	• Batch formula for proposed commercial batch size is submitted
3.2.P.5	• Justification shall be submitted for not including the test for content uniformity in finished product specifications as per innovator's product review document • Justification shall be submitted for not mentioning the time of dissolution test in finish product specifications • Analytical procedure for all the tests given in finished product specifications shall be submitted • Justification shall be submitted for selection of the assay method of drug product via UV-Vis spectrophotometer instead of HPLC method • Justification shall be submitted as you have submitted analytical method validation studies by HPLC method while analytical method for assay test for sofosbuvir by UV method.	• The firm submitted that content uniformity test is required if API in product is less less than 25mg/tablet. In sofowel both API (sofosbuvir+velpatasvir) more than 25mg/tablet. • The firm submitted that dissolution time is mentioned in analytical procedure but was not mentioned in product specification due to typographical error, it is reattached. Revised specifications is not submitted. • Analytical procedure for API is submitted instead of finished product • The firm submitted that assay of drug product done by HPLC, reports and chromatograms are attached. • Firm submitted that method validation is done by HPLC, and no justification is submitted.
3.2.P.6	• COA of primary / secondary reference standard of sofosbuvir and velpatasvir including source and lot number shall be provided	• COA of secondary reference standard of sofosbuvir and velpatasvir including source and lot number is submitted
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import). • Clarification of applying HPLC method for Assay analysis of applied formulation in stability study while submitted for assay is UV Spectrophotometric. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is required	• Firm has submitted copy of commercial invoice cleared dated 03-04-2020 specifying 0.4Kg Ledipasvir and 1.8kg Sofosbuvir. The invoice is cleared by AD (I&E) DRAP. • Firm has also submitted copy of commercial invoice cleared dated 10-01-2020 specifying 6.5Kg Ledipasvir. The invoice is cleared by AD (I&E) DRAP. • No clarification is submitted • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Previous Decision (M-339th-DRB): Deferred for submission of following:

- Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required
- Copies of analytical procedures used for routine testing of Sofosbuvir and Velpatasvir by Drug Product manufacturer.

- Results of accuracy and specificity test of Sofosbuvir in analytical method verification studies
- Justification for not performing the test for residue on ignition, in batch analysis of drug substance velpatasvir by drug product manufacturer as per drug substance manufacturer
- Detailed results of CDP studies of the applied drug with the innovator / reference / comparator product
- Revised finished product specifications
- Analytical procedure for all the tests given in finished product specifications
- Clarification of applying HPLC method for Assay analysis of applied formulation in stability study while submitted for assay is UV Spectrophotometric.

Firm's Response:

S No.	Deferment Reason	Firm's Response
1	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	Copy of DML from another manufacturer is submitted
2	• Copies of analytical procedures used for routine testing of Sofosbuvir and Velpatasvir by Drug Product manufacturer.	Submitted
3	• Results of accuracy and specificity test of Sofosbuvir in analytical method verification studies	Results of accuracy test is not submitted
4	• Justification for not performing the test for residue on ignition, in batch analysis of drug substance velpatasvir by drug product manufacturer as per drug substance manufacturer	Firm has submitted revised batch analysis report of drug substance velpatasvir in which test for residue on ignition has been performed by drug product manufacturer
5	• Detailed results of CDP studies of the applied drug with the innovator / reference / comparator product	Results of CDP studies at each time point and of each API is not submitted
6	• Revised finished product specifications	Firm has submitted revised finished product specifications
7	• Analytical procedure for all the tests given in finished product specifications	Not submitted
8	• Clarification of applying HPLC method for Assay analysis of applied formulation in stability study while submitted method for assay is UV Spectrophotometric.	Firm has submitted that assay of drug product is done by HPLC and submitted chromatograms and reports at zero month time point for reference

Decision: Deferred for submission of following:

- Valid copy of cGMP certificate / DML of the Drug Substance manufacturer (both sofosbuvir and velpatasvir) issued by relevant regulatory authority of country of origin
- Results of accuracy test of Sofosbuvir in analytical method verification studies
- Detailed results of CDP studies of the applied drug with the innovator / reference / comparator product at each time point and of each API
- Clarification of applying HPLC method for Assay analysis of applied formulation in stability study while submitted for assay is UV Spectrophotometric.

Firm's Response:

S No.	Deferment Reason	Firm's Response
1	• Valid copy of cGMP certificate / DML of the Drug Substance manufacturer (both sofosbuvir and velpatasvir) issued by relevant regulatory authority of country of origin	**Velpatasvir:** Firm has submitted copy of cGMP certificate of API manufacturer issued by Gaoling Food and Drug Administration valid upto 27-12-2025. **Sofosbuvir:** Copy of DML from another manufacturer is submitted
2	• Results of accuracy test of Sofosbuvir in analytical method verification studies	Results of analytical method verification studies is submitted including results of accuracy test.

3	• Detailed results of CDP studies of the applied drug with the innovator / reference / comparator product at each time point and of each API	Firm has submitted CDP results of their product against the product Velpaget 400mg/100mg ODT by Getz Pharma.
4	• Clarification of applying HPLC method for Assay analysis of applied formulation in stability study while submitted for assay is UV Spectrophotometric.	The firm submitted that we applied HPLC method for assay analysis. In this regard firm has submitted revised analytical method and attached the report along with chromatogram

Decision: Approved. Registration Board further decided that Registration letter will be issued after submission of valid copy of cGMP certificate / DML of the Drug Substance manufacturer for sofosbuvir issued by relevant regulatory authority of country of origin

245.	Name, address of Applicant / Marketing Authorization Holder	M/s Jawa Pharmaceuticals Private Limited., 112/10 Quaid-e-Azam Industrial Area Kot Lakhpat, Lahore
	Name, address of Manufacturing site.	M/s Jawa Pharmaceuticals Private Limited., 112/10 Quaid-e-Azam Industrial Area Kot Lakhpat, 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 of grant of additional section dated 25-06-2019 specifying Opthalmic 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 19731 dated 06-07-2022
	Details of fee submitted	Rs.30,000/- dated 26-03-2022 (Deposit slip#07753305605)
	The proposed proprietary name / brand name	**Dicon Ophthalmic Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Tobramycin……3mg Dexamethasone …..1 mg
	Pharmaceutical form of applied drug	White to off-white sterile solution packed in a 5ml LDPE dropper container with crew cap
	Pharmacotherapeutic Group of (API)	Antibacterial and Corticosteroids
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	1 x 5ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Tobradex (tobramycin 0.3% and dexamethasone 0.1% ophthalmic suspension) Sterile USFDA Approved
	For generic drugs (me-too status)	Bracin D Sterile Ophthalmic Suspension of M/s Atco Laboratories (Reg.No. 030904)

	Name and address of API manufacturer.	**Tobramycin:** M/s Livzon New North River Pharmaceutical Co., Ltd., Renmin One Road, Qingyuan City, Guangdong Province, P. R. China **Dexamethasone:** M/s Zhejiang Xianju Junye, Pharmaceutical Co., Ltd., No. 1 Junye Road, Xianju, Taizhou, Zhejiang, 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, 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 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, 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)	**Tobramycin:** 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 48 months. **Dexamethasone:** 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 study.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against Tobradex Suspension manufactured by M/s Alcon Switzerland by performing quality tests

		(Appearance, Assay)		
	Analytical method validation/verification of product	Firm has submitted analytical method verification studies including Accuracy, Precision, Repeatability, Specificity.		
STABILITY STUDY DATA				
Manufacturer of API		**Tobramycin:** M/s Livzon New North River Pharmaceutical Co., Ltd., Renmin One Road, Qingyuan City, Guangdong Province, P. R. China **Dexamethasone:** M/s Zhejiang Xianju Junye, Pharmaceutical Co., Ltd., No. 1 Junye Road, Xianju, Taizhou, Zhejiang, China		
API Lot No.		Tobramycin: 25152112009 Dexamethasone: 25152112009 *(API COA seems forged)*		
Description of Pack (Container closure system)		Milky white suspension in a white opaque plastic bottle with blue colored plastic cap finally packed in a bleach board box		
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.		T01	T02	T03
Batch Size		2000 Packs	2000 Packs	2000 Packs
Manufacturing Date		08-2021	08-2021	08-2021
Date of Initiation		16-08-2021	17-08-2021	19-08-2021
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.	**Tobramycin:** The firm has submitted copy of cGMP certificate of M/s Livzon New North River Pharmaceutical Co., Ltd., Renmin One Road, Qingyuan City, Guangdong Province, P. R. China issued by CFDA China valid upto 31/01/2024 **Dexamethasone:** The firm has submitted copy of cGMP certificate of M/s Zhejiang Xianju Pharmaceutical Co., Ltd., 15 West Fengxi Road, Modern Industrial Park, Xianju, Taizhou, Zhejiang China issued by CFDA China valid upto 04/08/2024		
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 document like chromatograms, Raw data sheets, COA, summary data sheets etc.	Firm has submitted data of stability batches supported by attested respective document like chromatograms, summary data sheets etc.		

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)	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
1.3.2	• Provide valid copy of DML
1.3.5	• Submit GMP certificate / GMP inspection report of the applicant conducted with in last three years
1.5.10	• Clarification is required as you have stated that the applied product is "*White to off-white sterile solution"* while the reference product is ophthalmic suspension
1.6.5	• Address of API manufacturer for Dexamethasone mentioned in section 1.6.5 is different than that given in submitted GMP certificate
3.2.S.4	• Justify the Specificity test for drug substance tobramycin in the presence of excipients • Justification shall be submitted for selecting different limit of assay test (97-103% instead of 97-102%) and optical rotation test (+75° to +80° instead of +72° to +80°) of drug substance by drug substance manufacturer and drug product manufacturer than USP monograph • Justification shall be submitted for analytical method of assay test of dexamethasone by UV method by drug substance manufacturer and drug product manufacturer instead of HPLC as per USP monograph • Justification shall be submitted for not including test for residue on ignition in drug substance specifications of dexamethasone by drug substance manufacturer and drug product manufacturer • COA of Dexamethasone API seems forged
3.2.P.1	• Justification is required for not using sulfuric acid and/or sodium hydroxide for pH adjustment as used by innovator product
3.2.P.2	• Details of innovator product including manufacturer, batch number manufacturing and expiry date used in pharmaceutical equivalence studies shall be submitted • Justification shall be submitted for not performing the tests in pharmaceutical equivalence studies as per submitted specifications (Identification, sterility, pH)
3.2.P.5	• Clarification is required as the batch No# mentioned on the COA of Drug substance tobramycin and dexamethasone are 25152112009 and 25152112009 respectively while batch No# of tobramycin and dexamethasone mentioned on COA of finished drug product are TB-1712040 and 30511504013 respectively.
3.2.P.6	• Submit COA of reference standard or material of both Tobramycin and Dexamethasone used in stability study
3.2.P.8	• Justification shall be submitted as same values of chromatogram areas are reported at real time and accelerated conditions (at 3rd and 6th month time point) of stability study for both the APIs • Raw data sheets and chromatograms at initial time point of stability study is not submitted. • COA and raw data sheets of stability batches at 3rd month and 6th month time point (both accelerated and real time conditions) is not submitted • Submit documents for the procurement of API with approval from DRAP (in case of import).

Previous Decision (M-331st-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Firm's Response:

Section	Observations	Firm's Response
1.3.2	• Provide valid copy of DML	• Copy of DML valid upto 23-12-2024 is submitted

1.3.5	• Submit GMP certificate / GMP inspection report of the applicant conducted with in last three years	• Firm has submitted copy of cGMP certificate of the firm based on inspection dated 13-10-2023 & 07-11-2023.
1.5.10	• Clarification is required as you have stated that the applied product is "*White to off-white sterile solution"* while the reference product is ophthalmic suspension	• The firm submitted that dosage form of our applied product is suspension. The word solution was used by mistake
1.6.5	• Address of API manufacturer for Dexamethasone mentioned in section 1.6.5 is different than that given in submitted GMP certificate	• Firm has revised address of API manufacturer for Dexamethasone in section 1.6.5 as per GMP. M/s Zhejiang Xianju Junye, Pharmaceutical Co., Ltd., No. 1 Junye Road, Xianju, Taizhou, Zhejiang, China
3.2.S.4	• Justify the Specificity test for drug substance tobramycin in the presence of excipients • Justification shall be submitted for selecting different limit of assay test (97-103% instead of 97-102%) and optical rotation test (+75° to +80° instead of +72° to +80°) of drug substance by drug substance manufacturer and drug product manufacturer than USP monograph • Justification shall be submitted for analytical method of assay test of dexamethasone by UV method by drug substance manufacturer and drug product manufacturer instead of HPLC as per USP monograph • Justification shall be submitted for not including test for residue on ignition in drug substance specifications of dexamethasone by drug substance manufacturer and drug product manufacturer • COA of Dexamethasone API seems forged	• Firm has submitted analytical method verification report of drug substance performed by drug product manufacturer. • The firm has submitted revised drug substance specifications. However, the details of assay test remains the same. • No justification for analytical method of assay test of dexamethasone is submitted • No reply submitted
3.2.P.1	• Justification is required for not using sulfuric acid and/or sodium hydroxide for pH adjustment as used by innovator product	• The firm submitted that it is mentioned as discussed that 1N sulfuric acid & 1N sodium hydroxide solutions have been used for pH adjustment as per requirements.
3.2.P.2	• Details of innovator product including manufacturer, batch number manufacturing and expiry date used in pharmaceutical equivalence studies shall be submitted • Justification shall be submitted for not performing the tests in pharmaceutical equivalence studies as per submitted specifications (Identification, sterility, pH)	• No details submitted. • No justification is submitted.
3.2.P.5	• Clarification is required as the batch No# mentioned on the COA of Drug substance tobramycin and dexamethasone are 25152112009 and 25152112009 respectively while batch No# of tobramycin and dexamethasone mentioned on COA of finished drug product are TB-1712040 and 30511504013 respectively.	• Firm has submitted revised batch analysis report of drug product and COA of both drug substance. The batch number mentioned in batch analysis are same as per submitted COA
3.2.P.6	• Submit COA of reference standard or material of both Tobramycin and Dexamethasone used in stability study	• COA of secondary reference standard of Dexamethasone used in stability study is submitted

3.2.P.8	• Justification shall be submitted as same values of chromatogram areas are reported at real time and accelerated conditions (at 3rd and 6th month time point) of stability study for both the APIs • Raw data sheets and chromatograms at initial time point of stability study is not submitted. • COA and raw data sheets of stability batches at 3rd month and 6th month time point (both accelerated and real time conditions) is not submitted • Submit documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted complete stability study data supported by attested respective documents like stability summary sheets, raw data sheets, COA and chromatograms. • The firm submitted copy of Letter No. 633/2020/DRAP-AD-CD(I&E) dated 13-01-2020 for "permission to Import API as per guidelines for import of pharmaceutical raw material for the purpose of test/analysis and stability studies" containing dexamethasone 30.50gm and tobramycin 21.0gm issued by AD (I&E) DRAP Lahore

Decision: Registration Board deferred the case for submission of following:

i. **Justification for selecting different limit of assay test (97-103% instead of 97-102%) of drug substance by drug substance manufacturer and drug product manufacturer than USP monograph**
ii. **Justification for analytical method of assay test of dexamethasone by UV method by drug substance manufacturer and drug product manufacturer instead of HPLC as per USP monograph**
iii. **Justification for not including test for residue on ignition in drug substance specifications of dexamethasone by drug substance manufacturer and drug product manufacturer**
iv. **Details of innovator product including manufacturer, batch number manufacturing and expiry date used in pharmaceutical equivalence studies**
v. **Justification for not performing the tests in pharmaceutical equivalence studies as per submitted specifications (Identification, sterility, pH)**

246.	Name, address of Applicant / Marketing Authorization Holder	M/s BJ Pharmaceuticals., Mandialai Stop, Bhattianwala Road, 18-Km Lahore-Sheikhupura Road, Lahore
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals., Mandialai Stop, Bhattianwala Roada, 18-Km Lahore-Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 18741 dated 25-07-2023
	Details of fee submitted	Rs.30,000/- dated 08-07-2023 (Deposit slip#632884248)
	The proposed proprietary name / brand name	**Azitith 250mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Azithromycin Dihydrate eq. to Azithromycin……..…250mg
	Pharmacotherapeutic Group of (API)	Macrolides Antibiotics
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	ZITHROMAX 250mg Capsule, MHRA Approved.

	For generic drugs (me-too status)	Azomax 250mg Capsule by M/s AGP Limited (Reg#112797)
	Proposed Pack size and unit price	10's, 20's, 30's; As per SRO

Evaluation by PEC[XI]:

Section	Observations	Response
1.3.4	• Submit Valid copy of Drug Manufacturing License (DML)	• Firm has submitted copy of DML and application applied for renewal of DML dated 06-02-2023
1.3.5	• Submit valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of routine GMP inspection reported date 15-01-2020 and conclusion of inspection was: • The firm has required equipment/machinery. HVAC system and qualified staff was present. Firm showed good intention to further improvement in future. However, overall hygienic condition of the firm is satisfactory at the time of inspection.
3.2.S.4	• Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance shall be submitted.	• Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance is submitted.
3.2.P.2	• Submit results of drug excipient compatibility study as the qualitative composition of applied product is not similar to reference product • Justification shall be submitted for not performing dissolution test in pharmaceutical equivalence studies of applied product	• Results of drug excipient compatibility study is submitted • The firm submitted that we performed dissolution test in pharmaceutical equivalence study but unfortunately we mistakenly not mention in report. Now revised pharmaceutical report is submitted containing results of dissolution test
3.2.P.5	• Justification shall be submitted for not mentioning the time of dissolution test in finish product specifications • Justification shall be submitted for not including the test for uniformity of dosage units and water content in finish product specifications as per USP monograph • Justification shall be submitted for submitting assay method of API for finished product. • Provide evidence of Amperometric electrochemical detector for assay test of finished product as required by USP monograph claimed by firm in section 1.5.6	• The firm submitted that we mistakenly not mentioned dissolution time in the finished product specifications and submitted revised finished product specifications in which time of dissolution test has been incorporated • The firm revised finish product specifications in which test for uniformity of dosage units and water content has been included. • The firm submitted that we mistakenly added API assay method rather than drug product assay method. The firm has now submitted assay method as per USP monograph. • The firm submitted that unfortunately due to lack of Amperometric detector we use UV-detector for the analysis of the product as mentioned in USP monograph of tablet and drug substance.
3.2.P.8	• Submit documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of clearance certificate cleared dated 03-10-2022 specifying 100kg Azithromycin Dihydrate. The invoice is cleared by AD (I&E) DRAP.

Previous Decision (M-340th): Deferred for submission of following:

- Valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years
- Fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(l)2024 dated 30-08-2024
- Justification for claiming USP specifications for drug product and not adopting assay method of USP monograph

Firm Response:

S No	Observations	Response
1	• Valid copy of cGMP certificate / GMP inspection report of manufacturing unit conducted with in last three years	• Firm has submitted copy of letter submitted to Assistant Director (E&M) DRAP Lahore for issuance of cGMP certificate dated 20.09.2024
2	• Fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(l)2024 dated 30-08-2024	• Firm has submitted fee Rs. 9000/- vide challan #18605593 correction/pre-approval change/ in product specifications
3	• Justification for claiming USP specifications for drug product and not adopting assay method of USP monograph	• The firm submitted that we use USP specifications for drug product and not adopting assay method of USP monograph because of non-availability of amperometric electrochemical detector for assay test. So, we use simple UV spectrometer method for product assay. Furthermore, we already submitted fee of Rs. 9000/- for pre approval change in product specifications from USP to BP. • The standard testing method for product as per BP specs is submitted

Decision: Registration Board deferred for confirmation of restoration of production activities as suspended due to GMP non-compliance.

Case No. 03; Deferred Registration application on Form 5

247.	Name and address of manufacture / 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 and Strength	Tramofix SR 100mg capsule
	Composition	Each sustained release tablet contains: Tramadol Hydrochloride…..100mg
	Dairy No. date of R &I fee	Form-5 Dy.No 40736 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018
	Pharmacological Group	Opioid Analgesic
	Type of form	Form 5
	Finished product specifications	USP
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Tramulief SR 100mg prolonged-release tablets MHRA Approved
	Me-too-status	Zultra SR 100mg M/s Wilshire Laboratories (Reg#80713)
	GMP Status	The firm was inspected on 24.04.2018, conclusion of inspection was: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"

	Remark of the Evaluator [XI]	• The firm have applied for capsule dosage form and following deficiencies were communicated to the firm: • The applied formulation is not as per reference formulation. The reference formulation consists of extended release film coated white beads and an immediate release tablet encapsulated in white opaque, size 1, 0 and 00, hard gelatin capsules in following combination. Tramadol ER Capsule Configuration Capsule Strength: 100 mg; IR-Tablet Strength: 25 mg; ER-Beads Strength: 75 mg Revise the formulation as per reference formulation. • Revise the weight of API in master formulation without considering the salt factor • Provide evidence of equipments used in manufacturing of applied formulation Later on the firm replied the change of dosage form Tramofix SR 100mg capsule to Tramofix SR 100mg tabelts along with submission of Rs. 20000/- on deposite slip#1977704 dated 10.03.2020
	Previous Decision (M-295th-DRB)	• Deferred for rectification of short comings
	Firm's Response	• The firm submitted the change of formulation from capsule dosage form to tablet dosage form. The firm submitted that fee for change of formulation Rs. 20000/- on deposite slip#1977704 dated 10.03.2020 has already been submitted. The firm has submitted the label claim as: Each sustained release tablet contains: Tramadol Hydrochloride…..100mg • Evidence of RRA; TRAMAL SR tramadol hydrochloride 100mg modified release tablet blister pack TGA Approved • Evidence of mee-too; Tonoflex SR 100mg tablet by M/s Sami Pharma (Reg#24498) Firm has submitted copy of cGMP certificate of the firm based on inspection dated 15-02-2024.
	Decision: Approved with following label claim: **Each sustained release tablet contains:** **Tramadol Hydrochloride…..100mg**	

248.	**Name and address of manufacture / Applicant**	**M/s Ophth Pharma (Pvt) Ltd.Plot No. 241, Sector 24, Korangi Industrial Area, Karachi**
	Brand Name + Dosage Form and Strength	**Moxidex Eye drops (solution)**
	Composition	Each ml contains: Moxifloxacin (as HCl)……5mg Dexamethasone (as sodium phosphate)…….1mg
	Dairy No. date of R &I fee	Dy.No 39556 dated 03-12-2018 Rs.20,000/- Dated 03-12-2018
	Pharmacological Group	Flouroquinolone and corticosteroid combination
	Type of form	Form-5
	Finished product specifications	Manufacturer's Specifications
	Pack size and Demand Price	5ml; As per SRO

	Approval status of product in Reference Regulatory Authorities	
	Me-too-status	
	GMP Status	GMP certificate issued based on the inspection report dated 10-05-2018
	Previous Remark of Evaluator [XI]	• The firm submitted that mentioning "for export purpose" on form 5 was a typographical mistake and the application may be considered for local market. • The firm did not provide evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. • The firm did not provide evidence of applied formulation/ drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • The firm submitted that bulk material of the batch is sterilized by steam sterilization and the plastic bottles are sterilized by ETO gas and the material are filled in class A environment. The terminal sterilization is not performed due to plastic bottle because the product will be leaked from bottles due to high pressure (15 PSI) and temperature (121ºC).
	Previous Decision (297-DRB)	Deferred for following: • 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
	Evaluation by PEC	• The firm provided evidence of me-too. Eyemox-D Eye Drops by M/s Vega Pharmaceuticals (Reg#77193) • However, the provided reference in reference regulatory authorities / agencies could not be verified.
	Previous Decision (307-DRB)	• 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 of Firm	• The firm submitted that following brands containinfg same molecule are being manufactured in Pakistan • Comox drops by M/s Sante Pharma • Eyemox-D drops by M/s Vega Pharma • Ocumox-D drops by M/s Remington Pharma • Demox drops by M/s Barrette Hodgson • The firm submitted these companies are producing the same molecules locally and we believe this evidence should support approval of our product
	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.	

Agenda of Mr. Adil Saeed

Form-5F routine Cases

250.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Aulton Pharmaceuticals Plot No. 84/1, Block-A Phase 5, Industrial Estate Hattar.**

	Name, address of Manufacturing site.	M/s Aulton Pharmaceuticals Plot No. 84/1, Block-A Phase 5, Industrial Estate Hattar. (DML No. 000828)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 24887: 12.10.2023
	Details of fee submitted	PKR 30,000/- : 5156676790
	The proposed proprietary name / brand name	**AULTCOL 1gm/4ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml ampoule contains; Citicoline sodium eq to Citicoline…….1g
	Pharmacotherapeutic Group of (API)	Other psychostimulants and nootropics ATC Code: N06BX06
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	Valid reference not available.
	For generic drugs (me-too status)	Citolin injection by M/s Global Pharma
	Proposed Pack size	As per SRO

Evaluation by PEC (No IX):

Sr. No.	Section	Observation
1.	-	Evidence of ampoule general section is required.
2.	-	Evidence of Approval of similar product in any RRA is required
3.	2.3.S.2.1	Manufacturer of drug substance mentioned in Module 2 is M/s Bajaj Healthcare Ltd. (unit-IV) 1717/1718, GIDC Panoli Tal….Gujrat India, Clarification is required.
4.	3.2.S.4.2	Analytical procedure and its validation by Drug Substance manufacturer (M/s Dhanuka Laboratories Limited) is required.
5.	3.2.P.2.2	The details of reference product (Neurolin Inj) like its batch no. strength and manufacturer are not submit.
6.	3.2.P.3.2	In batch formula, per ampoule Citicoline is mentioned as 1076mg, please justify this 76mg excess quantity.
7.	3.2.P.8	Submit names, qualifications and other details of all technical persons who have signed the BMRs of trial batches and analytical data sheets.
8.	Firm has submitted duplicate dossier for application from both firms' M/s Athan and M/s Aulton. All values in P part are exactly similar. Same signatures are present on Analytical Calculation Sheet over QC analyst and QC manager heading.	

	Copies of same chromatograms are attached in both dossiers with only different product name (indicating that chromatograms are no Authentic). Data logger data is same. BMR are signed by same technical persons and have same names of operators.

Decision: Registration Board deferred the case for verification of authenticity of submitted data by the panel constituted by the Chairman Registration Board.

251.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Athan Pharmaceuticals Plot No. 84/1, Block-B Phase 5, Industrial Estate Hattar.**
	Name, address of Manufacturing site.	M/s Athan Pharmaceuticals Plot No. 84/1, Block-A Phase 5, Industrial Estate Hattar. (DML No. 000900)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 24887: 12.10.2023
	Details of fee submitted	PKR 30,000/- : 220836428
	The proposed proprietary name / brand name	**Sitory 1gm/4ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml ampoule contains; Citicoline sodium eq to Citicoline…….1g
	Pharmacotherapeutic Group of (API)	Other psychostimulants and nootropics ATC Code: N06BX06
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	Valid reference not available.
	For generic drugs (me-too status)	Citolin injection by M/s Global Pharma
	Proposed Pack size	As per SRO

Evaluation by PEC (No IX):

Sr. No.	Section	Observation
1.	-	Evidence of Approval of similar product in any RRA is required
2.	2.3.S.2.1	Manufacturer of drug substance mentioned in Module 2 is M/s Bajaj Healthcare Ltd. (unit-IV) 1717/1718, GIDC Panoli Tal…..Gujrat India, Clarification is required.
3.	3.2.S.4.2	Analytical procedure and its validation by Drug Substance manufacturer (M/s Dhanuka Laboratories Limited) is required.
4.	3.2.P.2.2	The details of reference product (Neurolin Inj) like its batch no. strength and manufacturer are not submit.
5.	3.2.P.3.2	In batch formula, per ampoule Citicoline is mentioned as 1076mg, please justify this 76mg excess quantity.

6.	3.2.P.8	Submit names, qualifications and other details of all technical persons who have signed the BMRs of trial batches and analytical data sheets.
7.	Firm has submitted duplicate dossier for application from both firms' M/s Athan and M/s Aulton. All values in P part are exactly similar. Same signatures are present on Analytical Calculation Sheet over QC analyst and QC manager heading. Copies of same chromatograms are attached in both dossiers with only different product name (indicating that chromatograms are no Authentic). Data logger data is same. BMR are signed by same technical persons and have same names of operators.	

Decision: Registration Board deferred the case for verification of authenticity of submitted data by the panel constituted by the Chairman Registration Board.

252.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bajwa Pharmaceuticals Pvt. Ltd. 36-Km, Lahore Gujranwala Road, Khori District Sheikhupura.**
	Name, address of Manufacturing site.	M/s Bajwa Pharmaceuticals Pvt. Ltd. 36-Km, Lahore Gujranwala Road, Khori District Sheikhupura (DML No. 000805)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26770: 08.11.2023
	Details of fee submitted	PKR 30,000/- : 1760295447
	The proposed proprietary name / brand name	**Levetiracetam 500mg/5ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml ampoule contains; Levetiracetam……..500mg
	Pharmacotherapeutic Group of (API)	other antiepileptics, ATC Code: N03AX14
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Lerace 500mg Injection. M/s Hilton
	Proposed Pack size	1's 5's

Evaluation by PEC (No IX):

Sr. No.	Section	Observation	Reply
9.	3.2.P.5.4.2	In master batch record, under heading Active Pharmaceutical Ingredient calculation, the weight calculated for batch of 300 ampoules is 161.094 grams. (this gives strength of 536.98mg per ampoule) whereas keeping in view the assay of 98.7%,	The firm has submitted their response vide letter No. BPL/DP-RB/24/005 dated 28.11.2024 wherein they have stated that actual fill volume of ampoule is 5.3ml. This is in accordance with Chapter 698 of

		the overage should have been 1.32%, whereas as per calculations 7.4% overage has been used. Why amount of drug substance is not 506.6mg per ampoule and 151.98 grams for the batch of 300 ampoules? Please justify. Also give justification of the formula used for calculating the quantity of drug substance for the whole batch.	USP, this also overcomes the dead volumes and ensures proper dose administration. The reply of firm is satisfactory.
10.	3.2.P.5 3.2.P.8	Why particulate matter testing is not part of drug specifications and is also not checked in stability?	Liquid particle counter tests reports are submitted.

Decision: Approved

253.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bajwa Pharmaceuticals Pvt. Ltd. 36-Km, Lahore Gujranwala Road, Khori District Sheikhupura.**
	Name, address of Manufacturing site.	M/s Bajwa Pharmaceuticals Pvt. Ltd. 36-Km, Lahore Gujranwala Road, Khori District Sheikhupura (DML No. 000805)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26771: 08.11.2023
	Details of fee submitted	PKR 30,000/- : 1760295447
	The proposed proprietary name / brand name	**ROPIVACINE HCl Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 10ml ampoule contains; Ropivacaine HCl……..50mg
	Pharmacotherapeutic Group of (API)	ANESTHETICS, LOCAL, Amides ATC Code: N01BB09
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	ARTG ID 52402 NAROPIN 0.5% ropivacaine hydrochloride 50mg/10mL injection ampoule TGA Australia Approved.
	For generic drugs (me-too status)	Ropicain Epidural, M/s LCPW
	Proposed Pack size	1's, 5's, 10's, 50's

Evaluation by PEC (No IX):

Sr. No.	Section	Observation	Reply
1.	3.2.P.5 3.2.P.8	Why particulate matter testing is not part of drug specifications and is also not checked in stability?	The firm vide letter No. BPL/DP-Rb/24/004 dated 28.11.2024 has submitted their response.

			The firm has submitted test report of liquid particle count.

Decision: Approved

254.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s BF Biosciences Ltd. 05-KM Sundar Raiwind Road, Raiwind Lahore.**
	Name, address of Manufacturing site.	M/s BF Biosciences Ltd. 05-KM Sundar Raiwind Road, Raiwind Lahore. (DML No. 000655)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27570: 24.11.2023
	Details of fee submitted	PKR 30,000/- : 735440725057
	The proposed proprietary name / brand name	**H2F 40mg/4ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml vial contains; Famotidine……..40mg
	Pharmacotherapeutic Group of (API)	H2-receptor antagonists ATC Code: A02BA03
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	Famotidine Mylan 10mg/ml USFDA Approved.
	For generic drugs (me-too status)	Famot 40mg Injection M/s Shaigan
	Proposed Pack size	As per SRO

Evaluation by PEC (No IX):

S. No.	Section	Observation	Reply
1	3.2.P.8	Please submit stability data of 3rd time point	Firm has submitted their response vide letter No. BF/RG/CTD/230212(aa) dated 22.11.2024. Stability data is submitted.
2	-	In chromatograms of products, there is a peak at retention time approx. 3 min, having % area approx. 6. (RRT approx. 0.64, RRT of benzyl alcohol in USP monograph is 0.4). Please clarify/ identify this peak at RT 3 min and also label peak of benzyl alcohol in the chromatograms.	Firm has submitted chromatograms wherein at 3 min RT peak of benzyl alcohol is identified and marked. Regarding difference of RRT, firm has stated that such minor differences do occur between different brands of same column (L3) and nature of stationery phase.
3	-	Copy of AD attested invoice or clearance certificate of drug substance is required.	Firm has submitted copy of drug import license dated 05.09.2022 wherein Famotidine 300grams is mentioned.

Decision: Approved.

255.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio-Labs (Pvt.) Ltd. Plot No. 145 Industrial Triangle Kahuta Road Islamabad.**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt.) Ltd. Plot No. 145 Industrial Triangle Kahuta Road Islamabad (DML No. 000296)
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26040: 27.10.2023
	Details of fee submitted	PKR 30,000/- : 438806969012
	The proposed proprietary name / brand name	**VONZAN 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Vonoprazan fumarate equivalent to Vonoprazan……..10mg
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors ATC Code: A02BC08
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	Voquenza 10mg and 20mg Tablets USFDA Approved.
	For generic drugs (me-too status)	Vonozan 10mg and 20mg Tablts M/s Getz
	Proposed Pack size	14's, 20's
Evaluation by PEC (No IX):		
Decision: Approved		
256.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Crystolite Pharmaceticals Plot No. 1 & 2, S-2, National Industrial Zone Rawat.**
	Name, address of Manufacturing site.	M/s Crystolite Pharmaceticals Plot No. 1 & 2, S-2, National Industrial Zone Rawat. (DML No. 000778)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 21768: 04.09.2023
	Details of fee submitted	PKR 30,000/- : 674936323742
	The proposed proprietary name / brand name	**VALTRIL 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Sacubitril……24mg Valsartan ……...26mg (as sacubitril valsartan sodium salt complex)
	Pharmacotherapeutic Group of (API)	Angiotensin II receptor blockers (ARBs), other combinations ATC Code: C09DX04
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	ENTRESTO 24 MG/26 MG FILM COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	Sacvin 50mg Tablet M/s PharmEvo.
	Proposed Pack size	As per SRO
Evaluation by PEC (No IX):		
Decision: Approved.		

257.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Crystolite Pharmaceticals Plot No. 1 & 2, S-2, National Industrial Zone Rawat.**
	Name, address of Manufacturing site.	M/s Crystolite Pharmaceticals Plot No. 1 & 2, S-2, National Industrial Zone Rawat. (DML No. 000778)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 24314: 04.10.2023
	Details of fee submitted	PKR 30,000/- : 08201733891
	The proposed proprietary name / brand name	**VALTRIL 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Sacubitril……49mg Valsartan ……...51mg (as sacubitril valsartan sodium salt complex)
	Pharmacotherapeutic Group of (API)	Angiotensin II receptor blockers (ARBs), other combinations ATC Code: C09DX04
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	ENTRESTO 49 MG/51 MG FILM COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	Sacvin 100mg Tablet M/s PharmEvo.
	Proposed Pack size	As per SRO
Evaluation by PEC (No IX):		
Decision: Approved.		
258.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Crystolite Pharmaceticals Plot No. 1 & 2, S-2, National Industrial Zone Rawat.**
	Name, address of Manufacturing site.	M/s Crystolite Pharmaceticals Plot No. 1 & 2, S-2, National Industrial Zone Rawat. (DML No. 000778)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25792: 25.10.2023
	Details of fee submitted	PKR 30,000/- : 1499229892
	The proposed proprietary name / brand name	**Vorazan 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Vonoprazan fumarate equivalent to Vonoprazan……..10mg
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors ATC Code: A02BC08
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	Voquenza 10mg and 20mg Tablets USFDA Approved.

	For generic drugs (me-too status)	Vonozan 10mg and 20mg Tablts M/s Getz
	Proposed Pack size	14's

Evaluation by PEC (No IX):

Sr. No.	Section	Observation	Reply
1.	3.2.P.8	3rd time point stability data is required.	3rd time point stability data submitted vide letter No. nil dated 21.11.2024

Decision: Approved

259.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Crystolite Pharmaceticals Plot No. 1 & 2, S-2, National Industrial Zone Rawat.**
	Name, address of Manufacturing site.	M/s Crystolite Pharmaceticals Plot No. 1 & 2, S-2, National Industrial Zone Rawat. (DML No. 000778)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25793: 25.10.2023
	Details of fee submitted	PKR 30,000/- : 074725488
	The proposed proprietary name / brand name	**Vorazan 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Vonoprazan fumarate equivalent to Vonoprazan……..20mg
	Pharmacotherapeutic Group of (API)	Proton pump inhibitors ATC Code: A02BC08
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	Voquenza 10mg and 20mg Tablets USFDA Approved.
	For generic drugs (me-too status)	Vonozan 10mg and 20mg Tablts M/s Getz
	Proposed Pack size	14's

Evaluation by PEC (No IX):

Sr. No.	Section	Observation	Reply
1.	3.2.P.8	3rd time point stability data is required.	3rd time point stability data submitted vide letter No. nil dated 21.11.2024

Decision: Approved

260.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera.**
	Name, address of Manufacturing site.	M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera (DML No. 000038)
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22481: 13.09.2023
	Details of fee submitted	PKR 30,000/- : 212219291
	The proposed proprietary name / brand name	**BISOVIA 2.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Bisoprolol fumarate.....2.5mg
	Pharmacotherapeutic Group of (API)	Beta Blocking Agent ATC Code: C07AB07
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Concor 2.5mg Tablet
	Proposed Pack size	7's 10's 14's 20's 28's 30's
Evaluation by PEC (No IX):		
Decision: Approved		
261.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera.**
	Name, address of Manufacturing site.	M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera (DML No. 000038)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22482: 13.09.2023
	Details of fee submitted	PKR 30,000/- : 7810412293
	The proposed proprietary name / brand name	**BISOVIA 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Bisoprolol fumarate.....5mg
	Pharmacotherapeutic Group of (API)	Beta Blocking Agent ATC Code: C07AB07
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Concor 5mg Tablet
	Proposed Pack size	7's 10's 14's 20's 28's 30's
Evaluation by PEC (No IX):		
Decision: Approved		
262.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera.**
	Name, address of Manufacturing site.	M/s Ferozsons Laboratories Limited, P.O. Ferozsons, Amangarh, Nowshera (DML No. 000038)
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22483: 13.09.2023
	Details of fee submitted	PKR 30,000/- : 92172150
	The proposed proprietary name / brand name	**BISOVIA 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Bisoprolol fumarate.....10mg
	Pharmacotherapeutic Group of (API)	Beta Blocking Agent ATC Code: C07AB07
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Concor 10mg Tablet
	Proposed Pack size	7's 10's 14's 20's 28's 30's
Evaluation by PEC (No IX):		
Decision: Approved		
263.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Getz Pharma (Pvt.) Ltd, Plot No. 1, Sector 25, Industrial Area Karachi.**
	Name, address of Manufacturing site.	M/s Getz Pharma (Pvt.) Ltd, Plot No. 1, Sector 25, Industrial Area Karachi. (DML No. 000933)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22424: 12.09.2023
	Details of fee submitted	PKR 75,000/- : 472899965
	The proposed proprietary name / brand name	**VERCIGUT 2.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Vericiguat……2.5mg
	Pharmacotherapeutic Group of (API)	Other vasodilators used in cardiac diseases ATC Code: C01DX22
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	Verquvo 2.5 mg film-coated tablets MHRA Approved.
	For generic drugs (me-too status)	NA (Fee submitted for New drug product)
	Proposed Pack size	14, 28
Evaluation by PEC (No IX):		

Sr. No.	Section	Observation	Reply
1.		Fee is submitted from DML No. 000284 whereas registration is applied on DML No. 000933.	Firm has submitted their response vide letter No. Ra-RL/314/1124 dated 05.11.2024

			Fee of Rs. 75000/- is submitted vide slip No. 6483189166 on DML 000933
2.		Submit section approval letter.	Copy of DML issuance letter vide No. 2-9/2014-Lic (Vol-I) dated 07.06.2021 is submitted wherein tablet general section is mentioned

Decision: Approved

264.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Getz Pharma (Pvt.) Ltd, Plot No. 1, Sector 25, Industrial Area Karachi.**
	Name, address of Manufacturing site.	M/s Getz Pharma (Pvt.) Ltd, Plot No. 1, Sector 25, Industrial Area Karachi. (DML No. 000933)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22425: 12.09.2023
	Details of fee submitted	PKR 75,000/- : 90203503384
	The proposed proprietary name / brand name	**VERCIGUT 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Vericiguat……5mg
	Pharmacotherapeutic Group of (API)	Other vasodilators used in cardiac diseases ATC Code: C01DX22
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	Verquvo 5 mg film-coated tablets MHRA Approved.
	For generic drugs (me-too status)	NA (Fee submitted for New drug product)
	Proposed Pack size	14, 28

Evaluation by PEC (No IX):

Sr. No.	Section	Observation	Reply
1.		Fee is submitted from DML No. 000284 whereas registration is applied on DML No. 000933.	Firm has submitted their response vide letter No. Ra-RL/314/1124 dated 05.11.2024 Fee of Rs. 75000/- is submitted vide slip No. 1054777579 on DML 000933
2.		Submit section approval letter.	Copy of DML issuance letter vide No. 2-9/2014-Lic (Vol-I) dated 07.06.2021 is submitted wherein tablet general section is mentioned

Decision: Approved

265.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Getz Pharma (Pvt.) Ltd, Plot No. 1, Sector 25, Industrial Area Karachi.**
	Name, address of Manufacturing site.	M/s Getz Pharma (Pvt.) Ltd, Plot No. 1, Sector 25, Industrial Area Karachi. (DML No. 000933)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22426: 12.09.2023
	Details of fee submitted	PKR 75,000/- : 49314367
	The proposed proprietary name / brand name	**VERCIGUT 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Vericiguat……10mg
	Pharmacotherapeutic Group of (API)	Other vasodilators used in cardiac diseases ATC Code: C01DX22
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	Verquvo 10 mg film-coated tablets MHRA Approved.
	For generic drugs (me-too status)	NA (Fee submitted for New drug product)
	Proposed Pack size	14, 28

Evaluation by PEC (No IX):

Sr. No.	Section	Observation	Reply
3.		Fee is submitted from DML No. 000284 whereas registration is applied on DML No. 000933.	Firm has submitted their response vide letter No. Ra-RL/314/1124 dated 05.11.2024 Fee of Rs. 75000/- is submitted vide slip No. 52892395912 on DML 000933
4.		Submit section approval letter.	Copy of DML issuance letter vide No. 2-9/2014-Lic (Vol-I) dated 07.06.2021 is submitted wherein tablet general section is mentioned

Decision: Approved

266.	**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. (DML No. 000284)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 21684: 01.09.2023

	Details of fee submitted	PKR 30,000/- : 5448190853
	The proposed proprietary name / brand name	**VERIGET 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Voriconazole……50mg
	Pharmacotherapeutic Group of (API)	ANTIMYCOTICS FOR SYSTEMIC USE ATC Code: J02AC03
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	VORICONAZOLE 50MG FILM-COATED TABLETS MHRA Approved
	For generic drugs (me-too status)	VORIF Tablets 50mg M/s Ferozsons
	Proposed Pack size	10's, 20's
Evaluation by PEC (No IX):		
Decision: Approved		
267.	**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. (DML No. 000284)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 21683: 01.09.2023
	Details of fee submitted	PKR 30,000/- : 954613283270
	The proposed proprietary name / brand name	**VERIGET 200mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Voriconazole……200mg
	Pharmacotherapeutic Group of (API)	ANTIMYCOTICS FOR SYSTEMIC USE ATC Code: J02AC03
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	VORICONAZOLE 200MG FILM-COATED TABLETS MHRA Approved
	For generic drugs (me-too status)	VORIF Tablets 200mg M/s Ferozsons
	Proposed Pack size	10's, 20's
Evaluation by PEC (No IX):		
Decision: Approved.		
268.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Hoover Pharmaceuticals (Pvt.) Ltd, Plot No: 16, Zain Part, Industrial Area, Saggian Bye Pass Road, Lahore**
	Name, address of Manufacturing site.	M/s Hoover Pharmaceuticals (Pvt.) Ltd, Plot No: 16, Zain Part, Industrial Area, Saggian Bye Pass Road, Lahore. (DML No. 000676)
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22330: 11.09.2023
	Details of fee submitted	PKR 30,000/- : 373567956509
	The proposed proprietary name / brand name	**NO-DROSE Oral Liquid**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains; Ebastine……..5mg
	Pharmacotherapeutic Group of (API)	Antihistamines. ATC Code: R06AX22
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	EBASTEL 1 mg/ml ORAL SOLUTION Registration number: 58358 CIMA Spain Approved.
	For generic drugs (me-too status)	Kestine Liquid M/s Highnoon
	Proposed Pack size	30ml, 60ml, 120ml

Evaluation by PEC (No IX):

Sr. No.	Section	Observation
1.	3.2.P.2.5 3.2.P.5	Its stated that *"no microbial contamination study is addressed in innovator work so there is no need of such type of study in this case.*" Why microbial enumeration test as per general chapters of pharmacopoeia is not performed?
2.	3.2.P.5 3.2.P8	Why HPLC method (instead of UV method) is not used in assay of drug product?
3.	3.2.P.8	Copies of BMR of trial batches are required.
4.	-	AD attested invoice/ clearance certificate of import of drug substance is required.

The board was informed that deficiencies have been communicated to the firm and reply is awaited

Decision: The case was deferred for submission of Reply of above mentioned deficiencies.

269.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jenner Pharmaceuticals, Plot No. 3, M-2 Pharmazone, 26 KM, Lahore Sharaqpur Road, District Sheikhupura.**
	Name, address of Manufacturing site.	M/s Jenner Pharmaceuticals, Plot No. 3, M-2 Pharmazone, 26 KM, Lahore Sharaqpur Road, District Sheikhupura. (DML No. 000823)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25006: 13.10.2023
	Details of fee submitted	PKR 30,000/- : 07749793
	The proposed proprietary name / brand name	**JENSIPAR 30mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Cinacalcet (as hydrochloride)……..30mg
	Pharmacotherapeutic Group of (API)	Other anti-parathyroid agents ATC Code: H05BX01

	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	CINACALCET TILLOMED 30MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	Censipar 30 & 60mg Tablets M/s CCL
	Proposed Pack size	10's. 14's. 28's
Evaluation by PEC (No IX):		
Decision: Approved.		
270.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jenner Pharmaceuticals, Plot No. 3, M-2 Pharmazone, 26 KM, Lahore Sharaqpur Road, District Sheikhupura.**
	Name, address of Manufacturing site.	M/s Jenner Pharmaceuticals, Plot No. 3, M-2 Pharmazone, 26 KM, Lahore Sharaqpur Road, District Sheikhupura. (DML No. 000823)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25007: 13.10.2023
	Details of fee submitted	PKR 30,000/- : 777327492069
	The proposed proprietary name / brand name	**JENSIPAR 60mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Cinacalcet (as hydrochloride)……..60mg
	Pharmacotherapeutic Group of (API)	Other anti-parathyroid agents ATC Code: H05BX01
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	CINACALCET TILLOMED 60MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	Censipar 30 & 60mg Tablets M/s CCL
	Proposed Pack size	10's. 14's. 28's
Evaluation by PEC (No IX):		
Decision: Approved.		
271.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Jenner Pharmaceuticals, Plot No. 3, M-2 Pharmazone, 26 KM, Lahore Sharaqpur Road, District Sheikhupura.**
	Name, address of Manufacturing site.	M/s Jenner Pharmaceuticals, Plot No. 3, M-2 Pharmazone, 26 KM, Lahore Sharaqpur Road, District Sheikhupura. (DML No. 000823)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25008: 13.10.2023
	Details of fee submitted	PKR 30,000/- : 85424861626
	The proposed proprietary name / brand name	**JENSIPAR 90mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Cinacalcet (as hydrochloride)……..90mg
	Pharmacotherapeutic Group of (API)	Other anti-parathyroid agents ATC Code: H05BX01
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	CINACALCET TILLOMED 90MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	Could not be verified.
	Proposed Pack size	10's. 14's. 28's

Evaluation by PEC (No IX):

S. No.	Observation
1	Submit verifiable evidence of me-too product.

Decision: Approved. Firm shall submit evidence of previously registered generic product or else submit differential fee of Rs. 45000/- before issuance of registration letter.

272.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt.) Ltd. Plot No. E-127, E-128 & E-129, North Western Industrial Zone Bin Qasim Karachi.**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals (Pvt.) Ltd. Plot No. E-127, E-128 & E-129, North Western Industrial Zone Bin Qasim Karachi.(DML No. 000755)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 21773: 04.09.2023
	Details of fee submitted	PKR 30,000/- : 59551285724
	The proposed proprietary name / brand name	**RACECA 10mg Granules for Oral Suspension.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains; Racecadotril…….10mg
	Pharmacotherapeutic Group of (API)	Other antidiarrheals ATC Code: A07XA04
	Reference to Finished product specifications	Innovator Specifications.
	The status in reference regulatory authorities	HIDRASEC INFANTS 10 MG GRANULES FOR ORAL SUSPENSION MHRA Approved.
	For generic drugs (me-too status)	Dirasec Sachet 10mg M/s Genome
	Proposed Pack size	10's, 16's, 20's, 30's.

Evaluation by PEC (No IX):

Sr. No.	Section	Observation	Reply
1.	3.2.P.5	Why test for microbial enumeration is not made part of testing of finished drug product?	The firm vide letter No. RA/ DRAP/892/2024 dated 16.10.2024 has submitted their response. The firm has stated that they did perform microbial enumeration test

			but was not made part of COA of drug product. The revised COA is submitted wherein microbial enumeration test is mentioned.
2.	3.2.P.7	Details are not given that what material will be used to make sachets.	Firm has stated that final packing of the product is paper foil that is inner lined with aluminium foil.
3.	3.2.P.8	Please clarify why moisture content testing is not part of stability studies.	The firm has stated that they did perform moisture content test but was not made part of stability summary sheets. The revised stability summary sheets are submitted wherein moisture content is mentioned.

Decision: Approved.

273.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt.) Ltd. Plot No. E-127, E-128 & E-129, North Western Industrial Zone Bin Qasim Karachi.**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals (Pvt.) Ltd. Plot No. E-127, E-128 & E-129, North Western Industrial Zone Bin Qasim Karachi.(DML No. 000755)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 21774: 04.09.2023
	Details of fee submitted	PKR 30,000/- : 191035431903
	The proposed proprietary name / brand name	**RACECA 30mg Granules for Oral Suspension.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains; Racecadotril…….30mg
	Pharmacotherapeutic Group of (API)	Other antidiarrheals ATC Code: A07XA04
	Reference to Finished product specifications	Innovator Specifications.
	The status in reference regulatory authorities	HIDRASEC Children30 MG GRANULES FOR ORAL SUSPENSION MHRA Approved.
	For generic drugs (me-too status)	HIDRASEC Sachet 30mg
	Proposed Pack size	10’s, 16’s, 20’s, 30’s.

Evaluation by PEC (No IX):

Sr. No.	Section	Observation	Reply
1.	3.2.P.3.2 & 	The batch formula given in document No. PRD/BMR/536 mentions total quantity of batch as 1kg whereas material is for 3kg batch. As per bill of material in BMR,	Firm has submitted reply vide letter No. RA/DRAP/891/2024 dated 16.10.2024.

	3.2.P.8	dispensing is also done for material having quantity of total 3kg. Further in stability summary sheets batch size mentioned in 1000grams. Please clarify this difference of batch size in different documents submitted in dossier.	Firm has stated that it is a topographic mistake. Batch size is 3kg and 1000 sachet. Revised documents are submitted.
2.	3.2.P.5	Why test for microbial enumeration is not made part of testing of finished drug product?	The firm has stated that they did perform microbial enumeration test but was not made part of COA of drug product. The revised COA is submitted wherein microbial enumeration test is mentioned.
3.	3.2.P.7	Details are not given that what material will be used to make sachets. (either paper sachet or Alu PVC coated sachet?). Please submit details of primary packaging in which stability batches were packed.	Firm has stated that final packing of the product is paper foil that is inner lined with aluminium foil.
4.	3.2.P.8	Please clarify why moisture content testing is not part of stability studies.	The firm has stated that they did perform moisture content test but was not made part of stability summary sheets. The revised stability summary sheets are submitted wherein moisture content is mentioned.

Decision: Approved.

274.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt.) Ltd. Plot No. E-127, E-128 & E-129, North Western Industrial Zone Bin Qasim Karachi.**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals (Pvt.) Ltd. Plot No. E-127, E-128 & E-129, North Western Industrial Zone Bin Qasim Karachi.(DML No. 000755)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 21272: 04.09.2023
	Details of fee submitted	PKR 75,000/- : 22611054288
	The proposed proprietary name / brand name	**RACECA 4mg/ml Oral Suspension.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml Contains; Racecadotril…….4mg
	Pharmacotherapeutic Group of (API)	Other antidiarrheals ATC Code: A07XA04
	Reference to Finished product specifications	Innovator Specifications.
	The status in reference regulatory authorities	TIORFAN 4 mg/mL INFANTS AND CHILDREN, oral suspension ANSM Approved.

	For generic drugs (me-too status)	NA fee for new drug product is submitted.
	Proposed Pack size	50ml, 180ml

Evaluation by PEC (No IX):

Sr. No.	Section	Observation	Reply
1.	3.2.P.5	Why test for microbial enumeration is not made part of testing of finished drug product?	The firm has submitted their reply vide letter No. RA/DRAP/893/2024 dated 16.10.2024 The firm has stated that they did perform microbial enumeration test but was not made part of COA of drug product. The revised COA is submitted wherein microbial enumeration test is mentioned.
2.	3.2.P.8	The size of stability batches is 1 Litre (20 bottles per batch. How such small size batch can be used to support stability studies?	Firm has stated that per batch 20 bottles are sufficient for stability testing. For long term stability 6 bottles of each batch are required and for accelerated 2 bottles per batch are required.

Decision: Approved.

275.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt.) Ltd. Plot No. E-127, E-128 & E-129, North Western Industrial Zone Bin Qasim Karachi.**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals (Pvt.) Ltd. Plot No. E-127, E-128 & E-129, North Western Industrial Zone Bin Qasim Karachi.(DML No. 000755)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22603: 04.09.2023
	Details of fee submitted	PKR 30,000/- : 8385253809
	The proposed proprietary name / brand name	**RACECA 100mg Capsule.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains; Racecadotril…….100mg
	Pharmacotherapeutic Group of (API)	Other antidiarrheals ATC Code: A07XA04
	Reference to Finished product specifications	Innovator Specifications.
	The status in reference regulatory authorities	HIDRASEC 100 MG HARD CAPSULES MHRA approved.
	For generic drugs (me-too status)	Hidrasec 100mg capsule
	Proposed Pack size	6, 10, 20, 100, 500

Evaluation by PEC (No IX):

Sr. No.	Section	Observation	Reply
1.	3.2.P.2 3.2.P.5 3.2.P.8	In CDP the drug release of both reference and your test product is less than 30% in all dissolution media, in drug product specifications, specs for dissolution are mentioned as NLT 70%(Q) of the labelled amount. In stability studies Dissolution is more than 90%. Please clarify why %age dissolution is less in CDP than in batch release and stability. Also justify value of limit of 70%(Q) for dissolution, (how it was determined).	The firm has submitted their reply vide letter No. RA/DRAP/890/2024 dated 16.10.2024. The firm has stated that in dissolution testing of product SLS was used to enhance it. In CDP, SLS was not used and molecule is very poorly soluble. That's why in CDP dissolution is less than in finished product testing. Further as per CDP the test and reference product both have performed the same. The firm has further stated that they have revised the limits of dissolution to 75% and revised testing method is submitted.

Decision: Approved.

276.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt.) Ltd. Plot No. E-127, E-128 & E-129, North Western Industrial Zone Bin Qasim Karachi.**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals (Pvt.) Ltd. Plot No. E-127, E-128 & E-129, North Western Industrial Zone Bin Qasim Karachi.(DML No. 000755)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 21775: 04.09.2023
	Details of fee submitted	PKR 75,000/- : 9218468642
	The proposed proprietary name / brand name	**RACECA 175mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains; Racecadotril…….175mg
	Pharmacotherapeutic Group of (API)	Other antidiarrheals ATC Code: A07XA04
	Reference to Finished product specifications	Innovator Specifications.
	The status in reference regulatory authorities	HIDRASEC 175MG FILM-COATED TABLETS MHRA approved.
	For generic drugs (me-too status)	NA, fee submitted for new drug product.
	Proposed Pack size	12s

Evaluation by PEC (No IX):

Sr. No.	Section	Observation	Reply
1.	3.2.P.2 3.2.P.5 3.2.P.8	In CDP the drug release of both reference and your test product is less than 30% in all dissolution media, in drug product specifications, specs for dissolution are mentioned as NLT 70%(Q) of the labelled amount. In stability studies Dissolution is more than 90%. Please clarify why %age dissolution is less in CDP than in batch release and stability. Also justify value of limit of 70%(Q) for dissolution, (how it was determined).	The firm has submitted their reply vide letter No. RA/DRAP/890/2024 dated 16.10.2024. The firm has stated that in dissolution testing of product SLS was used to enhance it. In CDP, SLS was not used and molecule is very poorly soluble. That's why in CDP dissolution is less than in finished product testing. Further as per CDP the test and reference product both have performed the same. The firm has further stated that they have revised the limits of dissolution to 75% and revised testing method is submitted.

Decision: Approved.

277.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Lucky Core Industries. 32/2A, Phase-III, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	M/s Lucky Core Industries. 32/2A, Phase-III, Industrial Estate, Hattar. (DML No. 000363)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 24318: 04.10.2023
	Details of fee submitted	PKR 30,000/- : 096338667655
	The proposed proprietary name / brand name	**VANLEP 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Sacubitril……24mg Valsartan ……...26mg (as sacubitril valsartan sodium salt complex)
	Pharmacotherapeutic Group of (API)	Angiotensin II receptor blockers (ARBs), other combinations ATC Code: C09DX04
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	ENTRESTO 24 MG/26 MG FILM COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	Sacvin 50mg Tablet M/s PharmEvo.
	Proposed Pack size	As per SRO

Evaluation by PEC (No IX):

Sr. No.	Section	Observation	Reply
11.	-	DML/ GMP certificate of drug substance manufacturer is required. (Submitted one is not issued by Government authority)	Firm has submitted their response vide letter no. nil dated 06.11.2024. Copy of DML issued by Guangdong FDA valid till 10.12.2025 is submitted.
12.	3.2.P.8	Copies of executed BMR of Trial batches are required.	Submitted.

Decision: Approved.

278.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Lucky Core Industries. 32/2A, Phase-III, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	M/s Lucky Core Industries. 32/2A, Phase-III, Industrial Estate, Hattar. (DML No. 000363)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 24319: 04.10.2023
	Details of fee submitted	PKR 30,000/- : 8725771902
	The proposed proprietary name / brand name	**VANLEP 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Sacubitril……49mg Valsartan ……...51mg (as sacubitril valsartan sodium salt complex)
	Pharmacotherapeutic Group of (API)	Angiotensin II receptor blockers (ARBs), other combinations ATC Code: C09DX04
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	ENTRESTO 49 MG/51 MG FILM COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	Sacvin 100mg Tablet M/s PharmEvo.
	Proposed Pack size	As per SRO

Evaluation by PEC (No IX):

Sr. No.	Section	Observation	Reply
1.	-	DML/ GMP certificate of drug substance manufacturer is required. (Submitted one is not issued by Government authority)	Firm has submitted their response vide letter no. nil dated 06.11.2024. Copy of DML issued by Guangdong FDA valid till 10.12.2025 is submitted.

2.	3.2.P.8	Copies of executed BMR of Trial batches are required.	Submitted.

Decision: Approved.

279.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Lucky Core Industries. 32/2A, Phase-III, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	M/s Lucky Core Industries. 32/2A, Phase-III, Industrial Estate, Hattar. (DML No. 000363)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 24320: 04.10.2023
	Details of fee submitted	PKR 30,000/- : 97719413908
	The proposed proprietary name / brand name	**VANLEP 200mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Sacubitril……97mg Valsartan ……...103mg (as sacubitril valsartan sodium salt complex)
	Pharmacotherapeutic Group of (API)	Angiotensin II receptor blockers (ARBs), other combinations ATC Code: C09DX04
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	ENTRESTO 97 MG/103 MG FILM COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	Sacvin 200mg Tablet M/s PharmEvo.
	Proposed Pack size	As per SRO

Evaluation by PEC (No IX):

Sr. No.	Section	Observation	Reply
1.	-	DML/ GMP certificate of drug substance manufacturer is required. (Submitted one is not issued by Government authority)	Firm has submitted their response vide letter no. nil dated 06.11.2024. Copy of DML issued by Guangdong FDA valid till 10.12.2025 is submitted.
2.	3.2.P.8	Copies of executed BMR of Trial batches are required.	Submitted.

Decision: Approved.

280.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Marker Ltd. 7, Jail road, Quetta.**
	Name, address of Manufacturing site.	M/s Martin Dow Marker Ltd. 7, Jail road, Quetta. (DML No. 0000028)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 24883: 12.10.2023
	Details of fee submitted	PKR 30,000/- : 6709273642
	The proposed proprietary name / brand name	**Klaribact Oral Drops 125mg/5ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains; Clarithromycin…….125mg (27.5% Granules)
	Source of granules:	M/s Surge Laboratories (Pvt.) Ltd. 10th KM Faisalabad Road, Bikhi District, Sheikhupura
	Pharmacotherapeutic Group of (API)	Macrolides ATC Code: J01FA09
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	Clarithromycin 125mg/5ml oral suspension MHRA Approved.
	For generic drugs (me-too status)	Claritek 125mg/5ml Granules
	Proposed Pack size	As per SRO

Evaluation by PEC (No IX):

Sr. No.	Section	Observation	Reply
1.	3.2.S.2.2	In Description of manufacturing process and process control, there is a heading "Enteric Coating Stage" (page 132). It indicates that pellets are being enteric coated. Please clarify that whether these are enteric coated pellets, if yes, then provide evidence that such formulation is available in RRA, if No, then why is enteric coating stage part of manufacturing process?	Firm has submitted their response vide letter No. SMI/mm/RA/305/2024. The drug substance manufacturer has stated that enteric coating is the process involved in the formulation for the taste masking of the granules, without it complete taste masking cannot be achieved. Further they have requested to consider it as taste masked granules.
2.	3.2.S.4.1	In specifications its mentioned that drug release in dissolution in 0.1N HCl should not be more than 10% and in buffer pH 6.8 it should not be less than 80%, indicating that granules are enteric coated. Please submit RRA an me-too reference of enteric coated granules of clarithromycin.	The drug substance manufacturer has stated that taste masked granules manufactured by Surge labs have same formulation as reference product mentioned in MHRA (Klaricid). They have further stated that they have surge specifications to test these granules. They are testing it on 0.1N HCl to ensure that complete taste masking of clarithromycin is achieved because taste masking of clarithromycin is a pH sensitive process, acidic pH can disturb the taste masking.

3.	3.2.P.5 3.2.P.8	The USP monograph for the drug product does not indicate that product should be enteric coated, so please justify that USP monograph is applicable on your product. Further the pH of constituted suspension is around 5.2, what will be the dissolution profile of granules at this pH? Is it justified to make an enteric coated product that has to be reconstituted wherein after reconstitution drug will be slowly released in vehicle over the time of its use?	Drug substance manufacturer has stated that USP monograph represents quality specifications of finished product, and it does not apply on semi-finished product (taste masked granules) The firm has stated that they are controlling their product around pH 5 for effective taste masking. pH test is just a control test for effective taste masking, it has no relation with drug release. Drug release at pH 6.8
4.	3.2.P.8	3rd time point (6th month) stability data is not submitted.	Submitted
5.	-	How is it justified to make modified release dosage form of clarithromycin?	Firm has stated that its not a modified release dosage form and neither do they claim it as modified release. Their claim is of taste masked granules. Finished product complies with SP specifications while taste masked granules comply surge specifications.

Decision: Approved.

281.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s McOlson Research Laboratories (Pvt.) Ltd. 26-KM Lahore Sharikpur ROAD, District Sheikhupura.**
	Name, address of Manufacturing site.	M/s McOlson Research Laboratories (Pvt.) Ltd. 26-KM Lahore Sharikpur ROAD, District Sheikhupura. (DML No. 000664)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 24780: 11.10.2023
	Details of fee submitted	PKR 30,000/- : 14404948272
	The proposed proprietary name / brand name	**CINAMAC 30mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Cinacalcet (as hydrochloride)……..30mg
	Pharmacotherapeutic Group of (API)	Other anti-parathyroid agents ATC Code: H05BX01
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	CINACALCET TILLOMED 30MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	Censipar 30 & 60mg Tablets M/s CCL
	Proposed Pack size	10’s. 14’s. 28’s

Evaluation by PEC (No IX):		
Decision: Approved.		
282.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s McOlson Research Laboratories (Pvt.) Ltd. 26-KM Lahore Sharikpur ROAD, District Sheikhupura.**
	Name, address of Manufacturing site.	M/s McOlson Research Laboratories (Pvt.) Ltd. 26-KM Lahore Sharikpur ROAD, District Sheikhupura. (DML No. 000664)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 24781: 11.10.2023
	Details of fee submitted	PKR 30,000/- : 846914914236
	The proposed proprietary name / brand name	**CINAMAC 60mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Cinacalcet (as hydrochloride)……..60mg
	Pharmacotherapeutic Group of (API)	Other anti-parathyroid agents ATC Code: H05BX01
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	CINACALCET TILLOMED 60MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	Censipar 30 & 60mg Tablets M/s CCL
	Proposed Pack size	10’s. 14’s. 28’s
Evaluation by PEC (No IX):		
Decision: Approved.		
283.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s McOlson Research Laboratories (Pvt.) Ltd. 26-KM Lahore Sharikpur ROAD, District Sheikhupura.**
	Name, address of Manufacturing site.	M/s McOlson Research Laboratories (Pvt.) Ltd. 26-KM Lahore Sharikpur ROAD, District Sheikhupura. (DML No. 000664)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 24782: 11.10.2023
	Details of fee submitted	PKR 30,000/- : 31654070
	The proposed proprietary name / brand name	**CINAMAC 90mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Cinacalcet (as hydrochloride)……..90mg
	Pharmacotherapeutic Group of (API)	Other anti-parathyroid agents ATC Code: H05BX01
	Reference to Finished product specifications	Innovator Specifications

	The status in reference regulatory authorities	CINACALCET TILLOMED 90MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	Could not be verified.
	Proposed Pack size	10's. 14's. 28's

Evaluation by PEC (No IX):

S. No.	Observation	Reply
1	Submit verifiable evidence of me-too product.	Firm has stated that there is no me-too of applied product so it may please be considered a NDP. Additional fee of Rs. 45000/- is submitted vide slip No. 1744566840

Decision: Approved.

284.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s NabiQasim Industries (Pvt.) Ltd. 17/24 Korangi Industrial Area, Korangi Karachi.**
	Name, address of Manufacturing site.	M/s NabiQasim Industries (Pvt.) Ltd. 17/24 Korangi Industrial Area, Korangi Karachi. (DML No. 000105)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27949: 01.12.2023
	Details of fee submitted	PKR 75,000/- : 3234434948
	The proposed proprietary name / brand name	**Stir-Up XR 14mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains; Memantine Hydrochloride 10% extended release pellets eq. to Memantine Hydrochloride……..14mg
	Source of Pellets	M/s Lee Pharma Limited, Plot No. V, Phase-II VSEZ Duvvada, sabbavaram (M) Visakhapatnam Andhra Pradesh India,
	Pharmacotherapeutic Group of (API)	Other anti-dementia drugs ATC Code: N06DX01
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	NA, fee submitted is for NDP
	Proposed Pack size	10's., 14's, 20's, 28's & 30's

Evaluation by PEC (No IX):

Decision: Approved.

285.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s NabiQasim Industries (Pvt.) Ltd. 17/24 Korangi Industrial Area, Korangi Karachi.**
	Name, address of Manufacturing site.	M/s NabiQasim Industries (Pvt.) Ltd. 17/24 Korangi Industrial Area, Korangi Karachi. (DML No. 000105)

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27950: 01.12.2023
	Details of fee submitted	PKR 75,000/- : 8119310462
	The proposed proprietary name / brand name	**Stir-Up XR 21mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains; Memantine Hydrochloride 10% extended release pellets eq. to Memantine Hydrochloride……..21mg
	Source of Pellets	M/s Lee Pharma Limited, Plot No. V, Phase-II VSEZ Duvvada, sabbavaram (M) Visakhapatnam Andhra Pradesh India,
	Pharmacotherapeutic Group of (API)	Other anti-dementia drugs ATC Code: N06DX01
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	NA, fee submitted is for NDP
	Proposed Pack size	10's., 14's, 20's, 28's & 30's
Evaluation by PEC (No IX):		
Decision: Approved.		
286.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s NabiQasim Industries (Pvt.) Ltd. 17/24 Korangi Industrial Area, Korangi Karachi.**
	Name, address of Manufacturing site.	M/s NabiQasim Industries (Pvt.) Ltd. 17/24 Korangi Industrial Area, Korangi Karachi. (DML No. 000105)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27951: 01.12.2023
	Details of fee submitted	PKR 75,000/- : 742988657332
	The proposed proprietary name / brand name	**Stir-Up XR 28mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains; Memantine Hydrochloride 10% extended release pellets eq. to Memantine Hydrochloride……..28mg
	Source of Pellets	M/s Lee Pharma Limited, Plot No. V, Phase-II VSEZ Duvvada, sabbavaram (M) Visakhapatnam Andhra Pradesh India,
	Pharmacotherapeutic Group of (API)	Other anti-dementia drugs ATC Code: N06DX01
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	USFDA Approved.

	For generic drugs (me-too status)	NA, fee submitted is for NDP
	Proposed Pack size	10's., 14's, 20's, 28's & 30's
Evaluation by PEC (No IX):		
Decision: Approved.		
287.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Neutro Pharma (Pvt.) Ltd. 9.5Km, Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt.) Ltd. 9.5Km, Sheikhupura Road, Lahore (DML No. 000576)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25010: 13.10.2023
	Details of fee submitted	PKR 30,000/- : 2190269836
	The proposed proprietary name / brand name	**NEUTRETIN 0.05% Cream**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram contains; Tretinoin……..0.5mg
	Pharmacotherapeutic Group of (API)	Retinoids for topical use in acne ATC Code: D10AD01
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Triton Cream M/s Valor
	Proposed Pack size	20gm As per SRO
Evaluation by PEC (No IX):		
Decision: Approved.		
288.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s PharmEvo Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi.**
	Name, address of Manufacturing site.	M/s PharmEvo Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi. (DML No. 000504)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27748: 28.11.2023
	Details of fee submitted	PKR 75,000/- : 6955755266
	The proposed proprietary name / brand name	**FINEVO 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Finerenone…….10mg
	Pharmacotherapeutic Group of (API)	Aldosterone antagonists ATC Code: C03DA05
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	KERENDIA 10 MG FILM-COATED TABLETS MHRA Approved.

	For generic drugs (me-too status)	NA (Fee submitted for New drug product)
	Proposed Pack size	7, 10, 14, 20, 28, 30, 56, 84 100, 122

Evaluation by PEC (No IX):

Sr. No.	Section	Observation	Reply
13.	3.2.P.8	Stability data of 3rd time point is required.	Submitted vide letter no. nil dated 12.11.2024

Decision: Approved.

289.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s PharmEvo Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi.**
	Name, address of Manufacturing site.	M/s PharmEvo Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi. (DML No. 000504)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27749: 28.11.2023
	Details of fee submitted	PKR 75,000/- : 19634394929
	The proposed proprietary name / brand name	**FINEVO 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Finerenone…….20mg
	Pharmacotherapeutic Group of (API)	Aldosterone antagonists ATC Code: C03DA05
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	KERENDIA 20 MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	NA (Fee submitted for New drug product)
	Proposed Pack size	7, 10, 14, 20, 28, 30, 56, 84 100, 122

Evaluation by PEC (No IX):

Sr. No.	Section	Observation	Reply
1.	3.2.P.8	Stability data of 3rd time point is required.	Submitted vide letter no. nil dated 12.11.2024

Decision: Approved.

290.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s PharmEvo Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi.**
	Name, address of Manufacturing site.	M/s PharmEvo Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi. (DML No. 000504)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27436: 22.11.2023
	Details of fee submitted	PKR 75,000/- : 752131991674
	The proposed proprietary name / brand name	**IVADIN-C 6.25mg + 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Carvedilol…….6.25mg Ivabradine Hydrochloride eq. to Ivabradine……..5mg
	Pharmacotherapeutic Group of (API)	Beta blocking agents, other combinations. ATC Code: C07FX06
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	Carivalan 6,25 mg/5 mg filmomhulde tabletten CBG MEB Netherlands approved.
	For generic drugs (me-too status)	NA (Fee submitted for New drug product)
	Proposed Pack size	7, 10, 14, 20, 28, 30, 56, 84 100, 122

Evaluation by PEC (No IX):

Sr. No.	Section	Observation	Reply
1.	3.2.P.8	Stability data of 3rd time point is required.	Submitted vide letter no. nil dated 12.11.2024

Decision: Approved.

291.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s PharmEvo Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi.**
	Name, address of Manufacturing site.	M/s PharmEvo Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi. (DML No. 000504)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27437: 22.11.2023
	Details of fee submitted	PKR 75,000/- : 23229288211
	The proposed proprietary name / brand name	**IVADIN-C 6.25mg + 7.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Carvedilol…….6.25mg Ivabradine Hydrochloride eq. to Ivabradine……..7.5mg
	Pharmacotherapeutic Group of (API)	Beta blocking agents, other combinations. ATC Code: C07FX06
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	Carivalan 6,25 mg/7.5 mg filmomhulde tabletten CBG MEB Netherlands approved.
	For generic drugs (me-too status)	NA (Fee submitted for New drug product)
	Proposed Pack size	7, 10, 14, 20, 28, 30, 56, 84 100, 122

Evaluation by PEC (No IX):

Sr. No.	Section	Observation	Reply
2.	3.2.P.8	Stability data of 3rd time point is required.	Submitted vide letter no. nil dated 12.11.2024

Decision: Approved.

292.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s PharmEvo Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi.**
	Name, address of Manufacturing site.	M/s PharmEvo Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi. (DML No. 000504)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27750: 28.11.2023
	Details of fee submitted	PKR 75,000/- : 65012616213
	The proposed proprietary name / brand name	**IVADIN-C 12.5mg + 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Carvedilol…….12.5mg Ivabradine Hydrochloride eq. to Ivabradine……..5mg
	Pharmacotherapeutic Group of (API)	Beta blocking agents, other combinations. ATC Code: C07FX06
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	Carivalan 12.5 mg/5 mg filmomhulde tabletten CBG MEB Netherlands approved.
	For generic drugs (me-too status)	NA (Fee submitted for New drug product)
	Proposed Pack size	7, 10, 14, 20, 28, 30, 56, 84 100, 122

Evaluation by PEC (No IX):

Sr. No.	Section	Observation	Reply
1.	3.2.P.8	Stability data of 3rd time point is required.	Submitted vide letter no. nil dated 12.11.2024

Decision: Approved.

293.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s PharmEvo Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi.**
	Name, address of Manufacturing site.	M/s PharmEvo Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi. (DML No. 000504)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27438: 22.11.2023
	Details of fee submitted	PKR 75,000/- : 6277426428
	The proposed proprietary name / brand name	**IVADIN-C 25mg + 7.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Carvedilol…….25mg Ivabradine Hydrochloride eq. to Ivabradine……..7.5mg
	Pharmacotherapeutic Group of (API)	Beta blocking agents, other combinations. ATC Code: C07FX06
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	Carivalan 25 mg/7.5 mg filmomhulde tabletten CBG MEB Netherlands approved.
	For generic drugs (me-too status)	NA (Fee submitted for New drug product)
	Proposed Pack size	7, 10, 14, 20, 28, 30, 56, 84 100, 122

Evaluation by PEC (No IX):

Sr. No.	Section	Observation	Reply
1.	3.2.P.8	Stability data of 3rd time point is required.	Submitted vide letter no. nil dated 12.11.2024
2.	3.2.P.2	CDP needs to be submitted as per ICH guidelines. The guidelines referred to for exemption of CDP are for bioequivalence.	The firm has again quoted ICH guidelines for Bioequivalence and have requested for exemption.

Decision: The Board deferred the case for submission of Pharmaceutical Equivalence studies including CDP performed against innovator or comparator product.

294.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s PharmEvo Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi.**
	Name, address of Manufacturing site.	M/s PharmEvo Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi. (DML No. 000504)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27751: 28.11.2023
	Details of fee submitted	PKR 75,000/- : 802064769161
	The proposed proprietary name / brand name	**IVADIN-C 25mg + 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Carvedilol…….25mg Ivabradine Hydrochloride eq. to Ivabradine……..5mg
	Pharmacotherapeutic Group of (API)	Beta blocking agents, other combinations. ATC Code: C07FX06
	Reference to Finished product specifications	Innovator Specifications

	The status in reference regulatory authorities	Carivalan 25 mg/5 mg filmomhulde tabletten CBG MEB Netherlands approved.
	For generic drugs (me-too status)	NA (Fee submitted for New drug product)
	Proposed Pack size	7, 10, 14, 20, 28, 30, 56, 84 100, 122

Evaluation by PEC (No IX):

Sr. No.	Section	Observation	Reply
1.	3.2.P.8	Stability data of 3rd time point is required.	Submitted vide letter no. nil dated 12.11.2024

Decision: Approved.

295.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Platinum Pharmaceuticals (Pvt.) Ltd. A-20 North Western Industrial Zone, Bin Qasim, Karachi.**
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals (Pvt.) Ltd. A-20 North Western Industrial Zone, Bin Qasim, Karachi. (DML No. 000415)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26556: 03.11.2023
	Details of fee submitted	PKR 30,000/- : 25709053126
	The proposed proprietary name / brand name	**EZETIMIBE + ATORVASTATIN 10mg 10mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains; Atorvastatin…...10mg Ezetimibe……..10mg
	Pharmacotherapeutic Group of (API)	Beta Blocking Agent ATC Code: C07AB07
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	Lypqozet 10/10, 20/10, 40/10, 80/10 USFDA Approved.
	For generic drugs (me-too status)	Jezeta 10/10 Tablet M/s Hilton
	Proposed Pack size	10 20 30

Evaluation by PEC (No IX):

Sr. No.	Section	Observation	Reply
1.	1.5.2	Label needs to be revised as per innovator product along with submission of requisite fee for Pre-registration variation.	The firm has submitted their response wide letter No. nil dated 22.11.2024. Firm has revised the label as under Each film coated tablet contains; Ezetimibe……..…..10mg Atorvastatin calcium eq. to Atorvastatin……..10mg

			Fee of Rs. 9000/- is submitted vide slip No. 6337669
2.	-	Ad attested invoices or clearance certificates of both drug substances are required.	Clearance certificate mentioning Atorvastatin Calcium 5kg is submitted. Import license mentioning 0.5kg Ezetimibe is submitted.
3.	**Further firm has requested for name "Statin Plus",** The firm already have registration of product Statin having atorvastatin alone in 10mg 20mg and 40mg strength.		

Decision: Approved with following label;

Each film coated tablet contains;

Ezetimibe……..…..10mg

Atorvastatin calcium eq. to Atorvastatin……..10mg

Letter shall be issued after submission of differential fee of Rs. 28000/-, for revision of label and brand name in pre-registration variation.

296.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Platinum Pharmaceuticals (Pvt.) Ltd. A-20 North Western Industrial Zone, Bin Qasim, Karachi.**
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals (Pvt.) Ltd. A-20 North Western Industrial Zone, Bin Qasim, Karachi. (DML No. 000415)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26557: 03.11.2023
	Details of fee submitted	PKR 30,000/- : 1183091081
	The proposed proprietary name / brand name	**EZETIMIBE + ATORVASTATIN 10mg 20mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains; Atorvastatin…...20mg Ezetimibe……..10mg
	Pharmacotherapeutic Group of (API)	Beta Blocking Agent ATC Code: C07AB07
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	Lypqozet 10/10, 20/10, 40/10, 80/10 USFDA Approved.
	For generic drugs (me-too status)	Jezeta 10/20 Tablet M/s Hilton
	Proposed Pack size	10 20 30

Evaluation by PEC (No IX):

Sr. No.	Section	Observation	Reply
1.	1.5.2	Label needs to be revised as per innovator product along with submission of requisite fee for Pre-registration variation.	The firm has submitted their response wide letter No. nil dated 22.11.2024. Firm has revised the label as under Each film coated tablet contains; Ezetimibe……..…..10mg

			Atorvastatin calcium eq. to Atorvastatin……..20mg Fee of Rs. 9000/- is submitted vide slip No. 542706695
2.	-	AD attested invoices or clearance certificates of both drug substances are required.	Clearance certificate mentioning Atorvastatin Calcium 5kg is submitted. Import license mentioning 0.5kg Ezetimibe is submitted.
3.	Further firm has requested for name "Statin Plus", The firm already have registration of product Statin having atorvastatin alone in 10mg 20mg and 40mg strength.		

Decision: Approved with following label;

Each film coated tablet contains;

Ezetimibe…….…..…..10mg

Atorvastatin calcium eq. to Atorvastatin……..20mg

Letter shall be issued after submission of differential fee of Rs. 28000/-, for revision of label and brand name in pre-registration variation.

297.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Platinum Pharmaceuticals (Pvt.) Ltd. A-20 North Western Industrial Zone, Bin Qasim, Karachi.**
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals (Pvt.) Ltd. A-20 North Western Industrial Zone, Bin Qasim, Karachi. (DML No. 000415)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26559: 03.11.2023
	Details of fee submitted	PKR 75,000/- : 634702490
	The proposed proprietary name / brand name	**EZETIMIBE + ATORVASTATIN 10mg 80mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains; Atorvastatin…...80mg Ezetimibe……..10mg
	Pharmacotherapeutic Group of (API)	Beta Blocking Agent ATC Code: C07AB07
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	Lypqozet 10/10, 20/10, 40/10, 80/10 USFDA Approved.
	For generic drugs (me-too status)	NA, fee submitted is for NDP
	Proposed Pack size	10 20 30

Evaluation by PEC (No IX):

Sr. No.	Section	Observation	Reply
1.	1.5.2	Label needs to be revised as per innovator product along with submission of requisite fee for Pre-registration variation.	The firm has submitted their response wide letter No. nil dated 22.11.2024. Firm has revised the label as under

			Each film coated tablet contains; Ezetimibe……..…..10mg Atorvastatin calcium eq. to Atorvastatin……..80mg Fee of Rs. 9000/- is submitted vide slip No. 4113664647
2.	-	AD attested invoices or clearance certificates of both drug substances are required.	Clearance certificate mentioning Atorvastatin Calcium 5kg is submitted. Import license mentioning 0.5kg Ezetimibe is submitted.
3.	Further firm has requested for name "Statin Plus", The firm already have registration of product Statin having atorvastatin alone in 10mg 20mg and 40mg strength.		

Decision: Approved with following label;

Each film coated tablet contains;

Ezetimibe…….…..…..10mg

Atorvastatin calcium eq. to Atorvastatin……..80mg

Letter shall be issued after submission of differential fee of Rs. 66000/-, for revision of label and brand name in pre-registration variation.

298.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Platinum Pharmaceuticals (Pvt.) Ltd. A-20 North Western Industrial Zone, Bin Qasim, Karachi.**
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals (Pvt.) Ltd. A-20 North Western Industrial Zone, Bin Qasim, Karachi. (DML No. 000415)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26558: 03.11.2023
	Details of fee submitted	PKR 30,000/- : 908316392510
	The proposed proprietary name / brand name	**EZETIMIBE + ATORVASTATIN 10mg 40mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains; Atorvastatin…...40mg Ezetimibe……..10mg
	Pharmacotherapeutic Group of (API)	Beta Blocking Agent ATC Code: C07AB07
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	Lypqozet 10/10, 20/10, 40/10, 80/10 USFDA Approved.
	For generic drugs (me-too status)	Jezeta 10/40 M/s Hilton
	Proposed Pack size	10 20 30

Evaluation by PEC (No IX):

Sr. No.	Section	Observation	Reply

1.	1.5.2	Label needs to be revised as per innovator product along with submission of requisite fee for Pre-registration variation.	The firm has submitted their response wide letter No. nil dated 22.11.2024. Firm has revised the label as under Each film coated tablet contains; Ezetimibe……..…..10mg Atorvastatin calcium eq. to Atorvastatin……..40mg Fee of Rs. 9000/- is submitted vide slip No. 22216435
2.	-	AD attested invoices or clearance certificates of both drug substances are required.	Clearance certificate mentioning Atorvastatin Calcium 5kg is submitted. Import license mentioning 0.5kg Ezetimibe is submitted.
3.	Further firm has requested for name "Statin Plus", The firm already have registration of product Statin having atorvastatin alone in 10mg 20mg and 40mg strength.		

Decision: Approved with following label;

Each film coated tablet contains;

Ezetimibe…….…..…..10mg

Atorvastatin calcium eq. to Atorvastatin……..40mg

Letter shall be issued after submission of differential fee of Rs. 28000/-, for revision of label and brand name in pre-registration variation.

299.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Polyfine Chemical Pharmaceuticals, 51 Industrial Estate, Jamrud Road, Peshawar.**
	Name, address of Manufacturing site.	M/s Polyfine Chemical Pharmaceuticals, 51 Industrial Estate, Jamrud Road, Peshawar. (DML No. 000216)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22059: 07.09.2023
	Details of fee submitted	PKR 30,000/- : 303729367277
	The proposed proprietary name / brand name	**I-CARE 10mg/ml Eye Drops**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains; Tropicamide……10mg
	Pharmacotherapeutic Group of (API)	Anticholinergics ATC Code: S01FA06
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	MINIMS TROPICAMIDE 1%W/V MHRA Approved.
	For generic drugs (me-too status)	Mydromide Ophthalmic solution M/s Remington
	Proposed Pack size	As per SRO

Evaluation by PEC (No IX):

Sr. No.	Section	Observation
1.	-	GMP certificate of drug substance manufacturer is required.
2.	-	GMP Certificate of drug product manufacturer is required.
3.	3.2.S.4	Analytical method verification studies data for drug substance performed by drug product manufacturer is required. (along with chromatograms)
4.	3.2.P.1	Please justify use of Benzalkonium Chloride in light of innovator product formulation. Further also justify 2% NaCl in formulation, how is it making it isotonic as claimed in 3.2.P.1
5.	3.2.P.8	Copies of BMR of trial batches are required.
6.	3.2.P.8	Please submit water loss studies data performed with stability studies. (as container is of plastic)

The board was informed that deficiencies have been communicated to the firm and reply is awaited

Decision: The case was deferred for submission of Reply of above mentioned deficiencies.

300.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scilife Pharma (Pvt.) Ltd, Plot No. FD-57/58-A2, Korangi Creek Industrial Park, Karachi.**
	Name, address of Manufacturing site.	M/s Scilife Pharma (Pvt.) Ltd, Plot No. FD-57/58-A2, Korangi Creek Industrial Park, Karachi. (DML No. 000837)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 23146: 20.09.2023
	Details of fee submitted	PKR 75,000/- : 3156700374
	The proposed proprietary name / brand name	**VERICA 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Vericiguat……5mg
	Pharmacotherapeutic Group of (API)	Other vasodilators used in cardiac diseases ATC Code: C01DX22
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	Verquvo 5 mg film-coated tablets MHRA Approved.
	For generic drugs (me-too status)	NA (Fee submitted for New drug product)
	Proposed Pack size	As per SRO

Evaluation by PEC (No IX):

Decision: Approved.

301.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s The Searle Company Limited. Plot No. F-319, Sindh Industrial Trading Estate Karachi.**

	Name, address of Manufacturing site.	M/s The Searle Company Limited. Plot No. F-319, Sindh Industrial Trading Estate Karachi. (DML No. 000016)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 24544: 09.10.2023
	Details of fee submitted	PKR 75,000/- : 58653475
	The proposed proprietary name / brand name	**XADUXAT 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Roxadustat……..20mg
	Pharmacotherapeutic Group of (API)	Other antianemic preparations ATC Code: B03XA05
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	EVRENZO 20 MG FILM-COATED TABLETS MHRA Approved
	For generic drugs (me-too status)	NA, fee is submitted for NDP
	Proposed Pack size	As per SRO
Evaluation by PEC (No IX):		
Decision: Approved.		
302.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s The Searle Company Limited. Plot No. F-319, Sindh Industrial Trading Estate Karachi.**
	Name, address of Manufacturing site.	M/s The Searle Company Limited. Plot No. F-319, Sindh Industrial Trading Estate Karachi. (DML No. 000016)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 24545: 09.10.2023
	Details of fee submitted	PKR 75,000/- : 624209485541
	The proposed proprietary name / brand name	**XADUXAT 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Roxadustat……..50mg
	Pharmacotherapeutic Group of (API)	Other antianemic preparations ATC Code: B03XA05
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	EVRENZO 50 MG FILM-COATED TABLETS MHRA Approved
	For generic drugs (me-too status)	NA, fee is submitted for NDP
	Proposed Pack size	As per SRO
Evaluation by PEC (No IX):		
Decision: Approved.		

303.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s The Searle Company Limited. Plot No. F-319, Sindh Industrial Trading Estate Karachi.**
	Name, address of Manufacturing site.	M/s The Searle Company Limited. Plot No. F-319, Sindh Industrial Trading Estate Karachi. (DML No. 000016)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 24546: 09.10.2023
	Details of fee submitted	PKR 75,000/- : 0086868506
	The proposed proprietary name / brand name	**XADUXAT 70mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Roxadustat……..70mg
	Pharmacotherapeutic Group of (API)	Other antianemic preparations ATC Code: B03XA05
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	EVRENZO 70 MG FILM-COATED TABLETS MHRA Approved
	For generic drugs (me-too status)	NA, fee is submitted for NDP
	Proposed Pack size	As per SRO
Evaluation by PEC (No IX):		
Decision: Approved.		
304.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s The Searle Company Limited. Plot No. F-319, Sindh Industrial Trading Estate Karachi.**
	Name, address of Manufacturing site.	M/s The Searle Company Limited. Plot No. F-319, Sindh Industrial Trading Estate Karachi. (DML No. 000016)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 24547: 09.10.2023
	Details of fee submitted	PKR 75,000/- : 475473854
	The proposed proprietary name / brand name	**XADUXAT 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Roxadustat……..100mg
	Pharmacotherapeutic Group of (API)	Other antianemic preparations ATC Code: B03XA05
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	EVRENZO 100 MG FILM-COATED TABLETS MHRA Approved
	For generic drugs (me-too status)	NA, fee is submitted for NDP
	Proposed Pack size	As per SRO
Evaluation by PEC (No IX):		

Decision: Approved.		
305.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s The Searle Company Limited. Plot No. F-319, Sindh Industrial Trading Estate Karachi.**
	Name, address of Manufacturing site.	M/s The Searle Company Limited. Plot No. F-319, Sindh Industrial Trading Estate Karachi. (DML No. 000016)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 24548: 09.10.2023
	Details of fee submitted	PKR 75,000/- : 86333628879
	The proposed proprietary name / brand name	**XADUXAT 150mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Roxadustat……..150mg
	Pharmacotherapeutic Group of (API)	Other antianemic preparations ATC Code: B03XA05
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	EVRENZO 150 MG FILM-COATED TABLETS MHRA Approved
	For generic drugs (me-too status)	NA, fee is submitted for NDP
	Proposed Pack size	As per SRO
Evaluation by PEC (No IX):		
Decision: Approved.		
306.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceuticals (Pvt.) Ltd. 14KM Adyala Road, Post Office Dahgal, Rawalpindi.**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals (Pvt.) Ltd. 14KM Adyala Road, Post Office Dahgal, Rawalpindi. (DML No. 000333)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25423: 19.10.2023
	Details of fee submitted	PKR 30,000/- : 1118468990
	The proposed proprietary name / brand name	**CLATHRO 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Clarithromycin…….250mg
	Pharmacotherapeutic Group of (API)	Macrolides ATC Code: J01FA09
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	CLARITHROMYCIN 250MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	Claritek 250mg
	Proposed Pack size	As per SRO

Evaluation by PEC (No IX):

Sr. No.	Section	Observation	Reply
1.	3.2.P.5	As per USP monograph and the method of analysis submitted, the Detector wavelength should be 210nm (in both assay and dissolution), in some chromatograms the detection wavelength is 205, please clarify this deviation	The firm has submitted their response vide letter No. Shaigan/3831/11/2024 dated 04.11.2024. Firm has stated that chromatograms with detector wavelength 205 are for impurity profiling. The USP monograph does state that impurities should be checked at 205nm wavelength.
2.	3.2.P.5	Why system suitability is not part of method verification studies and why it is not performed before the assay of the product. Please submit system suitability performed on systems used in testing of drug product (equipment No QC-083 & QC-116) as per conditions mentioned in USP monograph (Resolving capacity of system: NLT 2.0 between clarithromycin and clarithromycin related compound A, System suitability solution) along with chromatograms of the run.	Firm has performed system suitability using Clarithromycin A and have submitted the data along wth dhromatograms.
3.	3.2.P.5	In all chromatograms submitted, there are unidentified peaks having larger area than the peak of clarithromycin (mainly peaks at RT around 1.6 & 3.1). These are not present in diluent/blank chromatograms and are present in all other chromatograms. These peaks need to be identified because multiple impurities mentioned in USP monograph have RRT in range similar to these peaks.	Firm has identified the peaks in chromatograms at RT 1.6 and, the firm has stated that both correspond to methanol that is used as the solvent in standard stock solution. (As per USP monograph the **mobile phase is Methanol** and 0.067M monobasic potassium Phosphate 13:7)
4.	-	Copy of AD attested invoice or clearance certificate is required. The copy of invoice submitted does not have attestation stamp.	Import license mentioning 9kg Clarithromycin powder USP is submitted.

Decision: Approved.

307.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Shaigan Pharmaceuticals (Pvt.) Ltd. 14KM Adyala Road, Post Office Dahgal, Rawalpindi.**
	Name, address of Manufacturing site.	M/s Shaigan Pharmaceuticals (Pvt.) Ltd. 14KM Adyala Road, Post Office Dahgal, Rawalpindi. (DML No. 000333)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25424: 19.10.2023
	Details of fee submitted	PKR 30,000/- : 169502110354
	The proposed proprietary name / brand name	**CLATHRO 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Clarithromycin…….500mg
	Pharmacotherapeutic Group of (API)	Macrolides ATC Code: J01FA09
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	CLARITHROMYCIN 500MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	Claritek 500mg
	Proposed Pack size	As per SRO

Evaluation by PEC (No IX):

Sr. No.	Section	Observation	Reply
1.	3.2.P.5	As per USP monograph and the method of analysis submitted, the Detector wavelength should be 210nm (in both assay and dissolution), in some chromatograms the detection wavelength is 205, please clarify this deviation	The firm has submitted their response vide letter No. Shaigan/3831/11/2024 dated 04.11.2024. Firm has stated that chromatograms with detector wavelength 205 are for impurity profiling. The USP monograph does state that impurities should be checked at 205nm wavelength.
2.	3.2.P.5	Why system suitability is not part of method verification studies and why it is not performed before the assay of the product. Please submit system suitability performed on systems used in testing of drug product (equipment No QC-083 & QC-116) as per conditions mentioned in USP monograph (Resolving capacity of system: NLT 2.0 between clarithromycin and clarithromycin related compound A, System suitability solution) along with chromatograms of the run.	Firm has performed system suitability using Clarithromycin A and have submitted the data along wth dhromatograms.
3.	3.2.P.5	In all chromatograms submitted, there are unidentified peaks having larger area than the peak of clarithromycin (mainly peaks at RT around 1.6 & 3.1). These are not present in diluent/blank chromatograms and are present in all other chromatograms. These peaks need to be identified because multiple	Firm has identified the peaks in chromatograms at RT 1.6 and, the firm has stated that both correspond to methanol that is used as the solvent in standard stock solution.

		impurities mentioned in USP monograph have RRT in range similar to these peaks.	(As per USP monograph the **mobile phase is Methanol** and 0.067M monobasic potassium Phosphate 13:7)
4.	3.2.P.8	3rd time point (6th month) stability data is not submitted.	Data is submitted.
5.	-	Copy of AD attested invoice or clearance certificate is required. The copy of invoice submitted does not have attestation stamp.	Import license mentioning 9kg Clarithromycin powder USP is submitted.

Decision: Approved.

308.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals, Plot No. 69/2, Phase-II Industrial Area, Hattar.**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot No. 69/2, Phase-II Industrial Area, Hattar. (DML No. 000644)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26513: 18.10.2023
	Details of fee submitted	PKR 75,000/- : 058047556381
	The proposed proprietary name / brand name	**AZCHLO 40mg/12.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Azilsartan Medoxomil Potassium eq. to Azilsartan Medoxomil……40mg Chlorthalidone…….12.5mg
	Pharmacotherapeutic Group of (API)	Angiotensin II receptor blockers (ARBs) and diuretics ATC Code: C09DA09
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	EDARBYCLOR EQ 40MG MEDOXOMIL;12.5MG, EQ 40MG MEDOXOMIL;25MG USFDA Approved.
	For generic drugs (me-too status)	NA, fee submitted for NDP
	Proposed Pack size	10's. 14's. 28's

Evaluation by PEC (No IX):

Decision: Approved.

309.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals, Plot No. 69/2, Phase-II Industrial Area, Hattar.**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot No. 69/2, Phase-II Industrial Area, Hattar. (DML No. 000644)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26514: 18.10.2023

	Details of fee submitted	PKR 75,000/- : 0590872398
	The proposed proprietary name / brand name	**AZCHLO 40mg/25mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Azilsartan Medoxomil Potassium eq. to Azilsartan Medoxomil…….……40mg Chlorthalidone…….25mg
	Pharmacotherapeutic Group of (API)	Angiotensin II receptor blockers (ARBs) and diuretics ATC Code: C09DA09
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	EDARBYCLOR EQ 40MG MEDOXOMIL;12.5MG, EQ 40MG MEDOXOMIL;25MG USFDA Approved.
	For generic drugs (me-too status)	NA, fee submitted for NDP
	Proposed Pack size	10's. 14's. 28's
Evaluation by PEC (No IX):		
Decision: Approved.		
310.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s WnsFeild Pharmaceuticals Plot No. 122, Block-A, Phase-V, Industrial Estate Hattar.**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceuticals Plot No. 122, Block-A, Phase-V, Industrial Estate Hattar. (DML No. 000610)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25296: 18.10.2023
	Details of fee submitted	PKR 30,000/- : 18493413465
	The proposed proprietary name / brand name	**CINAKAL 60mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Cinacalcet (as hydrochloride)……..60mg
	Pharmacotherapeutic Group of (API)	Other anti-parathyroid agents ATC Code: H05BX01
	Reference to Finished product specifications	Innovator Specifications
	The status in reference regulatory authorities	CINACALCET TILLOMED 60MG FILM-COATED TABLETS MHRA Approved.
	For generic drugs (me-too status)	Censipar 30 & 60mg Tablets M/s CCL
	Proposed Pack size	10's. 14's. 28's
Evaluation by PEC (No IX):		

S. No.	Section	Observation	Reply
1	-	Submit section approval letter.	Firm has submitted their response vide letter No. nil dated 27.11.2024. Copy of DML renewal letter No. 3-2/2006-Lic (Vol-II) dated 11.06.2024

			is submitted wherein Tablet general section is mentioned.
2	3.2.P.8	Submit 3rd time point (6th month) stability data.	Stability data is submitted.

Decision: Approved.

311.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s WnsFeild Pharmaceuticals Plot No. 122, Block-A, Phase-V, Industrial Estate Hatta.**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceuticals Plot No. 122, Block-A, Phase-V, Industrial Estate Hatta. (DML No. 000610)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25295: 18.10.2023
	Details of fee submitted	PKR 75,000/- : 6997673534
	The proposed proprietary name / brand name	**MEDRON 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains; Midodrine Hydrochloride…….5mg
	Pharmacotherapeutic Group of (API)	Adrenergic and dopaminergic agents ATC Code: C01CA17
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	NA, fee submitted is of ND
	Proposed Pack size	As per SRO

Evaluation by PEC (No IX):

S. No.	Section	Observation	Reply
1	-	Submit section approval letter.	Firm has submitted their response vide letter No. nil dated 27.11.2024. Copy of DML renewal letter No. 3-2/2006-Lic (Vol-II) dated 11.06.2024 is submitted wherein Tablet general section is mentioned.

Decision: Approved.

Contract Cases Form 5F (PEC-IX)

312.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s FAAS Pharmaceuticals (Pvt.) Ltd. F.748 L S.I.T.E. Karachi.(DML No. 000767)**
	Name, address of Manufacturing site.	M/s Global Pharmaceuticals (Pvt.) Ltd. Plot No. 204-205 Industrial Triangle, Kahuta Road, Islamabad. (DML No. 000417)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 19773: 09.08.2023

	Details of fee submitted	PKR 75,000/- : 44049023192
	The proposed proprietary name / brand name	**Cefixifaas 100mg/5ml Powder for Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml contains; Cefixime as Trihydrate…100mg
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporins ATC Code: J01DD08
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Cefspan Oral suspension.
	Proposed Pack size	30ml
Evaluation by PEC (No IX):		
Decision: Approved.		
313.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Lawari International Valley Road, Gulkada Saidu Sharif, Swat.(DML No. 000658)**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt.) pLOT nO. 145 Industrial Triangle Kahuta Road Islamabad. (DML No. 000417)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26944: 13.11.2023
	Details of fee submitted	PKR 75,000/- : 3416142883
	The proposed proprietary name / brand name	**Katwari 30mg/ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml Ampoule contains; Ketorolac tromethamine……..30mg
	Pharmacotherapeutic Group of (API)	Acetic acid derivatives and related substances ATC Code: M01AB15
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Toradol Injection
	Proposed Pack size	As per SRO
Evaluation by PEC (No IX):		
Decision: Approved.		
314.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Linear Pharma Plot No. 18, Street No. S-4, Natinal Indsutrial Zone (RCCI) Rawat.(DML No. 000670)**
	Name, address of Manufacturing site.	M/s Evolution Pharmaceuticals (Pvt.) Ltd. Plot No. 25-26 St. No. S-3 national Industrial Zone, Rawat. (DML No. 000867)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27477: 23.11.2023
	Details of fee submitted	PKR 75,000/- : 20929852333
	The proposed proprietary name / brand name	**Lin-Paz 4.5g IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains; Piperacillin (as sodium) …….4gm Tazobactam (as sodium)……..0.5gm
	Pharmacotherapeutic Group of (API)	piperacillin and beta-lactamase inhibitor ATC Code: J01CR05
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Tanzo 4.5 g Injection by M/s Bosch, Reg. No. 039439
	Proposed Pack size	1's
Evaluation by PEC (No IX):		
Decision: Approved.		
315.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Swera Pharmaceuticals Plot No. 27, Street No. S-4, Industrial Area Rawat .(DML No. 000941)**
	Name, address of Manufacturing site.	M/s Evolution Pharmaceuticals (Pvt.) Ltd. Plot No. 25-26 Street S-3, RCCI National Industrial Zone Rawat . (DML No. 000867)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27476: 23.11.2023
	Details of fee submitted	PKR 75,000/- : 4692094360
	The proposed proprietary name / brand name	**TAZO-P 4.5g IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains; Piperacillin (as sodium) …….4gm Tazobactam (as sodium)……..0.5gm
	Pharmacotherapeutic Group of (API)	piperacillin and beta-lactamase inhibitor ATC Code: J01CR05
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Tanzo 4.5 g Injection by M/s Bosch, Reg. No. 039439
	Proposed Pack size	1's
Evaluation by PEC (No IX):		
Decision: Approved.		
316.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Danas Pharamceuticals (Pvt.) Ltd. 312-Industrial Triangle Kahuta Road Islamabad .(DML No. 000569)**

	Name, address of Manufacturing site.	M/s Evolution Pharmaceuticals (Pvt.) Ltd. Plot No. 25-26 Street S-3, RCCI National Industrial Zone Rawat . (DML No. 000867)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27478: 23.11.2023
	Details of fee submitted	PKR 75,000/- : 76759661250
	The proposed proprietary name / brand name	**DANCILIN 4.5g IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains; Piperacillin (as sodium) …….4gm Tazobactam (as sodium)……..0.5gm
	Pharmacotherapeutic Group of (API)	piperacillin and beta-lactamase inhibitor ATC Code: J01CR05
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Tanzo 4.5 g Injection by M/s Bosch, Reg. No. 039439
	Proposed Pack size	1's
Evaluation by PEC (No IX):		
Decision: Approved.		
317.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Lawari International Valley Road, Gulkada Saidu Sharif, Swat.(DML No. 000658)**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt.) Plot No. 145 Industrial Triangle Kahuta Road Islamabad. (DML No. 000417)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22479: 13.09.2023
	Details of fee submitted	PKR 75,000/- : 38643980520
	The proposed proprietary name / brand name	**SPIRO 2g IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Ceftriaxone sodium eq. to Ceftriaxone….2gm
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporins ATC Code: J01DD04
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Oxidil 2g injection M/s Sami
	Proposed Pack size	As per SRO
Evaluation by PEC (No IX):		
Decision: Approved.		

318.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winlet Pharmaceuticals (Pvt.) Ltd. 30-Km Lahore Sargodha Road, Sargodha. (DML No. 000874)**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt.) Plot No. 145 Industrial Triangle Kahuta Road Islamabad. (DML No. 000417)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22458: 12.09.2023
	Details of fee submitted	PKR 75,000/- : 70171648
	The proposed proprietary name / brand name	**Telecef 2g IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Ceftriaxone sodium eq. to Ceftriaxone….2gm
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporins ATC Code: J01DD04
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Oxidil 2g injection M/s Sami
	Proposed Pack size	As per SRO
Evaluation by PEC (No IX):		
Decision: Approved.		
319.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad. (DML No. 000874)**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt.) Plot No. 145 Industrial Triangle Kahuta Road Islamabad. (DML No. 000417)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 19303: 03.08.2023
	Details of fee submitted	PKR 75,000/- : 623400164002
	The proposed proprietary name / brand name	**Vanconext 500mg Powder for Solution for Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Vancomycin HCl eq. to Vancomycin…500mg
	Pharmacotherapeutic Group of (API)	Glycopeptide antibacterials ATC Code: J01XA01
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Vancomycin injection Abbott
	Proposed Pack size	As per SRO
Evaluation by PEC (No IX):		

Decision: Approved.		
320.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio-Next Pharmaceuticals Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad. (DML No. 000874)**
	Name, address of Manufacturing site.	M/s Bio-Labs (Pvt.) Plot No. 145 Industrial Triangle Kahuta Road Islamabad. (DML No. 000417)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 19304: 03.08.2023
	Details of fee submitted	PKR 75,000/- : 4418017500
	The proposed proprietary name / brand name	**Vanconext 1gm Powder for Solution for Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Vancomycin HCl eq. to Vancomycin…1gm
	Pharmacotherapeutic Group of (API)	Glycopeptide antibacterials ATC Code: J01XA01
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	MHRA Approved.
	For generic drugs (me-too status)	Vancomycin injection Abbott
	Proposed Pack size	As per SRO
Evaluation by PEC (No IX):		
Decision: Approved. Registration Letter shall be issued after capacity assessment of the contract manufacturer as per approved policy, as per decision of registration board in its 333rd and 336th meetings.		
321.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cherwell Pharmaceuticals (Pvt.) Ltd. Plot No. 20, Phase-4 Hattar Industrial Estate Hattar (DML No. 000606)**
	Name, address of Manufacturing site.	M/s Swiss Pharmaceuticals (Pvt.) Ltd, A/159 S.I.T.E. II Super Highway Karachi (DML No. 000438)
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27487: 23.11.2023
	Details of fee submitted	PKR 75,000/- : 07311923069
	The proposed proprietary name / brand name	**SIGNUM 250mg IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Ceftriaxone sodium eq. to Ceftriaxone….250mg
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporins ATC Code: J01DD04
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	MHRA Approved.

	For generic drugs (me-too status)	Oxidil 250mg injection M/s Sami
	Proposed Pack size	As per SRO

Evaluation by PEC (No IX):

Sr. No.	Section	Observation
1.	-	Section Approval letter of drug product manufacturer is required. (only layout approval is submitted)

Decision: Deferred for submission of evidence of approval of required section i.e., Dry Powder Injection (Cephalosporin) by the Central Licensing Board.

Cases of Import on Form 5F

322.	**Name, address of Applicant / Importer**	**M/s Getz Pharma (Pvt.) Ltd. Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi.**
	Details of Drug Sale License of importer	License No: 570 (Drug License by way of wholesale) Address: Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi. Validity: 16.08.2024
	Name and address of marketing authorization holder (abroad)	M/s Jewim Pharmaceutical (Shandong) Co. Ltd. West of Peitianment Street, Tai'an High-Tech Industrial Development Zone, Shandong Province China.
	Name, address of manufacturer(s)	M/s Jewim Pharmaceutical (Shandong) Co. Ltd. West of Peitianment Street, Tai'an High-Tech Industrial Development Zone, Shandong Province China.
	Name of exporting country	China
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 21680 dated 01.09.2023
	Details of fee submitted	Rs.150,000/- Slip No. 3211419652
	The proposed proprietary name / brand name	**IPROGET Nebuliser Solution 500mcg/2ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml unit dose LDPE vial (UDV) contains: Ipratropium bromide monohydrate equivalent to Ipratropium bromide……500mcg
	Pharmacotherapeutic Group of (API)	Anticholinergics ATC Code: R03BB01
	Reference to Finished product specifications	In-House
	The status in reference regulatory authorities	Approved by MHRA Atrovent UDVS
	For generic drugs (me-too status)	Atem Nebuliser Solution
	Proposed Pack size	5's, 10's :As per SRO
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted legalized copy of CoPP No. Shandong20231045 issued by Shandong Provincial Medical Product Administration China dated 08.05.2023.

		Valid till 07.05.2027 The certificate does confirm the free sale status of the product in country of Origin along with GMP of the manufacturing unit.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of "Authorization Letter" from M/s Jewim Pharmaceuticals (Shandong) Co. Ltd. China, for applied product.
	Stability studies of drug product	Real time (24 months): 30ºC ± 2 ºC /75% ± 5%RH Accelerated (6 months): 40ºC ± 2 ºC /75% ± 5%RH

Evaluation by PEC[IX]:

Sr.#	Observation	Firm's response
1.	Fee submitted is from account of DML No. 000284 whereas in application DSL is attached instead of DML, please clarify.	Firm has submitted reply vide letter No. RA-RL/331/1124 dated 18.11.2024 Firm has stated that at time of submission of application only one account was available that was of DML, that's why fee was submitted on DML. Further product is imported that's why DSL was attached. **Firm has requested to Register their imported drug on DML No. 000284 instead of submitted fee from DSL.**
2.	Copies of Authorization letter/NOC and GMP certificate submitted need to be notarized from country of origin.	Legalized documents are submitted.

Decision: Approved as per policy of insection of manufacturer abroad. Firm shall submit following before issuance of registration letter:

- **Full fee of registration from the head of DSL.**
- **Analytical record for the submitted drug product stability data including chromatograms/spectrums etc.**

323.	**Name, address of Applicant / Importer**	**M/s Getz Pharma (Pvt.) Ltd. Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi.**
	Details of Drug Sale License of importer	License No: 570 (Drug License by way of wholesale) Address: Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi. Validity: 16.08.2024
	Name and address of marketing authorization holder (abroad)	M/s Jewim Pharmaceutical (Shandong) Co. Ltd. West of Peitianment Street, Tai'an High-Tech Industrial Development Zone, Shandong Province China.
	Name, address of manufacturer(s)	M/s Jewim Pharmaceutical (Shandong) Co. Ltd. West of Peitianment Street, Tai'an High-Tech Industrial Development Zone, Shandong Province China.
	Name of exporting country	China
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 23471 dated 22.09.2023
	Details of fee submitted	Rs.150,000/- Slip No. 694714651164
	The proposed proprietary name / brand name	**IPROGET-S Nebuliser Solution 0.5mg+2.5mg/2.5ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2.5ml unit dose LDPE vial (UDV) contains: Ipratropium bromide monohydrate equivalent to Ipratropium bromide……..…0.5mg

		Salbutamol sulfate eq. to Salbutamol…..2.5mg
	Pharmacotherapeutic Group of (API)	Adrenergics in combination with Anticholinergics incl. triple combinations with corticosteroids. ATC Code: R03AL02
	Reference to Finished product specifications	In-House
	The status in reference regulatory authorities	Approved by MHRA Combivent UDVS
	For generic drugs (me-too status)	Combihale Nebuliser Solution M/s Hudson Pharma.
	Proposed Pack size	5's, 10's :As per SRO
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted legalized copy of CoPP No. Shandong20231002 issued by Shandong Provincial Medical Product Administration China dated 13.01.2023. Valid till 12.01.2025 The certificate does confirm the free sale status of the product in country of Origin along with GMP of the manufacturing unit.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of "Authorization Letter" from M/s Jewim Pharmaceuticals (Shandong) Co. Ltd. China, for applied product.
	Stability studies of drug product	Real time (24 months): 30ºC ± 2 ºC /75% ± 5%RH Accelerated (6 months): 40ºC ± 2 ºC /75% ± 5%RH

Evaluation by PEC[IX]:

Sr.#	Observation	Firm's response
1.	Fee submitted is from account of DML No. 000284 whereas in application DSL is attached instead of DML, please clarify.	Firm has submitted reply vide letter No. RA-RL/331/1124 dated 18.11.2024 Firm has stated that at time of submission of application only one account was available that was of DML, that's why fee was submitted on DML. Further product is imported that's why DSL was attached. **Firm has requested to Register their imported drug on DML No. 000284 instead of submitted fee from DSL.**
2.	Copies of Authorization letter/NOC and GMP certificate submitted need to be notarized from country of origin.	Legalized documents are submitted.

Decision: Approved as per policy of insection of manufacturer abroad. Firm shall submit following before issuance of registration letter:

- **Full fee of registration from the head of DSL.**
- **Analytical record for the submitted drug product stability data including chromatograms/spectrums etc.**

324.	**Name, address of Applicant / Importer**	**M/s Ghazali Brothers 1st Floor, Cambell street, Azzainab Court Complex 19-SR-7, Karachi.**
	Details of Drug Sale License of importer	License No: 143 Address: Validity:
	Name and address of marketing authorization holder (abroad)	M/s Shandong Luoxin Pharmaceutical Group Stock Co. Ltd. Luoqi Road, Linyi High and New Technology Industries Development Zone Shandong Province, China.
	Name, address of manufacturer(s)	M/s Shandong Luoxin Pharmaceutical Group Stock Co. Ltd. Luoqi Road, Linyi High and New Technology Industries Development Zone Shandong Province, China.

	Name of exporting country	China
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 25276 dated 17.10.2023
	Details of fee submitted	Rs.150,000/- Slip No. 7353012041
	The proposed proprietary name / brand name	**PRIMERO 500mg Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains; Meropenem Trihydrate equivalent to Meropenem…….500mg (Blended with Sodium Carbonate)
	Pharmacotherapeutic Group of (API)	Carbapenems ATC Code: J01DH02
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	MEROPENEM 500MG POWDER FOR SOLUTION FOR INJECTION OR INFUSION MHRA Approved
	For generic drugs (me-too status)	Maxnem 50mg IV injection M/s Indus
	Proposed Pack size	As per SRO
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted legalized copy of CoPP No. Shandong 20220007 issued by Shandong Drug Administration China dated 10.03.2022. Valid till 09.03.2024 The certificate does confirm the free sale status of the product in country of Origin along with GMP of the manufacturing unit.
	Details of letter of authorization / sole agency agreement	Firm has submitted legalized copy of "Exclusive Distribution Agreement" from M/s Shandong Luoxin Pharmaaceutical Group Co. Ltd. China for applied product. Dated 05.05.2023, valid for 5 years.
	Stability studies of drug product	Real time (36 months): 30ºC ± 2 ºC /75% ± 5%RH Accelerated (6 months): 40ºC ± 2 ºC /75% ± 5%RH

Evaluation by PEC[IX]:

Sr.#	Observation
1.	COPP has been expired on 09.03.2024.
2.	Please submit copy of valid DSL

Decision: Deferred for submission of following documents:

- **Valid legalized COPP indicating free sale status in country of origin.**
- **Analytical record for the submitted drug product stability data including chromatograms/spectrums etc.**
- **Copy of valid DSL.**

325.	**Name, address of Applicant / Importer**	**M/s Ghazali Brothers 1st Floor, Cambell street, Azzainab Court Complex 19-SR-7, Karachi.**
	Details of Drug Sale License of importer	License No: 143 Address: 19-SR-7 Combell Street AzzainabCourt 1st floor Karachi.

		Address of Godown: 1.S.NO.14 G/Floor Karimji & others Plot WO7/15 N.Napier . 2.2D, 2nd Floor Karimji & others Plot No W07/15, N.Napier Karachi. Validity: 26.10.2023 Applied for renewal on time.
	Name and address of marketing authorization holder (abroad)	M/s Shandong Luoxin Pharmaceutical Group Stock Co. Ltd. Luoqi Road, Linyi High and New Technology Industries Development Zone Shandong Province, China.
	Name, address of manufacturer(s)	M/s Shandong Luoxin Pharmaceutical Group Stock Co. Ltd. Luoqi Road, Linyi High and New Technology Industries Development Zone Shandong Province, China.
	Name of exporting country	China
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 25277 dated 17.10.2023
	Details of fee submitted	Rs.150,000/- Slip No. 7353012041
	The proposed proprietary name / brand name	**PRIMERO 1gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains; Meropenem Trihydrate equivalent to Meropenem…….1gm (Blended with Sodium Carbonate)
	Pharmacotherapeutic Group of (API)	Carbapenems ATC Code: J01DH02
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	MEROPENEM 1GM POWDER FOR SOLUTION FOR INJECTION OR INFUSION MHRA Approved
	For generic drugs (me-too status)	Maxnem 1gm IV injection M/s Indus
	Proposed Pack size	As per SRO
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted legalized copy of CoPP No. Shandong 20220005(5) issued by Shandong Drug Administration China dated 26.01.2022. Valid till 25.01.2024 The certificate does **not** confirm the free sale status of the product in country of Origin along with GMP of the manufacturing unit.
	Details of letter of authorization / sole agency agreement	Firm has submitted legalized copy of "Exclusive Distribution Agreement" from M/s Shandong Luoxin Pharmaaceutical Group Co. Ltd. China for applied product. Dated 05.05.2023, valid for 5 years.
	Stability studies of drug product	Real time (36 months): 30ºC ± 2 ºC /75% ± 5%RH Accelerated (6 months): 40ºC ± 2 ºC /75% ± 5%RH

Evaluation by PEC[IX]:

Sr.#	Observation
1.	COPP has been expired on 25.01.2024 Further in COPP its mentioned that this product is not licensed to be placed on market in China. Please clarify
2.	Please submit valid copy of DSL.

Decision: Deferred for submission of following documents:

- **Valid legalized COPP indicating free sale status in country of origin.**
- **Analytical record for the submitted drug product stability data including chromatograms/spectrums etc.**
- **Copy of valid DSL.**

Deferred Form-5F cases

326	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Polyfine Chemical Pharmaceuticals, 51 Industrial Estate, Jamrud Road, Peshawar.**
	Name, address of Manufacturing site.	M/s Polyfine Chemical Pharmaceuticals, 51 Industrial Estate, Jamrud Road, Peshawar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 13647: 01.06.2023
	Details of fee submitted	PKR 30,000/- : 372680590299
	The proposed proprietary name / brand name	**CEFTREX 2gm IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains; Ceftriaxone as sodium…….2g
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporins ATC Code: J01DD04
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Oxidil 2g IV Injection
	Proposed Pack size	

Evaluation by PEC (No IX):

S. No.	Observation
1	Copy of latest GMP certificate or inspection report is required.
2	Evidence of approval of Ceph Dry powder injection section is required.
3	Copy of DML/GMP certificate of drug substance manufacturer is required.
4	Copy of AD attested invoice or clearance certificate of drug substance is required.
5	3.2.P.5: Why test of Particulate matter in injections is not made part of product specifications?
6	3.2.P.5.3: It is mentioned that system suitability will be verified by repeatability of retention time and peak area value of Ceftriaxone. USP monograph states that it should be such that The relative retention times for ceftriaxone and ceftriaxone E-isomer are 1.0 and

1.4, respectively. Why USP monograph is not followed in performing assay of the drug product?

Decision of 339th RB: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

Evaluation by PEC (No IX):

S. No.	Observation	Reply
1	Copy of latest GMP certificate or inspection report is required.	The firm has submitted their response vide letter No. nil dated 12.09.2024. Copy of GMP certificate valid till 25.05.2025 is submitted.
2	Evidence of approval of Ceph Dry powder injection section is required.	Firm has submitted copy of Renewal letter No. 3-1/97-Lic(Vol-II) dated 21.07.2023 wherein Dry powder for injection (Cephalosporin) is mentioned.
3	Copy of DML/GMP certificate of drug substance manufacturer is required.	Copy of GMP certificate certifying inspection dated 16-20.03.2023, issued by Shanxi Medical Products Administration is submitted.
4	Copy of AD attested invoice or clearance certificate of drug substance is required.	Copy of clearance certificate mentioning 200kg Ceftriaxone Sodium sterile USP is submitted
5	3.2.P.5: Why test of Particulate matter in injections is not made part of product specifications?	**Firm has stated that they have performed completeness and clarity of Solution test which ultimately means no Particulate matter and complete solubility of powder in solvent.**
6	3.2.P.5.3: It is mentioned that system suitability will be verified by repeatability of retention time and peak area value of Ceftriaxone. USP monograph states that it should be such that The relative retention times for ceftriaxone and ceftriaxone E-isomer are 1.0 and 1.4, respectively. Why USP monograph is not followed in performing assay of the drug product?	**Firm has stated that they have run 5 standards and calculated the RSD from these values and their RSD are well within limits.**

Decision: Approved. The Registration letter shall be issued after submission of evidence of availability of functional Liquid Particle counter and performance of Liquid particle count test of the product at next stability time point.

327.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Mafins Pharma, Plot No. A-5, S.I.T.E. Super Highway Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s Mafins Pharma, Plot No. A-5, S.I.T.E. Super Highway Industrial Area, Karachi..
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26041: 27.10.2023
	Details of fee submitted	PKR 20,000/- : 863059859258 PKR 10,000/- : 54561062359
	The proposed proprietary name / brand name	**CLAMAF Suspension 125mg/5ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5 ml contains; Clarithromycin…….125mg
	Pharmacotherapeutic Group of (API)	Macrolides ATC Code: J01FA09

	Reference to Finished product specifications	USP specifications
	The status in reference regulatory authorities	CLARITHROMYCIN 125 MG/5ML GRANULES FOR ORAL SUSPENSION MHRA Approved.
	For generic drugs (me-too status)	Claritek 125mg/ml Granules for suspension
	Proposed Pack size	60ml

Evaluation by PEC (No IX):

S. No.	Observation
1	3.2.P.2, 3.2.P.3: In the description of dug product it is mentioned that its granules for oral suspension, in manufacturing method it is nowhere mentioned how granules will be manufactured. Further none of the manufacturing method indicate that final product will be in granular form. Please clarify.
2	Clearance certificate or AD attested invoice of API is required.

Decision of 339th RB: Registration Board was apprised that the letter of shortcoming has been issued to the firm and reply of applicant is awaited, hence Board deferred the case for submission of reply to the above cited shortcomings.

Evaluation by PEC-IX

Firm vide letter No. MP/RA/0129 dated 24.09.2024 has submitted their response.

S. No.	Observation	Reply
1	3.2.P.2, 3.2.P.3: In the description of dug product it is mentioned that its granules for oral suspension, in manufacturing method it is nowhere mentioned how granules will be manufactured. Further none of the manufacturing method indicate that final product will be in granular form. Please clarify.	Firm has submitted a very generic method of making taste masked granules 27.5% by enteric coating. No details of manufacturing and required equipment is submitted, neither any details of testing is submitted.
2	Clearance certificate or AD attested invoice of API is required.	Copy of drug import license is submitted

Decision: Deferred for submission of detailed method of manufacture of 27.5% taste masked granules of clarithromycin along with evidence of required manufacturing facility(equipments and machines).

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	Name, address of Applicant / Importer	**M/s Al-Habib Pharmaceuticals, Plot#81-B, block B, SMCHS, Karachi.**
	Details of Drug Sale License of importer	DSL No.: 1245 Address: M/s Al-Habib Pharmaceuticals, Plot#81-B, block B, SMCHS, Karachi.. Godown: Plot No. 10 Sector 25, K I A Karachi HT-8, Landhi Industrial Area, Karachi. Validity: 18/05/2022 Status: Drug License by way of wholesale
	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
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)

	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 5224: 24-02-2022
	Details of fee submitted	PKR 150,000/-: 26-01-2022
	The proposed proprietary name / brand name	**ALLTREX (Methotrexate) 2.5mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet contains: Methotrexate ……. 2.5 mg
	Pharmacotherapeutic Group of (API)	Anti-Metabolite (L04AX03)
	Reference to Finished product specifications	BP Specifications
	The status in reference regulatory authorities	Methotrexate Orion 2.5 mg tablets by Orion Pharma UK MHRA approved
	For generic drugs (me-too status)	Methotrexate Tablet 2.5mg by Werrick Pharmaceuticals (025084)
	Proposed Pack size	As per SRO
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Original legalized CoPP (certificate No. CoPP/CERT/KD/83894/2019/11/27844/143353) valid till 03-04-2022 issued by Food and Drug Administration Mahrashtra Estate Mumbai for Methotrexate Tablets 2.5mg . 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. **GMP:** Firm has submitted GMP certificate No. NEWWHO- GMP/CERT/KD/80691/2019/11/27530 issued by Food and Drug Administration Mahrashtra Estate Mumbai. Valid till 03.04.2022
	Details of letter of authorization / sole agency agreement	Firm has submitted Original Authorization letter from Naprod Life Sciences Pvt. Ltd. The letter species that the manufacturer appoints M/s Al-Habib Pharmaceuticals, Plot #81, block B, SMCHS, Karachi as a sole agent and distributor to register their products in Pakistan
	Stability studies of drug product	Real time (24 months): 30ºC $\pm$ 2 ºC /75% $\pm$ 5%RH Accelerated (6 months): 40ºC $\pm$ 2 ºC /75% $\pm$ 5%RH
Remarks of AD (PECXX): USFDA approved Box warning for methotrexate tablet is as follows:		

METHOTREXATE tablets, for oral use
Initial U.S. Approval: 1953

WARNING: EMBRYO-FETAL TOXICITY, HYPERSENSITIVITY REACTIONS, and SEVERE ADVERSE REACTIONS

See full prescribing information for complete boxed warning.

- **Methotrexate Tablets can cause embryo-fetal toxicity, including fetal death. For non-neoplastic diseases, Methotrexate Tablets are contraindicated in pregnancy. For neoplastic diseases, advise patients of reproductive potential of the potential risk to a fetus and to use effective contraception. (4, 5.1, 8.1, 8.3)**
- **Methotrexate Tablets are contraindicated in patients with a history of severe hypersensitivity reactions to methotrexate, including anaphylaxis. (4, 5.2)**
- **Serious adverse reactions, including death, have been reported with methotrexate. Closely monitor for adverse reactions of the bone marrow, gastrointestinal tract, liver, lungs, skin, and kidneys. Withhold or discontinue Methotrexate Tablets as appropriate. (5.3, 5.4, 5.5, 5.6, 5.7, 5.8)**

Registration Board was apprised regarding an e. mail received to Director PE&R Division form 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.

Decision 324th meeting: Deferred for verification of "Sole Agency Agreement" between M/s. Al Habib Pharmaceuticals, Plot # 81, Block B, SMCHS, Karachi & M/s Naprod Life Sciences Pvt. Ltd. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, India.

Updated Status: Firm has submitted Original Notarized Authorization Letter Dated: 14th July, 2023 wherein it has been mentioned that:

"We (NAPROD LIFE SCIENCES PVT LTD, India) having address at (304. Town Center-1, Andheri Kurla Road, Andheri (E), Mumbai) do hereby authorize M/s Al Habib Pharmaceuticals having address at Plot following 81, BLOCK B SMCHS, 74400, Karachi Pakistan, As a sole agent and distribution of following drugs only.

Regarding our email Dated June 6th 2023 about the Clarification of Mile International India as an exporter of Naprod Life Sciences Pvt ltd beside the below mentioned products. We are again giving a firm undertaking that Al-Habib Pharmaceuticals, Karachi is an Authorize Distributor and sole agent for the following Drugs."

S.No	Generics	Brand Name
	Capecitabine 500mg TAB	NAPROCAP -500
	Methotrexate 2.5mg TAB	ALLTREX
	Doxorubicin HCl for inj 50mg	NAPRODOX 50
	Leucovorin Calcium inj. 300mg	CAFONATE
	Fluorouracil inj. 500mg	FLUONCO
	Bicalutamide 50mg TAB	MACABI
	Doxorubicin HCl for inj 10mg	NAPRODOX 10

Decision of 336th RB: Deferred for following requirements:

- Verification of "Sole Agency Agreement" between M/s. Al Habib Pharmaceuticals, Plot # 81, Block B, SMCHS, Karachi & M/s Naprod Life Sciences Pvt. Ltd. Factory: G-17/1, M.I.D.C., Tarapur, Boisar, Dist. Thane-401 506, India through e-mail.
- Compatibility of the Drug Substance(s) with excipients such as Sodium Lauryl Sulphate and colloidal silicon dioxide .

Evaluation by PEC[IX]:

The firm vide letter no. nil dated 07.08.2024 has submitted excipient compatibility report only.

The e.mail form Naprod in name of Director PE&R was presented in 339 meeting wherein instant product was also declared. Previously the proucts listed in the firm's e.mail have been approved in 339 meeting.

Decision: Approved as per policy of insection of manufacturer abroad. Firm shall submit analytical record for the submitted drug product stability data, including chromatograms/spectrums etc before issuance of registration letter

Form 5 Deferred Cases;

329.	**Name and address of manufacturer / Applicant**	**M/s Pharmix Laboratories (Pvt) Ltd. 21-Km, Ferozepur Road, Lahore.**
	Brand Name + Dosage Form + Strength	NEURAL 500mg tablet
	Composition	Each film-coated tablet contains: Citicoline as Sodium…500mg
	Diary No. Date of R& I & fee	Dy. No. 8629 dated 22-09-2010, Rs. 8,000/- dated 22-09-2010. Dy. No. dated 06-12-2018, Differential fee Rs. 12,000/- vide challan No.0796977 dated 28-11-2018. "Duplicate dossier, R & I verified"
	Pharmacological Group	Neurotropics
	Type of Form	Form -5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Couldn't be confirmed
	Me-too status	Citolin 500mg tablet of M/s Global pharmaceuticals, Islamabad. Registration No.048336
	GMP status	GMP certificate dated 27-07-2021 issued on the basis of evaluation conducted on 26-05-2021 & 07-07-2021.
	Remarks of the Evaluator (PEC-XVII)	Provide evidence of approval of applied formulation in reference regulatory authorities as adopted by the Drug Registration Board in its 275th meeting. Firm has claimed manufacturer specifications, while the product is non-pharmacopoeial. Tablet Section (General) mentioned in Licensing Division letter No.F.1-28/93-Lic dated 30-06-2020 for renewal of DML.
	Decision of 323rd RB	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting as reference product is in tablet dosage form.
	Evaluation by PEC-IX	The firm vide letter No. nil dated 19.08.2024 has submitted that product is approved in Spain. By name of Somazina. **The mentioned reference is not verifiable from cima.aemps.es**
	Decision: Deferred for submission of verifiable valid RRA reference.	
330.	**Name and address of manufacturer / Applicant**	**M/s Parkar Pharma** **Plot No. 0/7-A S.I.T.E AREA KOTRI SINDH**
	Brand Name + Dosage Form + Strength	Citrokin syrup 5mg /5ml
	Composition	Each 5ml of syrup contains: Cetrizine dihydrochloride ….5mg
	Diary No. Date of R& I & fee	Dy.No; 16276: Date:07-03-19 , Rs.20,000/-
	Pharmacological Group	Anti-Histamine
	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 by MHRA of UK
	Me-too status	Rakzine Syrup by M/s Rakaposhi Pharmaceutical Ltd.,Peshawar (Reg.#033969).
	GMP status	Panel Inspection for grant of DML dated 11-04-18 recommended grant of DML by the way of formulation for Tablet(general), Capsule(general) & Liquid syrup

		(general) Sections.
	Remarks of the Evaluator (PEC-XVII)	Mention type of primary packaging material of applied formulation.
	Decision of 293rd RB	Deferred for submission of type of primary packaging material for applied formulation.
	Evaluation by PEC-IX	The firm vide letter No. PP/DRAP-REG-/07-2024/002 dated 30.07.2024 has submitted that packing would be of 60ml glass bottle.
	Decision: Approved.	
331.	**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 Specification (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 (PEC-XVII)	• 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 of 329th RB	Deferred for following: 1. Clarification regarding strength of API which is mentioned as 5mg/5ml in brand name and 2.5mg/5ml in composition. 2. Revised Label Claim as per innovator drug product along with fee of Rs. 30000/-. 3. 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.**
	Evaluation by PEC-IX	The firm vide letter No. PP/DRAP-REG-/07-2024/003 dated 30.07.2024 has submitted their response; The firm has stated that correct label is; Each 5ml contains; Levocetrizine dihydrochloride…..2.5mg

		Fee is not submitted. Specifications are claimed as **Manufacturer specifications**
	Decision: Approved with innovator specifications and following label; **Each 5ml contains;** **Levocetrizine dihydrochloride…..2.5mg** **(as per innovator Specifications).** **Letter shall be issued after submission of fee of Rs. 37000/- for pre-registration variation.**	
332.	**Name and address of manufacturer / Applicant**	M/s Parkar Pharma. Plot No. O/7-A, S.I.T.E Area Kotri, Sindh
	Brand Name + Dosage Form + Strength	Allernil Syrup 2mg/5ml
	Composition	Each 5ml Contains: Chlorpheniramine Maleate…2mg
	Diary No. Date of R& I & fee	Dy No.24904; 18-07-2018 ; Rs.20,000
	Pharmacological Group	Anti allergic/ Arylalkylamine
	Type of Form	Form -5
	Finished product Specification	BP **Specification**
	Pack size & Demanded Price	60ml, As per DRAP policy.
	Approval status of product in Reference Regulatory Authorities	Chlorpheniramine Maleate 2mg/5ml Syrup Discontinued in USFDA.
	Me-too status	068446 "Colen Syrup "Alliance Pharmaceuticals (Pvt) Ltd, 112-A, Hayatabad Industrial Estate Jamrud Road, Peshawar.
	GMP status	Grant of DML Approved dated:11-04-18
	Remarks of the Evaluator (PEC-XVII)	• Chlorpheniramine oral solution is present in BP.
	Decision of 287th RB	Deferred for following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Justification for submitted finished product specifications, since firm has referred to BP monograph, which is "Chlorpheniramine oral solution" whereas firm has applied for "Chlorpheniramine Syrup".
	Evaluation by PEC-IX	The firm has submitted response vide letter dated **30.07.2024.** The product reference is available in MHRA by name of Boots Children's Allergy Relief Antihistamine 2mg/5ml Syrup Chlorphenamine Maleate 2mg/5ml Oral Solution Reference is verifiable. Firm has stated that in compliance to decision of RB decision they would change the name of product from syrup to Allernil 2mg/5ml Oral Solution. Fee of Rs. 30,000/- is also submitted vide slip No. 73683000
	Decision: Approved.	

Agenda of Mr. Shahid Nawaz

Case 01: Registration applications Locally manufactured (Human) drugs Routine cases on Form 5F.

333.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s WnsFeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 21697 dated 01-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 893024395056 dated 04-08-2023.
	The proposed proprietary name / brand name	**Anestro 1mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Anastrozole…… 1mg
	Pharmacotherapeutic Group of (API)	Aromatase inhibitors. (L02BG)
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	ARIMIDEX® (Anastrozole) tablet, USFDA Approved.
	For generic drugs (me-too status)	Arimisol 1mg Tablet, Swiss Pharmaceuticals, Reg. No. 091125.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML and GMP certificate of the applicant shall be submitted.	Firm has submitted copy of DML No. 000610 renewed w.e.f. 13-04-2022.
2.	1.3.5	Evidence of manufacturing facility/section approval from licensing division shall be submitted.	Firm has submitted copy of letter No. F. 3-2/2006-Lic (Vol-II) dated 11-06-2024 specifying Tablet (General) section
3.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	1 x 14's.
4.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant/concerned regulatory authority shall be submitted.	Firm has submitted copy of GMP certificate No. K Dis. No. 16478/D1/4/2021 dated 31-05-2022 issued by Department of Food Safety and Drug Control Administration Govt. of Tamilnadu valid till 31-12-2024. *However, address of the DS in module 3 is different from the address mentioned in the submitted GMP certificate.*

5.	3.2.S.4.1	Specifications of the drug substance from drug product manufacturer shall be submitted.	Submitted.
6.	3.2.S.4.2	Analytical procedures of the drug substance from drug product manufacturer shall be submitted.	Submitted.
7.	3.2.S.4.4	COA of the drug substance submitted by the drug product manufacturer has pH limits while USP monograph and COA submitted by the drug substance manufacturer has no pH limits. Clarification shall be submitted.	No clarification is submitted by the firm against this point. They just submitted revised COA wherein they removed pH.
8.	3.2.S.5	COA and details of reference standard/working standard used shall be submitted.	Submitted.
9.	3.2.S.7	• Limits of water content test mentioned in stability data sheets is NMT 1.0% while specification provided by the drug substance manufacturer has mentioned NMT 0.3%. Clarification shall be submitted. • Stability data sheets have mentioned pH limit of 5-6 while COA of the drug product manufacturer has mentioned 5-6.5. clarification shall be submitted.	Firm has submitted revised stability data sheets wherein they have changed the limits of water content test from NMT 1.0% to NMT 0.3%. Firm has removed pH limit from their specifications as per USP method.
10.	3.2.P.2.2.1	• Complete CDP studies with each time point dissolution of both reference and test product with analytical record shall be submitted. • Pictorial evidence of the innovator product with visible details of the batch number, expiry date and name of manufacturer shall be submitted.	Submitted. Firm has submitted pictorial evidence of innovator product Arimidex 1mg tablets, B. No. RB739, manufacturing date 03-2019 manufactured by M/s AstraZeneca USA. However, the data submitted in the dossier and now submitted data is totally different from each other. F2 values calculated in the new data and previously submitted data are totally changed.
11.	3.2.P.5.1	Justification shall be submitted for not including Uniformity of dosage unit test in specifications as recommended by the USP monograph.	Firm has submitted revised specifications wherein they added the said test.
12.	3.2.P.5.2	Signed analytical procedures for the finished product from drug product manufacturer shall be submitted.	Submitted. Firm once again submitted the analytical method wherein they have prepared

			standard and sample solutions as per USP pharmacopoeia. *But again the raw data sheets and analytical method are in contrast to each other. And if we put the value of 0.04mg/ml in raw data sheets then the values of assay are totally out of specifications.*
13.	3.2.P.8	• Stability data sheets as per decision of Registration board with inclusion of API lot No. shall be submitted. • Justify the sample and standard concentration in the submitted raw data sheets with respect to analytical method submitted in 3.2.P.5.2. As analytical method has mentioned 0.04mg/ml while raw data sheets has 0.1mg/ml. • Chromatograms also does not reveal any wavelength. Clarification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Submitted with inclusion of API lot No. ABANSNF003. Firm has submitted that it was a typo error and corrected concentration is 0.1mg/ml and they also submitted revised analytical procedures. However, concentration is different from that mentioned in USP. No justification submitted by the firm. Submitted.

Decision: Deferred for the following;

- **Valid copy of GMP certificate of the drug substance manufacturer (as per information submitted in Module I and Module III) issued by relevant/concerned regulatory authority shall be submitted.**
- **Justification shall be submitted for provision of changed data from that of the initially submitted data in Comparative Dissolution studies.**
- **Justify the sample and standard concentration in the submitted raw data sheets with respect to analytical method submitted again in reply wherein the analytical method has mentioned 0.04mg/ml while raw data sheets have 0.1mg/ml.**
- **Chromatograms also does not reveal any wavelength. Clarification shall be submitted.**
- **Submission of 9000/- fee for pre-registration variations as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.**

334.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s WnsFeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22787 dated 15-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 85121070440 dated 05-09-2023.
	The proposed proprietary name / brand name	**Candeza 8mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Candesartan Cilexetil…… 8mg

	Pharmacotherapeutic Group of (API)	Angiotensin Ii Receptor Blockers (Arbs), Plain ATC Code: C09CA06.
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Candesartan Cilexetil 8 mg Tablets, MHRA Approved.
	For generic drugs (me-too status)	Miscand 8mg Tablet, Mission Pharma, Reg. No. 081603.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML of the applicant shall be submitted.	
2.	1.3.5	Evidence of manufacturing facility/section approval from licensing division shall be submitted.	
3.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	
4.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant/concerned regulatory authority shall be submitted.	
5.	2.3	• Copies of executed BMR's shall be submitted along with one copy of blank production document. • Table for literature references with correct information regarding both drug substance and drug product with applicable fee shall be submitted.	
6.	3.2.S.4.1	Specifications of the drug substance from drug product manufacturer shall be submitted.	
7.	3.2.S.4.2	Analytical procedures of the drug substance from drug product manufacturer shall be submitted.	
8.	3.2.S.4.4	Assay limit in COA are different from that in the specification provided by the drug substance manufacturer. Clarification shall be submitted.	
9.	3.2.S.5	COA and details of reference standard/working standard used shall be submitted.	
10.	3.2.S.7	Assay limit in stability data sheets i.e. 98% - 102% and loss on drying limits both are changed from that provided in	

		specifications (98.7% - 101%). Clarification shall be submitted.
11.	3.2.P.2.2.1	Complete CDP studies with each time point dissolution of both reference and test product with analytical record shall be submitted.
12.	3.2.P.5.1	Justification shall be submitted for not including Uniformity of dosage unit test in specifications as recommended by the USP monograph.
13.	3.2.P.5.2	Signed analytical procedures for the finished product from drug product manufacturer shall be submitted.
14.	3.2.P.5.3	Method verification studies submitted are for drug substance. Clarification shall be submitted.
15.	3.2.P.8	• Stability data sheets as per decision of Registration board with inclusion of API lot No. shall be submitted. • Complete six month stability studies shall be submitted. • Justify the sample and standard concentration in the submitted raw data sheets with respect to analytical method submitted in 3.2.P.5.2. As analytical method has mentioned 0.8mg/ml while raw data sheets has 0.05mg/ml. • USP monograph has mentioned 10µl injection volume while submitted chromatograms has 20µl. clarification shall be submitted. • USP monograph has mentioned Run time of NLT 2.7 times the retention time of candesartan Cilexetil while submitted chromatograms have shown retention time of 7.4 minutes and run time of 9 minutes. Clarification shall be submitted. • Raw data sheets for calculation of assay and dissolution as per calculation formula shall be submitted. • Chromatograms also does not reveal any wavelength. Clarification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.		

335.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s WnsFeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	M/s WnsFeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22786 dated 15-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 26175772757 dated 05-09-2023.
	The proposed proprietary name / brand name	**Candeza 16mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Candesartan Cilexetil…… 16mg
	Pharmacotherapeutic Group of (API)	Angiotensin Ii Receptor Blockers (Arbs), Plain ATC Code: C09CA06.
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Candesartan Cilexetil 16 mg Tablets, MHRA Approved.
	For generic drugs (me-too status)	Miscand 16mg Tablet, Mission Pharma, Reg. No. 081602.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML of the applicant shall be submitted.	
2.	1.3.5	Evidence of manufacturing facility/section approval from licensing division shall be submitted.	
3.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	
4.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant/concerned regulatory authority shall be submitted.	
5.	2.3	• Copies of executed BMR's shall be submitted along with one copy of blank production document. • Table for literature references with correct information regarding both drug substance and drug product with applicable fee shall be submitted.	
6.	3.2.S.4.1	Specifications of the drug substance from drug product manufacturer shall be submitted.	

7.	3.2.S.4.2	Analytical procedures of the drug substance from drug product manufacturer shall be submitted.	
8.	3.2.S.4.4	Assay limit in COA are different from that in the specification provided by the drug substance manufacturer. Clarification shall be submitted.	
9.	3.2.S.5	COA and details of reference standard/working standard used shall be submitted.	
10.	3.2.S.7	Assay limit in stability data sheets i.e. 98% - 102% and loss on drying limits both are changed from that provided in specifications (98.7% - 101%). Clarification shall be submitted.	
11.	3.2.P.2.2.1	Complete CDP studies with each time point dissolution of both reference and test product with analytical record shall be submitted.	
12.	3.2.P.5.1	Justification shall be submitted for not including Uniformity of dosage unit test in specifications as recommended by the USP monograph.	
13.	3.2.P.5.2	Signed analytical procedures for the finished product from drug product manufacturer shall be submitted.	
14.	3.2.P.5.3	Method verification studies submitted are for drug substance. Clarification shall be submitted.	
15.	3.2.P.8	• Stability data sheets as per decision of Registration board with inclusion of API lot No. shall be submitted. • Complete six month stability studies shall be submitted. • Justify the sample and standard concentration in the submitted raw data sheets with respect to analytical method submitted in 3.2.P.5.2. As analytical method has mentioned 0.8mg/ml while raw data sheets has 0.05mg/ml. • USP monograph has mentioned 10µl injection volume while submitted chromatograms has 20µl. clarification shall be submitted. • USP monograph has mentioned Run time of NLT 2.7 times the retention time of candesartan Cilexetil while submitted chromatograms have shown retention time of 7.4 minutes	

	and run time of 9 minutes. Clarification shall be submitted. • Raw data sheets for calculation of assay and dissolution as per calculation formula shall be submitted. • Chromatograms also does not reveal any wavelength. Clarification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

336.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 21690 dated 01-09-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 94078660903 dated 04-08-2023.
	The proposed proprietary name / brand name	**Finrox 10mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Finerenone …… 10mg
	Pharmacotherapeutic Group of (API)	Mineralocorticoid Receptor (MR) Antagonist (C03D) Aldosterone Antagonists and other Potassium-Sparing Agents.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Kerendia 10mg & 20mg tablets by Bayer Healthcare, USFDA Approved.
	For generic drugs (me-too status)	N/A.
	Proposed Pack size	10's, 14's, 20's & 30's. As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML of the applicant shall be submitted.	Firm has once again submitted copy of DML w.e.f. 27-09-2013. They also submitted copy of receiving for renewal of DML dated 21-09-2023.
2.	1.3.5	Evidence of manufacturing facility/section approval from licensing division shall be submitted.	Firm has submitted copy of letter No. F. 3-8/2007-Lic dated 05-05-2010 mentioning approval for change of Tablet

			(Psychotropic) Section into Tablet (General) section.
3.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	10's, 14's, 20's & 30's.
4.	2.3	Copies of executed BMR's shall be submitted along with one copy of blank production document.	Submitted.
5.	3.2.S.4.1	Specifications of the drug substance from drug substance manufacturer has mentioned residue on ignition limit of ≤ 0.1% while drug product manufacturer has mentioned NMT 1%. Clarification shall be submitted.	Firm has submitted that it was typo error and they also provided revised COA of the drug substance. *Fee required for pre-registration variation is not submitted by the firm.*
6.	3.2.S.4.2	Analytical procedures of the drug substance from drug product manufacturer is having diluent composition and run time both different from that of the drug substance manufacturer. Clarification shall be submitted.	*Firm has submitted no clarification. However, they just submitted revised SAP wherein they have changed these condition. Furthermore, they submitted specification of the drug substance wherein the value of residue on ignition is changed from that of the drug substance manufacturer.*
7.	3.2.S.4.3	Complete analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
8.	3.2.S.4.4	Justification shall be submitted for not performing Enantiomeric purity test as recommended by the drug substance manufacturer (H-D01-CP23022002).	Firm has submitted that enantiomeric purity test was performed according to the method provided by API manufacturer and no peak is detected. Same is mentioned in revised COA.
9.	3.2.S.7	Complete real time stability of the drug substance shall be submitted as submitted one is for six months only.	Not submitted. *Firm has once again submitted only six months stability data.*
10.	3.2.P.2.2.1	Pictorial evidence of the innovator product, against which PE & CDP studies are performed, with visible information of manufacturing date, name and address of the manufacturer etc. shall be submitted.	Submitted. Kereidia 10mg tablets, Mfg. date 17-01-2022, Exp. date 17-01-2025, B. No. BXJUUH1 manufactured by M/s Bayer Zydus pharma.
11.	3.2.P.5.1	• Justification shall be submitted for assay limit of 90% - 110% while the innovator product has shelf life assay limit of 95% - 105%. • Justification shall be submitted for not including content uniformity test as recommended by the innovator product.	Firm has submitted that as their results falls between 99% to 102% so they revised the assay limit from 95% - 105% and also submitted revised stability data sheets. *Fee required is not submitted.*

			Firm has submitted that content uniformity was performed and also updated in revised stability data sheets.
12.	3.2.P.5.2	Justification shall be submitted for difference in assay test parameters i.e. injection volume (10µl), Column, Temperature (35ºC), Diluent (Isocratic) & run time (6 minutes) to that of the innovator product i.e. injection volume (5µl), & Column, Temperature (25ºC), Diluent (Gradient) & run time (28 minutes).	Firm has submitted that mistakenly SAP of other product provided. Now they are providing revised accurate controlled sap is provided. Firm has submitted that they performed test according to the API manufacturer method with the run time of 28 minutes but no peak is detected after the peak 04 minutes. That's why we set the run time of 06 minutes. *Neither of the submitted chromatograms are of 28 minutes. Furthermore, the initially submitted SAP was for the same product. However, conditions were different from innovator product. Raw data was also on the initially submitted SAP, and now only conditions are changed.*
13.	3.2.P.8	• Stability data sheets as per decision of Registration board with inclusion of API lot No. shall be submitted. • Documents for the procurement of API with approval from DRAP (in case of import) with approval from DRAP shall be submitted. • Complete six month stability studies shall be submitted. • Justification shall be submitted for manufacturing only two trial batches. • Raw data sheets for calculation of assay and dissolution as per calculation formula shall be submitted. • Chromatograms also does not reveal any wavelength. Clarification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	H-D01-CP23022002. Firm has submitted copy of clearance certificate No. E-4855497035369 dated 28-03-2023 wherein M/s Horizon HealthCare has imported 350gm of Finerenone from M/s Fuxing Long Rui pharmaceuticals. Six-month time point data submitted by the firm. Firm has now submitted 03 trial batches data. Not submitted. Firm submitted that at the time of stability studies mistakenly not added but saved in project. Submitted.

Decision: Deferred for following;

- **Submission of 9000/- fee for pre-registration variations as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.**
- **Complete real time stability data of the drug substance shall be submitted till its claimed shelf life as submitted one is for six months only.**
- **Firm will submit next time point data on revised SAP along with raw data sheets and its chromatograms.**
- **Raw data sheets for calculation of assay and dissolution as per calculation formula shall be submitted.**

337.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 21691 dated 01-09-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 3812073763 dated 04-08-2023.
	The proposed proprietary name / brand name	**Finrox 20mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Finerenone …… 20mg
	Pharmacotherapeutic Group of (API)	Mineralocorticoid Receptor (MR) Antagonist (C03D) Aldosterone Antagonists and other Potassium-Sparing Agents.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Kerendia 10mg & 20mg tablets by Bayer Healthcare, USFDA Approved.
	For generic drugs (me-too status)	N/A.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML of the applicant shall be submitted.	Firm has once again submitted copy of DML w.e.f. 27-09-2013. They also submitted copy of receiving for renewal of DML dated 21-09-2023.
2.	1.3.5	Evidence of manufacturing facility/section approval from licensing division shall be submitted.	Firm has submitted copy of letter No. F. 3-8/2007-Lic dated 05-05-2010 mentioning approval for change of Tablet (Psychotropic) Section into Tablet (General) section.
3.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	10's, 14's, 20's & 30's.

4.	2.3	copies of executed BMR's shall be submitted along with one copy of blank production document.	Submitted.
5.	3.2.S.4.1	Specifications of the drug substance from drug substance manufacturer has mentioned residue on ignition limit of ≤ 0.1% while drug product manufacturer has mentioned NMT 1%. Clarification shall be submitted.	Firm has submitted that it was typo error and they also provided revised COA of the drug substance. *Fee required for pre-registration variation is not submitted by the firm.*
6.	3.2.S.4.2	Analytical procedures of the drug substance from drug product manufacturer is having diluent composition and run time both different from that of the drug substance manufacturer. Clarification shall be submitted.	*Firm has submitted no clarification. However, they just submitted revised SAP wherein they have changed these condition. Furthermore, they submitted specification of the drug substance wherein the value of residue on ignition is changed from that of the drug substance manufacturer.*
7.	3.2.S.4.3	Complete analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
8.	3.2.S.4.4	Justification shall be submitted for not performing Enantiomeric purity test as recommended by the drug substance manufacturer (H-D01-CP23022002).	Firm has submitted that enantiomeric purity test was performed according to the method provided by API manufacturer and no peak is detected. Same is mentioned in revised COA.
9.	3.2.S.7	Complete real time stability of the drug substance shall be submitted as submitted one is for six months only.	*Not submitted.* *Firm has once again submitted only six months stability data.*
10.	3.2.P.2.2.1	Pictorial evidence of the innovator product, against which PE & CDP studies are performed, with visible information of manufacturing date, name and address of the manufacturer etc. shall be submitted.	Submitted. Kereidia 20mg tablets, Mfg. date 25-01-2022, Exp. date 25-01-2025, B. No. BXJTVU1 manufactured by M/s Bayer Zydus pharma.
11.	3.2.P.5.1	• Justification shall be submitted for assay limit of 90% - 110% while the innovator product has shelf life assay limit of 95% - 105%. • Justification shall be submitted for not including content uniformity test as recommended by the innovator product.	Firm has submitted that as their results falls between 99% to 102% so they revised the assay limit from 95% - 105% and also submitted revised stability data sheets. *Fee required is not submitted.* Firm has submitted that content uniformity was performed and also updated in revised stability data sheets.
12.	3.2.P.5.2	Justification shall be submitted for difference in assay test parameters i.e. injection volume (10µl), Column,	Firm has submitted that mistakenly SAP of other product provided. Now they are providing revised accurate controlled sap is

		Temperature (35ºC), Diluent (Isocratic) & run time (6 minutes) to that of the innovator product i.e. injection volume (5µl), & Column, Temperature (25ºC), Diluent (Gradient) & run time (28 minutes).	provided. Firm has submitted that they performed test according to the API manufacturer method with the run time of 28 minutes but no peak is detected after the peak 04 minutes. That's why we set the run time of 06 minutes. *Neither of the submitted chromatograms are of 28 minutes. Furthermore, the initially submitted SAP was for the same product. However, conditions were different from innovator product. Raw data was also on the initially submitted SAP, and now only conditions are changed.*
13.	3.2.P.8	• For batch No. T-04 & T-05 Accelerated stability data sheets shall be submitted. • Stability data sheets as per decision of Registration board with inclusion of API lot No. shall be submitted. • Documents for the procurement of API with approval from DRAP (in case of import) with approval from DRAP shall be submitted. • Complete six-month stability studies shall be submitted. • Justification shall be submitted for manufacturing only two trial batches. • Raw data sheets for calculation of assay and dissolution as per calculation formula shall be submitted. • Chromatograms also does not reveal any wavelength. Clarification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Submitted. H-D01-CP23022002. Firm has submitted copy of clearance certificate No. E-4855497035369 dated 28-03-2023 wherein M/s Horizon HealthCare has imported 350gm of Finerenone from M/s Fuxing Long Rui pharmaceuticals. Six-month time point data submitted by the firm. Not submitted. Firm submitted that at the time of stability studies mistakenly not added but saved in project. Submitted.
Decision: Deferred for following; • **Submission of 9000/- fee for pre-registration variations as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.** • **Complete real time stability data of the drug substance shall be submitted till its claimed shelf life as submitted one is for six months only.**			

- **Firm will submit next time point data on revised SAP along with raw data sheets and its chromatograms.**
- **Raw data sheets for calculation of assay and dissolution as per calculation formula shall be submitted.**

338.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129 Sunder Industrial Estate, Raiwind Road, Lahore.
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 21975 dated 06-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 313025980 dated 01-09-2023.
	The proposed proprietary name / brand name	**Ibuprofen/Famotidine 800mg/26.6 Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Ibuprofen ……..… 800mg Famotidine ……... 26.6mg
	Pharmacotherapeutic Group of (API)	Ibuprofen: Analgesic and Anti-inflammatory. Famotidine: Histamine-2 receptor Antagonist.
	Reference to Finished product specifications	In-House Specifications.
	The status in reference regulatory authorities	DUEXIS (ibuprofen and famotidine) tablets, USFDA Approved. **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons** DUEXIS® 800 mg/26.6 mg Film-coated Tablets PL 36663/0002, MHRA approved.
	For generic drugs (me-too status)	Not provided.
	Proposed Pack size	2 x 7's, 1 x 10's, 2 x 10's, 3 x 10's, 6 x 10's, 9 x 10's.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of GMP certificate of the applicant shall be submitted.	Firm has submitted copy of GMP certificate No. 188/2023-DRAP(AD-3489860170) dated 14-11-2023 issued on the basis of inspection conducted on 03-04-2023.
2.	1.5.8	Provide evidence of me too product with brand name, registration number and name of the firm or otherwise submit fee for new molecule.	Firm has submitted copy of challan No. 05668630 dated 22-11-2024 wherein they have submitted differential fee of 45000/-
3.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer (Famotidine) issued by relevant/concerned authority shall be submitted.	Firm has submitted copy of GMP certificate No. 24034866 issued by FDCA Gujrat State India dated 20-03-2024 valid for a period of three years.

4.	3.2.P.2.2.1	Pictorial evidence of innovator product against which PE and CDP studies are performed with clear details of the batch number, manufacturing date and name of manufacturer shall be submitted.	Firm has submitted details of the innovator product as follows; Duxes tablets 800mg/26.6mg, Lot No. 95LBL025, Exp. date 02-2024 manufactured by M/s Horizon Pharma USA.

Decision: Approved.

339.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22058 dated 07-09-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 0597179264 dated 22-08-2023.
	The proposed proprietary name / brand name	**Peroxib 40mg Powder for injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: 42.36mg Parecoxib Sodium equivalent to Parecoxib ……..40mg.
	Pharmacotherapeutic Group of (API)	Anti-inflammatory and Anti-rheumatic.
	Reference to Finished product specifications	Innovator's Specifications.
	For generic drugs (me-too status)	N/A.
	The status in reference regulatory authorities	Parecoxib 40 mg Powder and solvent for solution for injection, MHRA approved.
	Proposed Pack size	1 vial.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copy of GMP certificate of Drug substance manufacturer shall be submitted.	Firm has submitted copy of DML M/s Zhejiang Haisen Pharmaceutical Co. Ltd., Xiangtan Village, Liushi Street, Dongyang, City Zhejiang Province, China. Validity 24-09-2025.
2.	3.2.S.4.1	Specification of the drug substance from drug substance manufacturer shall be submitted.	Submitted.
3.	3.2.S.4.2	Analytical method of the drug substance from drug substance manufacturer shall be submitted.	Submitted.

4.	3.2.S.4.3	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
5.	3.2.P.2.2.1	Pictorial evidence of the innovator product with clear and visible information of batch number, manufacturing date and name of manufacturer etc.	Firm has submitted pictorial evidence of innovator's i.e. Dynastat Injection 40mg, batch number 305203 manufactured by Pfizer Limited UK.

Decision: Approved.

340.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 22956 dated 19-09-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 8374595570 dated 16-08-2023.
	The proposed proprietary name / brand name	**Finone 20mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Finerenone …… 20mg
	Pharmacotherapeutic Group of (API)	Mineralocorticoid Receptor (MR) Antagonist (C03D) Aldosterone Antagonists and other Potassium-Sparing Agents.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Kerendia 10mg & 20mg tablets by Bayer Healthcare, USFDA Approved.
	For generic drugs (me-too status)	N/A.
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	**Section**	**Observation**	**Reply by the firm**
1.	3.2.S.4.1	Specifications of the drug substance from drug substance manufacturer shall be submitted.	Submitted.
2.	3.2.S.4.2	Analytical procedures of the drug substance from drug substance manufacturer shall be submitted.	Submitted.
3.	3.2.S.4.2	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Firm has submitted analytical method verification studies of the drug substance performed by the finished product manufacturer.

4.	3.2.P.1	This section has mentioned 5% of overages. Scientific justification of overages shall be submitted.	Firm has submitted that Finerenone is BCS class II drug. In the batch manufacturing process (Confirmatory trial), overage of 5% API was added for potential losses during Micronization and screening. This adjustment was necessary to ensure that the final quantity of API in each tablet was precisely 10mg and 20mg, as per the label claim. Without this overage, shortfall in the API recovery observed during trial stage, compromising the product's efficacy and compliance with the batch manufacturing record. Stability studies of the final product have confirmed that it meets all physical and chemical quality targets, demonstrating the effectiveness and necessity of 5% overage in maintaining consistent and accurate dosing after Micronization losses.
5.	3.2.P.2.2.1	Pictorial evidence of the innovator product, against which PE & CDP studies are performed, with visible information of batch number, manufacturing date etc. shall be submitted.	Firm has submitted picture of the innovator product i.e. Kerendia 20mg Tablets, B. No. 507206, Mfg. date of 08-2024 manufactured by Bayer Zydus Pharma.
6.	3.2.P.5.1	Justification shall be submitted for assay limit of 90% - 110% while the innovator product has shelf life assay limit of 95% - 105%.	Firm has revised their assay specifications limits to 95% - 105% with submission of 9000/- as pre-registration variation vide challan No. 642909300 dated 30-10-2024.
7.	3.2.P.5.2	Justification shall be submitted for difference in assay test parameters i.e. injection volume (10µl), Detector wavelength (225nm) & Column (C18, 4.6 x 250mm 5 micron or equivalent) to that of the innovator product i.e. injection volume (5µl), Detector wavelength (251nm) & Column (Steel, length 150 mm, inner diameter 3.0 mm).	Firm has submitted that during literature review, due to restricted access to the analytical testing conditions of the innovator's product, we adopted the parameters specified in the product standard operating procedure (SOP). Additionally, we have conducted a comprehensive analytical method validation, demonstrating that the method is specific, robust and suitable for its intended purpose. Product validation ensures this testing method is scientifically sound and both applied and reference product are pharmaceutically equivalent.

Decision: Approved. Registration Board further directed the firm to not use any overage in the commercial batches of the formulation.

341.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Tabros Pharma (Pvt.) Ltd., Plot No. L-20/B, Sector 22, F.B. Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s Tabros Pharma (Pvt.) Ltd., Plot No. L-20/B, Sector 22, F.B. Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22456 dated 12-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 1984676029 dated 29-08-2023.
	The proposed proprietary name / brand name	**NAPZ 375/20mg Tablets.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Modified Release Tablet contains: Naproxen ……375mg (Enteric coated delayed release) Esomeprazole as Magnesium Trihydrate …. 20mg (Immediate release Coat)
	Pharmacotherapeutic Group of (API)	Anti-inflammatory and Anti-Rheumatic Products, Non-Steroids. ATC Code: M01AE52.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Vimovo Tablets USFDA approved. EQ 20MG BASE;375MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	For generic drugs (me-too status)	Glomov Tablets, Global pharma, Reg. No. 109339.
	Proposed Pack size	2 x 14's.
	Proposed unit price	As per DPC.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer for Naproxen issued by relevant regulatory authority shall be submitted.	Firm has submitted copy of certificate No. HMF07-14051/377/2024-ADMN-DCA dated 26-06-2024 issued on the basis of inspection dated 27 & 28-05-2024 valid for three years.
2.	3.2.S.7.3	Real time stability studies at zone IVb for the same batches for which accelerated stability data is provided shall be submitted.	Firm has submitted that the manufacturer conducted real time stability studies at 25˚C ± 2˚C / 60% ± 5%RH on the same batches for which accelerated stability data was provided. However, in response to our request for real time stability under zone IVb conditions, the manufacturer provided data from additional ongoing stability batches. Based on the submitted stability data, the product has demonstrated stability under zone IVb conditions as well.
3.	3.2.P.2.2.1	• Justification shall be submitted for using 75 minutes' time for Esomeprazole while the innovator product has mentioned a time of 45 minutes.	Firm has submitted that by using 75-minute dissolution for esomeprazole, while the innovator product specifies 45 minutes, However, as per FDA database, which indicates a dissolution time of 90 minutes. Therefore, we selected a 75-minute time point to meet the required Q value in a single time point. They further stated that they acknowledge the innovator's specified dissolution time of 45 minute; however, based on practical results, this time didn't consistently meet Q value limit. Thus, the 75-minute dissolution ensures that our

	• CDP data has also shown less release i.e. 80% within 45 minutes. Clarification shall be submitted for less release in CDP data with respect to the data of the innovator product.	products Q value remain within acceptable limit. *FDA data referred by the firm is for different time points during CDP studies. Innovator product has mentioned a dissolution time of 45 minutes.* Firm has submitted that less than 80% release within 45-minute in CDP data is as follows; While both the innovator and applied product have to achieve Q levels at the 45-minute mark, we have set a dissolution time of 75 minute to ensure consistent release that align with Q requirement. This adjustment accommodates the specific release profile of our product while maintaining compliance with dissolution standards as per FDA database.

Decision: Approved. Firm shall submit following before issuance of registration letter:

- **Revised formulation with performance of dissolution test, at the time of batch release, as per limits recommended by the innovator drug product.**
- **Fee for pre-registration variations as per notification vide No. S.R.O. 1324(I)/2024 dated 30-08-2024.**

342.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Tabros Pharma (Pvt.) Ltd., Plot No. L-20/B, Sector 22, F.B. Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s Tabros Pharma (Pvt.) Ltd., Plot No. L-20/B, Sector 22, F.B. Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22457 dated 12-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 4379218539 dated 29-08-2023.
	The proposed proprietary name / brand name	**NAPZ 500/20mg Tablets.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Modified Release Tablet contains: Naproxen ……500mg (Enteric coated delayed release) Esomeprazole as Magnesium Trihydrate …. 20mg (Immediate release Coat)
	Pharmacotherapeutic Group of (API)	Anti-inflammatory and Anti-Rheumatic Products, Non-Steroids. ATC Code: M01AE52.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Vimovo Tablets USFDA approved. EQ 20MG BASE;500MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	For generic drugs (me-too status)	Glomov Tablets, Global pharma, Reg. No. 109338.
	Proposed Pack size	2 x 14's.
	Proposed unit price	As per DPC.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer for Naproxen issued by relevant regulatory authority shall be submitted.	Firm has submitted copy of certificate No. HMF07-14051/377/2024-ADMN-DCA dated 26-06-2024 issued on the basis of inspection dated 27 & 28-05-2024 valid for three years.
2.	3.2.S.7.3	Real time stability studies at zone IVb for the same batches for which accelerated stability data is provided shall be submitted.	Firm has submitted that the manufacturer conducted real time stability studies at 25˚C ± 2˚C / 60% ± 5%RH on the same batches for which accelerated stability data was provided. However, in response to our request for real time stability under zone IVb conditions, the manufacturer provided data from additional ongoing stability batches. Based on the submitted stability data, the product has demonstrated stability under zone IVb conditions as well.
3.	3.2.P.2.2.1	• Justification shall be submitted for using 75 minutes' time for Esomeprazole while the innovator product has mentioned a time of 45 minutes. • CDP data has also shown less release i.e. 80% within 45 minutes. Clarification shall be submitted for less release in CDP data with respect to the data of the innovator product.	Firm has submitted that by using 75-minute dissolution for esomeprazole, while the innovator product specifies 45 minutes, However, as per FDA database, which indicates a dissolution time of 90 minutes. Therefore, we selected a 75-minute time point to meet the required Q value in a single time point. They further stated that they acknowledge the innovator's specified dissolution time of 45 minute; however, based on practical results, this time didn't consistently meet Q value limit. Thus, the 75-minute dissolution ensures that our products Q value remain within acceptable limit. *FDA data referred by the firm is for different time points during CDP studies. Innovator product has mentioned a dissolution time of 45 minutes.* Firm has submitted that less than 80% release within 45-minute in CDP data is as follows; While both the innovator and applied product have to achieve Q levels at the 45-minute mark, we have set a dissolution time of 75 minute to ensure consistent release that align with Q requirement. This adjustment accommodates the specific release profile of our product while maintaining compliance with dissolution standards as per FDA database.

Decision: Approved. Firm shall submit following before issuance of registration letter:

- **Revised formulation with performance of dissolution test, at the time of batch release, as per limits recommended by the innovator drug product.**

- **Fee for pre-registration variations as per notification vide No. S.R.O. 1324(I)/2024 dated 30-08-2024.**

343.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase-I&II, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase-I&II, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22784 dated 15-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 1906957949 dated 25-07-2023.
	The proposed proprietary name / brand name	**Winsal 5mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Solifenacin Succinate …… 5mg
	Pharmacotherapeutic Group of (API)	Drugs for urinary frequency and incontinence ATC Code: G04BD08.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Solifenacin 5 mg & 10mg film-coated tablets, MHRA approved.
	For generic drugs (me-too status)	Solifen Tablet, M/s Getz Pharma, Reg. No. 061202.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML and GMP certificate of the applicant shall be submitted.	
2.	1.3.5	Evidence of manufacturing facility/section approval from licensing division shall be submitted.	
3.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	
4.	1.6.5	Valid copy of GMP certificate of the drug substance manufacture issued by relevant/concerned regulatory authority shall be submitted.	
5.	2.3	Table for literature references with correct information regarding drug substance with applicable fee shall be submitted.	
6.	3.2.S.4.1	Specifications of the drug substance from drug product manufacturer shall be submitted.	
7.	3.2.S.4.2	Complete analytical procedures of the drug substance from both drug substance and drug product manufacturer shall be submitted. Submitted analytical procedures have no assay test.	
8.	3.2.S.4.3	• Complete analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	

		• Justification shall be submitted regarding the verification studies as it is by HPLC method while monograph has mentioned Titration method.
9.	3.2.S.5	Details and COA of the reference/working standard shall be submitted.
10.	3.2.S.7	• Signed stability study data sheets of the drug substance from drug substance manufacturer shall be submitted. • Specification has mentioned 99-101% assay limits while sheets have 98-102%. Clarification shall be submitted.
11.	3.2.P.2.2.1	• Pictorial evidence of the comparator product, against which PE & CDP studies are performed, with visible information of manufacturing date, name and address of the manufacturer etc. shall be submitted.
12.	3.2.P.5.1	• Justification shall be submitted for not including content uniformity test in the specifications.
13.	3.2.P.5.2	Analytical procedure for the finished product shall be submitted.
14.	3.2.P.8	• Stability data sheets as per decision of Registration board with inclusion of API lot No. shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

344.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase-I&II, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase-I&II, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22785 dated 15-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 7488867837 dated 25-07-2023.
	The proposed proprietary name / brand name	**Winsal 10mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Solifenacin Succinate …… 10mg
	Pharmacotherapeutic Group of (API)	Drugs for urinary frequency and incontinence ATC Code: G04BD08.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Solifenacin 5 mg & 10mg film-coated tablets, MHRA approved.
	For generic drugs (me-too status)	Solifen Tablet, M/s Getz Pharma, Reg. No. 061203.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	**Section**	**Observation**	**Reply by the firm**

1.	1.3.4	Valid copy of DML and GMP certificate of the applicant shall be submitted.
2.	1.3.5	Evidence of manufacturing facility/section approval from licensing division shall be submitted.
3.	1.5.4	Proposed pack size for the applied formulation shall be submitted.
4.	1.6.5	Valid copy of GMP certificate of the drug substance manufacture issued by relevant/concerned regulatory authority shall be submitted.
5.	2.3	Table for literature references with correct information regarding drug substance with applicable fee shall be submitted.
6.	3.2.S.4.1	Specifications of the drug substance from drug product manufacturer shall be submitted.
7.	3.2.S.4.2	Complete analytical procedures of the drug substance from both drug substance and drug product manufacturer shall be submitted. Submitted analytical procedures have no assay test.
8.	3.2.S.4.3	• Complete analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted. • Justification shall be submitted regarding the verification studies as it is by HPLC method while monograph has mentioned Titration method.
9.	3.2.S.5	Details and COA of the reference/working standard shall be submitted.
10.	3.2.S.7	• Signed stability study data sheets of the drug substance from drug substance manufacturer shall be submitted. • Specification has mentioned 99-101% assay limits while sheets have 98-102%. Clarification shall be submitted.
11.	3.2.P.2.2.1	Pictorial evidence of the comparator product, against which PE & CDP studies are performed, with visible information of manufacturing date, name and address of the manufacturer etc. shall be submitted.
12.	3.2.P.5.1	Justification shall be submitted for not including content uniformity test in the specifications.
13.	3.2.P.5.2	Analytical procedure for the finished product shall be submitted.
14.	3.2.P.8	• Stability data sheets as per decision of Registration board with inclusion of API lot No. shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

345.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase-I&II, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase-I&II, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26278 dated 31-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 30321217 dated 25-10-2023.
	The proposed proprietary name / brand name	**Wsdon 2mg Tablet.**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Risperidone …… 3mg
	Pharmacotherapeutic Group of (API)	Antipsychotics. ATC Code: N05AX08.
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Risperidone 2mg Tablets, MHRA approved.
	For generic drugs (me-too status)	Resjun 2mg tablet, M/s Jupiter Pharma, Reg. No. 081922.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML and GMP certificate of the applicant shall be submitted.	
2.	1.3.5	Evidence of manufacturing facility/section approval from licensing division shall be submitted.	
3.	1.5.2	This section has mentioned that each tablet contains 3 mg. clarification shall be submitted.	
4.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	
5.	1.6.5	Valid copy of GMP certificate of the drug substance manufacture issued by relevant/concerned regulatory authority shall be submitted.	
6.	2.3	Table for literature references with correct information regarding drug substance and drug product with applicable fee shall be submitted.	
7.	3.2.S.4.1	Specifications of the drug substance from drug product manufacturer shall be submitted.	
8.	3.2.S.4.2	Analytical procedures of the drug substance from drug product manufacturer shall be submitted.	
9.	3.2.S.4.3	• Complete analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
10.	3.2.S.5	Details and COA of the reference/working standard shall be submitted.	
11.	3.2.P.2.2.1	• Details of the manufacturer of the comparator product shall be submitted.	
12.	3.2.P.5.1	Justification shall be submitted for not including uniformity of dosage unit test as recommended by the USP in the specifications.	
13.	3.2.P.5.2	Signed analytical procedure for the finished product shall be submitted.	
14.	3.2.P.8	• Stability data sheets as per decision of Registration board with inclusion of API lot No. shall be submitted. • Justification shall be submitted for not performing uniformity of dosage units as recommended by the monograph.	

- Raw data sheets for dissolution and assay test at each time interval as per submitted calculation formula shall be submitted.
- Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

346.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase-I&II, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase-I&II, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26279 dated 31-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 52071233735 dated 25-10-2023.
	The proposed proprietary name / brand name	**Wsdon 4mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Risperidone …… 4mg
	Pharmacotherapeutic Group of (API)	Antipsychotics. ATC Code: N05AX08.
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Risperidone 4mg Tablets, MHRA approved.
	For generic drugs (me-too status)	Resjun 4mg tablet, M/s Jupiter Pharma, Reg. No. 081924.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	Valid copy of DML and GMP certificate of the applicant shall be submitted.	
2.	1.3.5	Evidence of manufacturing facility/section approval from licensing division shall be submitted.	
3.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	
4.	1.6.5	Valid copy of GMP certificate of the drug substance manufacture issued by relevant/concerned regulatory authority shall be submitted.	
5.	2.3	Table for literature references with correct information regarding drug substance and drug product with applicable fee shall be submitted.	
6.	3.2.S.4.1	Specifications of the drug substance from drug product manufacturer shall be submitted.	
7.	3.2.S.4.2	Analytical procedures of the drug substance from drug product manufacturer shall be submitted.	

8.	3.2.S.4.3	• Complete analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.
9.	3.2.S.5	Details and COA of the reference/working standard shall be submitted.
10.	3.2.P.2.2.1	• Details of the manufacturer of the comparator product shall be submitted.
11.	3.2.P.5.1	Justification shall be submitted for not including uniformity of dosage unit test as recommended by the USP in the specifications.
12.	3.2.P.5.2	Signed analytical procedure for the finished product shall be submitted.
13.	3.2.P.8	• Stability data sheets as per decision of Registration board with inclusion of API lot No. shall be submitted. • Justification shall be submitted for not performing uniformity of dosage units as recommended by the monograph. • Raw data sheets for dissolution and assay test at each time interval as per submitted calculation formula shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

347.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26042 dated 27-10-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 8254687634 dated 25-09-2023.
	The proposed proprietary name / brand name	**Synflex-D ER Tablets.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Bilayer Tablet Contains: Naproxen sodium (Immediate release) ……... 220mg Pseudoephedrine HCl (Extended release) …….. 120mg
	Pharmacotherapeutic Group of (API)	Naproxen Sodium: NSAIDs. Pseudoephedrine HCl: Decongestant.
	Reference to Finished product specifications	USP specifications.
	The status in reference regulatory authorities	ALEVE-D SINUS & COLD, USFDA Approved. **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	For generic drugs (me-too status)	N/A.
	Proposed Pack size	4 x 5's.
	Proposed unit price	As per DPC.

Evaluation by PEC:

Sr. No.	**Section**	**Observation**	**Reply submitted by the firm.**
1.	1.5.2	Clarification shall be submitted regarding the dosage form of applied formulation whether	Firm has submitted copy of a document from the review data of the innovator

		bi-layer tablet or otherwise, with reference to the innovator drug product.	product wherein the Review of Pharmacology and Toxicology data has mentioned that it is a bi-layer tablet containing the identical immediate release formulation found in ……..
2.	1.6.5	Valid copy of GMP certificate/DML of both the drug substance manufacturer issued by relevant authorities shall be submitted.	Firm has submitted copy of DML of manufacturer "Zhejiang Charioteer Pharmaceutical Co., Ltd., China." (# ZJ 20000308) issued by SFDA, China which is valid till 03/08/2025. Firm has also submitted a receiving dated 15-10-2020 for renewal of DML of M/s Alpha Chemicals.
3.	3.2.S.5	COA/details for the reference/working standard of naproxen used in the development studies shall be submitted.	Submitted.
4.	3.2.P.8	• Complete six-month stability data shall be submitted. • Documents for procurements of Naproxen sodium with approval from DRAP shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Submitted. Firm has submitted copy of Clearance Certificate No. E-4396062807364 dated 07-02-2023 mentioning 1000kg of Naproxen Sodium attested by Assistant Director DRAP, Karachi. Submitted.

Decision: Approved.

348.	Name, address of Applicant / Marketing Authorization Holder	**M/s High-Q Pharmaceuticals, B-64 KDA-1, Karsaz Road Karachi.**
	Name, address of Manufacturing site.	M/s High-Q Pharmaceuticals, Plot No. 224 & 225/1 Sector 23, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 24327 dated 04-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 500909733439 dated 29-08-2023.
	The proposed proprietary name / brand name	**Fortius plus Tablet**.
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated bilayer tablet contains: Rosuvastatin calcium eq. to Rosuvastatin …… 5mg Ezetimibe ……... 10mg
	Pharmacotherapeutic Group of (API)	Combinations of various Lipid Modifying Agents. (C10BA)
	Reference to Finished product specifications	Manufacturer Specifications.
	The status in reference regulatory authorities	Alzil plus 5 mg/10 mg film-coated tablets, CIMA Spain approved.
	For generic drugs (me-too status)	Rovista EZ Tablet, Getz pharma, Reg. No. 073716.
	Proposed Pack size	1 x 10's, 2 x 7', 4 x 7'.

	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer (Morepen) issued by relevant authority shall be submitted.	Firm has submitted copy of GMP certificate No. HFW-H(Drugs) 56/98 dated 01-01-2024 issued by Health and Family Welfare Department Himachal Pradesh valid for two years.
2.	3.2.S.4.1	• USP monograph and drug substance manufacturer has mentioned 98-102% assay limit for Ezetimibe while drug product manufacturer has mentioned 97-102%. Clarification shall be submitted. • Specifications for the drug substance Rosuvastatin provided by the drug product manufacturer are different in the assay limit, water content from that provided by the rug substance manufacturer. Clarification shall be submitted.	Firm has submitted revised specifications as per USP and drug substance manufacturer. However, fee required is not submitted. Firm has submitted revised specifications as per drug substance manufacturer.
3.	3.2.P.8	• Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Evidence of availability of bilayer tablet machine shall be submitted.	Submitted. Firm has submitted copy of an inspection report wherein the panel has reported the installation of double layer Rotary Compression Machine (Bi-layered) with a capacity of around 50000 tablets per hour.

Decision: Approved. Registration letter will be issued after submission of Rs. 9000/- fee for pre-registration variations as per notification vide No. S.R.O. 1324(I)/2024 dated 30-08-2024.

349.	Name, address of Applicant / Marketing Authorization Holder	**M/s High-Q Pharmaceuticals, B-64 KDA-1, Karsaz Road Karachi.**
	Name, address of Manufacturing site.	M/s High-Q Pharmaceuticals, Plot No. 224 & 225/1 Sector 23, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 24328 dated 04-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 88887783 dated 29-08-2023.
	The proposed proprietary name / brand name	**Fortius plus Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated bilayer tablet contains: Rosuvastatin calcium eq. to Rosuvastatin …… 10mg Ezetimibe ……... 10mg
	Pharmacotherapeutic Group of (API)	Combinations of various Lipid Modifying Agents. (C10BA)
	Reference to Finished product specifications	Manufacturer Specifications.

	The status in reference regulatory authorities	Alzil plus 10 mg/10 mg film-coated tablets, CIMA Spain approved.
	For generic drugs (me-too status)	Rovista EZ Tablet, Getz pharma, Reg. No. 073718.
	Proposed Pack size	1 x 10's, 2 x 7', 4 x 7'.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer (Morepen) issued by relevant authority shall be submitted.	Firm has submitted copy of GMP certificate No. HFW-H(Drugs) 56/98 dated 01-01-2024 issued by Health and Family Welfare Department Himachal Pradesh valid for two years.
2.	3.2.S.4.1	• USP monograph and drug substance manufacturer has mentioned 98-102% assay limit for Ezetimibe while drug product manufacturer has mentioned 97-102%. Clarification shall be submitted. • Specifications for the drug substance Rosuvastatin provided by the drug product manufacturer are different in the assay limit, water content from that provided by the rug substance manufacturer. Clarification shall be submitted.	Firm has submitted revised specifications as per USP and drug substance manufacturer. However, fee required is not submitted. Firm has submitted revised specifications as per drug substance manufacturer.
3.	3.2.P.8	• Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Evidence of availability of bilayer tablet machine shall be submitted.	Submitted. Firm has submitted copy of an inspection report wherein the panel has reported the installation of double layer Rotary Compression Machine (Bi-layered) with a capacity of around 50000 tablets per hour.

Decision: Approved. Registration letter will be issued after submission of Rs. 9000/- fee for pre-registration variations as per notification vide No. S.R.O. 1324(I)/2024 dated 30-08-2024.

350.	Name, address of Applicant / Marketing Authorization Holder	**M/s High-Q Pharmaceuticals, B-64 KDA-1, Karsaz Road Karachi.**
	Name, address of Manufacturing site.	M/s High-Q Pharmaceuticals, Plot No. 224 & 225/1 Sector 23, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 24329 dated 04-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 06408599631 dated 29-08-2023.
	The proposed proprietary name / brand name	**Fortius plus Tablet.**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated bilayer tablet contains: Rosuvastatin calcium eq. to Rosuvastatin …… 20mg Ezetimibe …….. 10mg
	Pharmacotherapeutic Group of (API)	Combinations of various Lipid Modifying Agents. (C10BA)
	Reference to Finished product specifications	Manufacturer Specifications.
	The status in reference regulatory authorities	Twicor 20 mg/10 mg film-coated tablets, MHRA approved.
	For generic drugs (me-too status)	Rovista EZ 20/10mg Tablet, Getz pharma, Reg. No. 073717.
	Proposed Pack size	1 x 10's, 2 x 7', 4 x 7'.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer (Morepen) issued by relevant authority shall be submitted.	Firm has submitted copy of GMP certificate No. HFW-H(Drugs) 56/98 dated 01-01-2024 issued by Health and Family Welfare Department Himachal Pradesh valid for two years.
2.	3.2.S.4.1	• USP monograph and drug substance manufacturer has mentioned 98-102% assay limit for Ezetimibe while drug product manufacturer has mentioned 97-102%. Clarification shall be submitted. • Specifications for the drug substance Rosuvastatin provided by the drug product manufacturer are different in the assay limit, water content from that provided by the rug substance manufacturer. Clarification shall be submitted.	Firm has submitted revised specifications as per USP and drug substance manufacturer. However, fee required is not submitted. Firm has submitted revised specifications as per drug substance manufacturer.
3.	3.2.P.8	• Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Evidence of availability of bilayer tablet machine shall be submitted.	Submitted. Firm has submitted copy of an inspection report wherein the panel has reported the installation of double layer Rotary Compression Machine (Bi-layered) with a capacity of around 50000 tablets per hour.

Decision: Approved. Registration letter will be issued after submission of Rs. 9000/- fee for pre-registration variations as per notification vide No. S.R.O. 1324(I)/2024 dated 30-08-2024.

351.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Variant Pharmaceuticals (Pvt.) Ltd., Plot No. 5, M-2, Pharmazone, 26Km Lahore-Sharikpur Road, Sheikhupura.**
	Name, address of Manufacturing site.	M/s Variant Pharmaceuticals (Pvt.) Ltd., Plot No. 5, M-2, Pharmazone, 26Km Lahore-Sharikpur Road, Sheikhupura.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 24686 dated 10-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 170875772941 dated 27-09-2023.
	The proposed proprietary name / brand name	**V-Cobal 500mcg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sugar Coated Tablet Contains: Methylcobalamin …..……. 500mcg
	Pharmacotherapeutic Group of (API)	Vitamin B12 (cyanocobalamin and analogues) ATC Code B03BA05.
	Reference to Finished product specifications	JP specifications.
	The status in reference regulatory authorities	PMDA Japan, Approved.
	For generic drugs (me-too status)	Methycobal Tablet, Hilton Pharma, Reg. No.010314.
	Proposed Pack size	100's.
	Proposed unit price	As per Rule.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply submitted by the firm.
1.	1.3.4	Valid copy of GMP certificate of the applicant shall be submitted.	
2.	3.2.S.4.1	Specifications of the drug substance by the finished product manufacturer shall be submitted.	
3.	3.2.S.4.2	Analytical procedures for the dug substance by the finished product manufacturer shall be submitted.	
4.	3.2.S.4.3	Verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
5.	3.2.P.1	Qualitative composition of the applied formulation is different from the innovator product. Clarification shall be submitted.	
6.	3.2.P.2.2.1	Calculation of F2 for CDP shall be submitted.	
7.	3.2.P.5.1	• Justification shall be submitted for not mentioning uniformity of dosage units test as recommended by the JP monograph. • Justification shall be submitted for disintegration test limit of NMT 60 minutes.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

352.	**Name, address of Applicant / Marketing Authorization Holder**	**Horizon Healthcare (Pvt.) Ltd., Plot # 33, Sunder Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	Horizon Healthcare (Pvt.) Ltd., Plot # 33, Sunder Industrial Estate, Lahore.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25797 dated 25-10-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 361297399145 dated 12-10-2023.
	The proposed proprietary name / brand name	**Rupazone 10mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Rupatadine fumarate equivalent to Rupatadine … 10mg
	Pharmacotherapeutic Group of (API)	Other antihistamines for systemic use. ATC code R06AX28.
	Reference to Finished product specifications	Innovator specifications.
	The status in reference regulatory authorities	Rupatadine 10mg MHRA Approved.
	For generic drugs (me-too status)	N/A.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply submitted by the firm.
1.	1.3	Valid copy of DML and GMP certificate of the applicant shall be submitted instead of M/s Horizon, Taxila.	Firm has submitted both valid GMP certificate and DML.
2.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	10's and 30's.
3.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. 24105310 dated 11-10-2024 issued by Food & Drugs Control Administration, Gujrat State, India valid till 28-02-2025.
4.	3.2.S.4.1	Specifications for assay test provided by drug product manufacturer are different from that of the drug substance manufacturer. Clarification shall be submitted.	Firm has submitted that raw material is available in BP and BP assay limits are more stringent than in house method. So, we adopted BP limits.
5.	3.2.P.2.2.1	Pictorial evidence of the innovator product with visible details of the batch number, manufacturer etc. shall be submitted.	Firm has submitted picture of Rupafin 10mg Tablets, B. No. 295786, Mfg. date 09-2021.
6.	3.2.P.8	Six-month time point stability data shall be submitted.	Submitted.

Decision: Approved.

353.	**Name, address of Applicant / Marketing Authorization Holder**	**Horizon Healthcare (Pvt.) Ltd., Plot # 33, Sunder Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	Horizon Healthcare (Pvt.) Ltd., Plot # 33, Sunder Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27667 dated 27-11-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 3319553383 dated 14-11-2023.
	The proposed proprietary name / brand name	**Rupazone 1mg/ml Oral Solution.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of oral solution contains: Rupatadine fumarate equivalent to Rupatadine.… 1mg
	Pharmacotherapeutic Group of (API)	Other antihistamines for systemic use. ATC code R06AX28.
	Reference to Finished product specifications	Innovator specifications.
	The status in reference regulatory authorities	Rupatadine 1mg/ml Oral Solution, MHRA Approved.
	For generic drugs (me-too status)	N/A.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply submitted by the firm.
1.	1.3	Valid copy of DML and GMP certificate of the applicant shall be submitted.	Firm has submitted both valid GMP certificate and DML.
2.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	30ml, 60ml and 120ml.
3.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. 24105310 dated 11-10-2024 issued by Food & Drugs Control Administration, Gujrat State, India valid till 28-02-2025.
4.	3.2.S.4.1	Specifications for assay test provided by drug product manufacturer are different from that of the drug substance manufacturer. Clarification shall be submitted.	Firm has submitted that raw material is available in BP and BP assay limits are more stringent than in house method. So, we adopted BP limits.
5.	3.2.P.2.2.1	Pictorial evidence of the innovator product with visible details of the batch number, manufacturer etc. shall be submitted.	Firm has submitted picture of Rupafin 1mg/ml oral solution, B. No. 23037160, Mfg. date 03-2023.
6.	3.2.P.8	Six-month time point stability data shall be submitted.	Submitted.

Decision: Approved.

354.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.**
	Name, address of Manufacturing site.	Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 24508 dated 06-10-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 64329003036 dated 05-09-2023.
	The proposed proprietary name / brand name	**Caberin 0.25mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Cabergoline …… 0.25mg
	Pharmacotherapeutic Group of (API)	Dopamine receptor agonists. ATC code G02CB03.
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Cabasal 0.25mg, 1mg Tablets, PMDA Japan Approved.
	For generic drugs (me-too status)	N/A.
	Proposed Pack size	1 x 10's, 10 x 10's (As per SRO)
	Proposed unit price	As per SRO

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant authority shall be submitted.	Copy of GMP certificate No. 6094082 dated 28-06-2023 issued by Food & Drugs Administration, Maharashtra State is submitted by the firm. Valid till 27-06-2025.
2.	2.3	Table for literature references shall be submitted.	Submitted.
3.	3.2.S.4.2	Analytical procedures of the drug substance by the drug product manufacturer are that of USP while the drug substance manufacturer has provided that of Ph.Eur. Clarification shall be submitted.	Firm has submitted that USP contains both the analytical procedures for drug substance and drug product, to make the product uniform we have used USP specifications for both drug substance and drug product. They further stated that all the tests that are mentioned in Ph. Eur. are included in the USP.
4.	3.2.P.2.2.1	Pictorial evidence of the innovator product with visible details of batch number, manufacturing date etc. shall be submitted.	Firm has submitted details of the innovator product.
5.	3.2.P.8.3	• Stability data sheets as per decision of 293rd meeting of Registration Board with inclusion of API lot number shall be submitted. • Content uniformity test is not performed as recommended by the USP monograph for the applied formulation. Clarify.	Submitted. Firm has submitted that they performed content uniformity during the testing of drug product but the parameter was not added in the specifications. Now they have

		submitted revised COAs of the finished product with inclusion of results for content uniformity test.
Decision: Approved.		
355.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.**
	Name, address of Manufacturing site.	Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 24509 dated 06-10-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 3127065717 dated 05-09-2023.
	The proposed proprietary name / brand name	**Caberin 0.5mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Cabergoline …… 0.5mg
	Pharmacotherapeutic Group of (API)	Dopamine receptor agonists. ATC code G02CB03.
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Dostinex 0.5mg Tablet **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	For generic drugs (me-too status)	N/A.
	Proposed Pack size	1 x 10's, 10 x 10's (As per SRO)
	Proposed unit price	As per SRO

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant authority shall be submitted.	Copy of GMP certificate No. 6094082 dated 28-06-2023 issued by Food & Drugs Administration, Maharashtra State is submitted by the firm. Valid till 27-06-2025.
2.	2.3	Table for literature references shall be submitted.	Submitted.
3.	3.2.S.4.2	Analytical procedures of the drug substance by the drug product manufacturer are that of USP while the drug substance manufacturer has provided that of Ph.Eur. Clarification shall be submitted.	Firm has submitted that USP contains both the analytical procedures for drug substance and drug product, to make the product uniform we have used USP specifications for both drug substance and drug product. They further stated that all the tests that are mentioned in Ph. Eur. are included in the USP.

4.	3.2.P.8.3	• Stability data sheets as per decision of 293rd meeting of Registration Board with inclusion of API lot number shall be submitted. • Content uniformity test is not performed as recommended by the USP monograph for the applied formulation. Clarify.	Submitted. Firm has submitted that they performed content uniformity during the testing of drug product but the parameter was not added in the specifications. Now they have submitted revised COAs of the finished product with inclusion of results for content uniformity test.

Decision: Approved.

356.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.**
	Name, address of Manufacturing site.	Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 26037 dated 27-10-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 8163931476 dated 03-10-2023.
	The proposed proprietary name / brand name	**Dexketo 12.5mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dexketoprofen Trometamol eq. to Dexketoprofen…… 12.5mg.
	Pharmacotherapeutic Group of (API)	Anti-inflammatory and Anti Rheumatic Products, Non-Steroids. ATC code M01AE17.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Dexketoprofen Normon 12.5 mg film-coated tablets EFG, CIMA Spain approved.
	For generic drugs (me-too status)	N/A.
	Proposed Pack size	10's, 20's, and 30's As per S.R.O.
	Proposed unit price	As per SRO

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate valid for five years till 13-11-2027.
2.	3.2.S.4.1	Specification provided by the drug product manufacturer has no R-enantiomeric content and Tromethamine content.	Firm has submitted that they didn't perform R-enantiomeric content and Tromethamine content in the testing of Drug substance, later

		Clarification shall be submitted.	we have performed these tests and also added them in the specifications. They also submitted revised specifications and COA with updated results of the said tests.
3.	3.2.S.4.4	COA of the drug substance from drug substance manufacturer with same batch number shall be submitted.	Submitted.
4.	3.2.P.8	• Stability data sheets as per decision of registration Board with inclusion of API lot number shall be submitted.	Submitted with inclusion of API lot No. DKT-P/200016.
		• Justification shall be submitted for using UV method for assay test instead of HPLC method which is more reliable.	Firm has submitted that during the analytical method development stage, they conducted the assay using both the UV spectrophotometric method and HPLC method. The results from both the procedures showed no differences. Therefore, we selected the UV test method as the final method. Additionally, all required analytical method validation parameters were performed, confirming the UV method used is accurate, specific & precise.

Decision: Approved. Registration letter will be issued upon submission of following:

- **Rs. 9000/- fee for pre-registration variations as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.**
- **Revised analytical procedure for assay test of drug product based upon HPLC method along with commitment to follow HPLC method of analysis for the assay test of commercial batches.**

357.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.**
	Name, address of Manufacturing site.	Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 26038 dated 27-10-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 83188607 dated 04-10-2023.
	The proposed proprietary name / brand name	**Dexketo 25mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Dexketoprofen Trometamol eq. to Dexketoprofen…… 25mg.
	Pharmacotherapeutic Group of (API)	Anti-inflammatory and Anti Rheumatic Products, Non-Steroids. ATC code M01AE17.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	HPRA, Ireland approved.
	For generic drugs (me-too status)	Dexket Tablets 25mg, Genix Pharma, Reg. No. 098909.
	Proposed Pack size	10's, 20's, and 30's As per S.R.O.

	Proposed unit price	As per SRO

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate valid for five years till 13-11-2027.
2.	3.2.S.4.1	Specification provided by the drug product manufacturer has no R-enantiomeric content and Tromethamine content. Clarification shall be submitted.	Firm has submitted that they didn't perform R-enantiomeric content and Tromethamine content in the testing of Drug substance, later we have performed these tests and also added them in the specifications. They also submitted revised specifications and COA with updated results of the said tests.
3.	3.2.S.4.4	COA of the drug substance from drug substance manufacturer with same batch number shall be submitted.	Submitted.
4.	3.2.P.8	• Stability data sheets as per decision of registration Board with inclusion of API lot number shall be submitted. • Justification shall be submitted for using UV method for assay test instead of HPLC method which is more reliable.	Submitted with inclusion of API lot No. DKT-P/200016. Firm has submitted that during the analytical method development stage, they conducted the assay using both the UV spectrophotometric method and HPLC method. The results from both the procedures showed no differences. Therefore, we selected the UV test method as the final method. Additionally, all required analytical method validation parameters were performed, confirming the UV method used is accurate, specific & precise.

Decision: Approved. Registration letter will be issued upon submission of following:

- **Rs. 9000/- fee for pre-registration variations as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.**
- **Revised analytical procedure for assay test of drug product based upon HPLC method along with commitment to follow HPLC method of analysis for the assay test of commercial batches.**

358.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.**
	Name, address of Manufacturing site.	Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 25554 dated 23-10-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 281923917002 dated 04-10-2023.

	The proposed proprietary name / brand name	**Dexketo 25mg Granules for oral solution.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet contains: Dexketoprofen Trometamol eq. to Dexketoprofen…… 25mg.
	Pharmacotherapeutic Group of (API)	Anti-inflammatory and Anti Rheumatic Products, Non-Steroids. ATC code M01AE17.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Dexketoprofen NORMON 25 mg granules for oral solution EFG, CIMA Spain approved.
	For generic drugs (me-too status)	N/A.
	Proposed Pack size	10, 20, and 30 Sachet per pack (As per S.R.O.)
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate valid for five years till 13-11-2027.
2.	3.2.S.4.1	Specification provided by the drug product manufacturer has no R-enantiomeric content and Tromethamine content. Clarification shall be submitted.	Firm has submitted that they didn't perform R-enantiomeric content and Tromethamine content in the testing of Drug substance, later we have performed these tests and also added them in the specifications. They also submitted revised specifications and COA with updated results of the said tests.
3.	3.2.S.4.4	COA of the drug substance from drug substance manufacturer with same batch number shall be submitted.	Submitted.
4.	3.2.P.8	• Stability data sheets as per decision of registration Board with inclusion of API lot number shall be submitted. • Justification shall be submitted for using UV method for assay test instead of HPLC method which is more reliable.	Submitted with inclusion of API lot No. DKT-P/200016. Firm has submitted that during the analytical method development stage, they conducted the assay using both the UV spectrophotometric method and HPLC method. The results from both the procedures showed no differences. Therefore, we selected the UV test method as the final method. Additionally, all required analytical method validation parameters were performed, confirming the UV method used is accurate, specific & precise.

Decision: Approved. Registration letter will be issued upon submission of following:

- **Rs. 9000/- fee for pre-registration variations as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.**

- **Revised analytical procedure for assay test of drug product based upon HPLC method along with commitment to follow HPLC method of analysis for the assay test of commercial batches.**

359.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.**
	Name, address of Manufacturing site.	Kaizen Pharmaceuticals (Pvt.) Ltd., Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25553 dated 23-10-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 328149207380 dated 03-10-2023.
	The proposed proprietary name / brand name	**Dexketo 12.5mg/gram Gel.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gram contains: Dexketoprofen Trometamol eq. to Dexketoprofen…… 12.5mg.
	Pharmacotherapeutic Group of (API)	Anti-inflammatory and Anti Rheumatic Products, Non-Steroids. ATC code M01AE17.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Enangel 12.5 mg/g gel, Menarini Laboratories, S.A, CIMA Spain approved.
	For generic drugs (me-too status)	N/A.
	Proposed Pack size	60 gram Tube (As per S.R.O.)
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.5.2	Justify the label claim with respect to the reference product.	
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	
3.	3.2.S.4.1	Specification provided by the drug product manufacturer has no R-enantiomeric content and Tromethamine content. Clarification shall be submitted.	
4.	3.2.S.4.4	COA of the drug substance from drug substance manufacturer with same batch number shall be submitted.	
5.	3.2.P.8	• Stability data sheets as per decision of registration Board with inclusion of API lot number shall be submitted. • Justification shall be submitted for using UV method for assay test instead of HPLC method which is more reliable. • Justify the batch size of the trial batches as only 10 tubes are manufactured in each trial batch.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

360.	**Name, address of Applicant / Marketing Authorization Holder**	**Horizon Healthcare (Pvt.) Ltd., 35-A, Punjab Small Industrial Estate, Taxila.**
	Name, address of Manufacturing site.	Horizon Healthcare (Pvt.) Ltd., 35-A, Punjab Small Industrial Estate, Taxila.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25895 dated 28-10-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 63489499878 dated 16-10-2023.
	The proposed proprietary name / brand name	**Zoanz XR Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated extended release tablet Contains: Torsemide …..… 20mg
	Pharmacotherapeutic Group of (API)	High-ceiling diuretics. ATC code c03ca04.
	Reference to Finished product specifications	Innovator specifications.
	The status in reference regulatory authorities	SOAANZ (Torsemide) tablets,, USFDA Approved.
	For generic drugs (me-too status)	N/A.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply submitted by the firm.
1.	1.3.5	Evidence of manufacturing facility/Section approval from licensing Division shall be submitted.	Firm has submitted copy of letter No. F. 1-17/2012-Lic (Vol-III) dated 08-11-2023 mentioning Tablet (General) section
2.	1.5.2	Reference shall be submitted for the label claim as extended release tablet for the applied formulation.	Firm has submitted that reference for their product is Soaanz tablets approved by USFDA and its pharmacodynamics shows it as extended release product on FDA label. Furthermore, on product's own website "Soaanz.com" it is mentioned as slow release product. *Soaanz tablet in 20mg and 60 mg strength is discontinued in USFDA and the reason is unknown.*
3.	1.5.4	Proposed pack size for the applied formulation shall be submitted.	Pack size of 30's tablets in Alu-Alu blister with leaflet finally packed in unit carton.
4.	3.2.P.1	• Qualitative composition of the applied formulation is different from the innovator product. Clarification shall be submitted.	Firm has submitted that Qualitative composition of the applied formulation is similar to innovator, the only difference is Methocel K15MCR. Firm has submitted that there is only difference of excipient namely Methocel

		• Justification shall be submitted for the role of Methocel K100 excipient in applied composition, with reference to the innovator drug product composition.	K 15MCR for core tablet formulation, that is used just for purpose to enhance its ability of slow release and to meet the target goal of slow release as its designated time to achieve good bioavailability.
5.	3.2.P.8	Six-month time point stability data shall be submitted.	Submitted.

Dissolution Acceptance Criteria: ACCEPTABLE

The Applicant's originally proposed dissolution acceptance criteria were not appropriately selected. However, the revised (in response to the FDA's recommendation) dissolution acceptance criteria are based on the dissolution data from the clinical and registration batches and are adequate to ensure

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: 4525310

QUALITY ASSESSMENT

quality control testing of the proposed product at the time of release and during stability. The following dissolution acceptance criteria are acceptable for Torsemide Tablets; 20 mg, 60 mg:

1 Hour: NMT (b)(4)%; 3 Hours: NMT (b)(4)%; 6 Hours: NLT (b)(4)% and 10 Hours: NLT (b)(4)% (Q).

Decision: Deferred for the following;

- **Clarification regarding the reason of "Discontinued" status of applied formulation in US FDA**
- **Regulatory status of applied formulation in other reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**

361.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129 Sunder Industrial Estate, Raiwind Road, Lahore.**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26545 dated 03-11-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 273935418 dated 20-10-2023.
	The proposed proprietary name / brand name	**Prucalopride Succinate 1mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Prucalopride Succinate Eq. to Prucalopride …… 1mg.
	Pharmacotherapeutic Group of (API)	Other drugs for constipation. ATC Code A06AX05.

	Reference to Finished product specifications	In-House Specifications.
	The status in reference regulatory authorities	MOTEGRITY (Prucalopride) 1mg & 2mg tablets, USFDA approved.
	For generic drugs (me-too status)	Not provided.
	Proposed Pack size	1 x 10's, 2 x 10's, 4 x 7's, 3 x 10's, 10 x 10's.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
5.	1.5.8	Provide evidence of me too product with brand name, registration number and name of the firm or otherwise submit fee for new molecule.	Pru-Cic Tablet 1mg, M/s Searle Company Limited, Reg. No. 116035.
6.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant/concerned authority shall be submitted.	Not submitted. Instead of drug substance manufacturer, they provided GMP certificate of the applicant.
7.	3.2.P.2.2.1	Pictorial evidence of comparator product against which PE and CDP studies are performed with clear details of the batch number, manufacturing date and name of manufacturer shall be submitted.	Firm has submitted details and picture of the product against which the PE and CDP studies are performed and details are as follows; Prrucalopride Auxinio 1mg Filmtabletten, B. No. PZN-16798945, Market authorization No. PL No. 47848/0023 approved by MHRA.
8.	3.2.P.5.1	Justify the limit of dissolution test i.e. NLT 75% (Q) in 30 minutes with respect to that of the innovator product i.e. in 20 minutes.	Firm has submitted that they are just taking general limits of dissolution test i.e. NLT 75% (Q) in 30 minutes with respect to that of the innovator product.
9.	3.2.P.8	• Six-month time point stability data shall be submitted. • Justification shall be submitted for not performing content uniformity test. • Justification shall be submitted for using wavelength of 215nm in the submitted raw data sheets, while analytical procedures have mentioned 232nm.	Submitted. Firm has submitted that they are performing the same and also submitted data for content uniformity test. Firm has submitted that it was a typographic error in the analytical method and they actually used 215nm. They also submitted revised analytical method with wavelength of 215nm.

Decision: Approved. Registration letter will be issued after submission of Rs. 9000/- fee for pre-registration variations as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.

- **Firm will also submit next time point data of dissolution studies with specification of dissolution test i.e. NLT 75% (Q) in 20 minutes as per the innovator product.**

362.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129 Sunder Industrial Estate, Raiwind Road, Lahore.**

	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26546 dated 03-11-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 8350024043 dated 20-10-2023.
	The proposed proprietary name / brand name	**Prucalopride Succinate 2mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Prucalopride Succinate Eq. to Prucalopride …… 2mg.
	Pharmacotherapeutic Group of (API)	Other drugs for constipation. ATC Code A06AX05.
	Reference to Finished product specifications	In-House Specifications.
	The status in reference regulatory authorities	MOTEGRITY (Prucalopride) 1mg & 2mg tablets, USFDA approved.
	For generic drugs (me-too status)	Not provided.
	Proposed Pack size	1 x 10's, 2 x 10's, 4 x 7's, 3 x 10's, 10 x 10's.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.5.8	Provide evidence of me too product with brand name, registration number and name of the firm or otherwise submit fee for new molecule.	Pru-Cic Tablet 2mg, M/s Searle Company Limited, Reg. No. 116036.
2.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant/concerned authority shall be submitted.	Not submitted. Instead of drug substance manufacturer, they provided GMP certificate of the applicant.
3.	3.2.P.2.2.1	Pictorial evidence of comparator product against which PE and CDP studies are performed with clear details of the batch number, manufacturing date and name of manufacturer shall be submitted.	Firm has submitted details and picture of the product against which the PE and CDP studies are performed and details are as follows; Prrucalopride Auxinio 2mg Filmtabletten, B. No. PZN-16798974, Market authorization No. PL No. 47848/0024 approved by MHRA.
4.	3.2.P.5.1	Justify the limit of dissolution test i.e. NLT 75% (Q) in 30 minutes with respect to that of the innovator product i.e. in 20 minutes.	Firm has submitted that they are just taking general limits of dissolution test i.e. NLT 75% (Q) in 30 minutes with respect to that of the innovator product.
5.	3.2.P.8	• Six-month time point stability data shall be submitted.	Submitted.

	• Justification shall be submitted for not performing content uniformity test. • Justification shall be submitted for using wavelength of 215nm in the submitted raw data sheets, while analytical procedures have mentioned 232nm.	Firm has submitted that they are performing the same and also submitted data for content uniformity test. Firm has submitted that it was a typographic error in the analytical method and they actually used 215nm. They also submitted revised analytical method with wavelength of 215nm.

Decision: Approved. Registration letter will be issued after submission of Rs. 9000/- fee for pre-registration variations as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.

- **Firm will also submit next time point data of dissolution studies with specification of dissolution test i.e. NLT 75% (Q) in 20 minutes as per the innovator product.**

363.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nabiqasim Industries Private Limited, 17/24, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s Nabiqasim Industries (Pvt.) Ltd., 17/24, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27475 dated 23-11-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 211432515465 dated 24-10-2023.
	The proposed proprietary name / brand name	**Prucal Tablet 2mg.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Prucalopride Succinate Eq. to Prucalopride …… 2mg.
	Pharmacotherapeutic Group of (API)	Other drugs for constipation. ATC Code A06AX05.
	Reference to Finished product specifications	Innovator Specifications.
	The status in reference regulatory authorities	MOTEGRITY (Prucalopride) 1mg & 2mg tablets, USFDA approved.
	For generic drugs (me-too status)	Prucic 2mg tablets, M/s Searle Company Limited, Reg. No. 116036.
	Proposed Pack size	10's, 20's,30's .
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant/concerned authority shall be submitted.	Firm has submitted copy of GMP certificate No. E-2242912/DD/DCA/VSP/2023 dated 01-12-2023 issued by DCA, Andhra Pradesh dated 01-12-2023 valid for one year.
2.	3.2.P.8	• Six-month time point stability data shall be submitted. • Justification shall be submitted for not performing content uniformity test.	Submitted. Firm has submitted that they performed content uniformity test and now they also submitted the raw data sheets for the same.

Decision: Approved.		
364.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nabiqasim Industries Private Limited, 17/24, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s Nabiqasim Industries (Pvt.) Ltd., 17/24, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 27474 dated 23-11-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 71102156 dated 24-10-2023.
	The proposed proprietary name / brand name	**Prucal Tablet 1mg.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Prucalopride Succinate Eq. to Prucalopride …… 1mg.
	Pharmacotherapeutic Group of (API)	Other drugs for constipation. ATC Code A06AX05.
	Reference to Finished product specifications	Innovator Specifications.
	The status in reference regulatory authorities	MOTEGRITY (Prucalopride) 1mg & 2mg tablets, USFDA approved.
	For generic drugs (me-too status)	Prucic 1mg tablets, M/s Searle Company Limited, Reg. No. 116035.
	Proposed Pack size	10's, 20's,30's .
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer issued by relevant/concerned authority shall be submitted.	Firm has submitted copy of GMP certificate No. E-2242912/DD/DCA/VSP/2023 dated 01-12-2023 issued by DCA, Andhra Pradesh dated 01-12-2023 valid for one year.
2.	3.2.P.8	• Six-month time point stability data shall be submitted. • Justification shall be submitted for not performing content uniformity test.	Submitted. Firm has submitted that they performed content uniformity test and now they also submitted the raw data sheets for the same.

Decision: Approved.		
365.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Linta Pharmaceuticals (Pvt.) Ltd., Plot No. 3, Street No. S-5, National Industrial Zone, Rawat.**
	Name, address of Manufacturing site.	M/s Linta Pharmaceuticals (Pvt.) Ltd., Plot No. 3, Street No. S-5, National Industrial Zone, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26044 dated 27-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 0383775970 dated 23-08-2023.

	The proposed proprietary name / brand name	**Lamegin 25mg tablets.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains; Lamotrigine 25mg
	Pharmacotherapeutic Group of (API)	Other antiepileptic's.
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Lamictal 25mg tablets, USFDA approved.
	For generic drugs (me-too status)	Lamictal 25mg tablets, M/s GSK Pakistan, Reg. No. 014918.
	Proposed Pack size	30's in one carton .
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.5	Valid copy of GMP certificate of the applicant shall be submitted.	Firm has submitted copy of GMP certificate No. 3-42/2019- Addl. Dir. (QA&LT-I)-20 dated 13-03-2024 issued on the basis of inspection conducted on 21-12-2023.
2.	3.2.S.4.1	Specifications of the drug substance from drug product manufacturer shall be submitted.	Submitted.
3.	3.2.S.4.2	Analytical procedures of the drug substance from drug product manufacturer shall be submitted.	Submitted.
4.	3.2.P.5.2	Signed analytical procedures for the finished product shall be submitted.	Submitted.
5.	3.2.P.8	Documents for procurements of API with approval from DRAP shall be submitted.	Firm has submitted copy of clearance certificate No. E-3974524808274 dated 11-01-2023 mentioning 10kg of Lamotrigine USP attested by Assistant Director DRAP, Islamabad.

Decision: Approved.

366.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Linta Pharmaceuticals (Pvt.) Ltd., Plot No. 3, Street No. S-5, National Industrial Zone, Rawat.**
	Name, address of Manufacturing site.	M/s Linta Pharmaceuticals (Pvt.) Ltd., Plot No. 3, Street No. S-5, National Industrial Zone, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26045 dated 27-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 80318023651 dated 23-08-2023.
	The proposed proprietary name / brand name	**Lamegin 100mg tablets.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains; Lamotrigine 100mg

	Pharmacotherapeutic Group of (API)	Other antiepileptic's.
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Lamictal 100mg tablets, USFDA approved.
	For generic drugs (me-too status)	Lamictal 100mg tablets, M/s GSK Pakistan, Reg. No. 014921.
	Proposed Pack size	30's in one carton .
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.5	Valid copy of GMP certificate of the applicant shall be submitted.	Firm has submitted copy of GMP certificate No. 3-42/2019- Addl. Dir. (QA&LT-I)-20 dated 13-03-2024 issued on the basis of inspection conducted on 21-12-2023.
2.	3.2.S.4.1	Specifications of the drug substance from drug product manufacturer shall be submitted.	Submitted.
3.	3.2.S.4.2	Analytical procedures of the drug substance from drug product manufacturer shall be submitted.	Submitted.
4.	3.2.P.5.2	Signed analytical procedures for the finished product shall be submitted.	Submitted.
5.	3.2.P.8	Documents for procurements of API with approval from DRAP shall be submitted.	Firm has submitted copy of clearance certificate No. E-3974524808274 dated 11-01-2023 mentioning 10kg of Lamotrigine USP attested by Assistant Director DRAP, Islamabad.

Decision: Approved.

Case 02: Registration applications Locally manufactured (Human) drugs deferred cases on Form 5F.

367.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Rasco Pharma, Plot No. 27, Holiday Park, Near Ali Raza Abad, 5.5 Km, Raiwind Road, Lahore.**
	Name, address of Manufacturing site.	M/s Rasco Pharma, Plot No. 27, Holiday Park, Near Ali Raza Abad, 5.5 Km, Raiwind Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 16616 dated 04-07-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 63632961966 dated 02-06-2023.
	The proposed proprietary name / brand name	**Docso Syrup.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Doxofylline ……..…100mg

	Pharmacotherapeutic Group of (API)	Other Systemic Drugs for Obstructive Airway Diseases. R03DA11
	Reference to Finished product specifications	In-House/Manufacturer specifications.
	The status in reference regulatory authorities	Ansimar Syrup AIFA (Italy) approved.
	For generic drugs (me-too status)	Fylod 100mg/5ml Syrup, M/s Sami Pharmaceuticals, Reg. No. 092698.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per Rule.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply submitted by the firm.
1.	1.5.3	This section has mentioned Docso 400mg. Clarification shall be submitted.	
2.	1.5.10	This section has mentioned tablet dosage form. Clarification shall be submitted.	
3.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	
4.	3.2.S.4.3	Analytical method verification studies of the drug product performed by the drug product manufacturer shall be submitted.	
5.	3.2.S.4.4	Certificate of Analysis (COA) of the same batch from both the Drug Substance / API manufacturer and drug product manufacturer used in the development of trial batches shall be submitted	
6.	3.2.P.8	• Stability data sheets as per decision of Registration Board in its 293rd meeting with inclusion of API lot number shall be submitted. • Justify the concentration of sample solution in submitted raw data sheets with respect to provided analytical method in 3.2.P.5.2. As submitted raw data sheets revealed that 2mg is dissolved in 100ml and further 2ml is taken from the solution and dissolved in 100ml. While analytical method has mentioned 40mg in 100ml further 2ml of the same solution in 100ml. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	

Decision of 340th meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	**Reason for deferment**	**Reply submitted by the firm**
1.	This section has mentioned Docso 400mg. Clarification shall be submitted.	Firm has submitted that it was a typo error. The correct product name is Docso 100mg/5ml syrup.
2.	This section has mentioned tablet dosage form. Clarification shall be submitted.	Firm has submitted that it was a typo error. The correct product name is Docso 100mg/5ml syrup.
3.	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. 6115784 dated 19-10-2023 issued by FDA Maharashtra State, India valid till 18-10-2024.

		Firm has further submitted that the drug substance manufacturer has also applied for new GMP certificate and they also provided draft for reference.
4.	Analytical method verification studies of the drug product performed by the drug product manufacturer shall be submitted.	Submitted.
5.	Certificate of Analysis (COA) of the same batch from both the Drug Substance / API manufacturer and drug product manufacturer used in the development of trial batches shall be submitted	Submitted.
6.	• Stability data sheets as per decision of Registration Board in its 293rd meeting with inclusion of API lot number shall be submitted.	Stability data sheets as per decision of the Registration Board with inclusion of API lot No. DOX/22137 are submitted.
	• Justify the concentration of sample solution in submitted raw data sheets with respect to provided analytical method in 3.2.P.5.2. As submitted raw data sheets revealed that 2mg is dissolved in 100ml and further 2ml is taken from the solution and dissolved in 100ml. While analytical method has mentioned 40mg in 100ml further 2ml of the same solution in 100ml.	Firm has submitted that please note that the raw data sheets, 2ml (not 2mg) is dissolved in 100ml. then, 2ml is taken from this solution is dissolved in another 100ml. in the analytical section, 2ml of this solution is equivalent to 40mg of Doxofylline in 100ml, and further, 2ml of the same solution is diluted in 100ml. They further acknowledge that there was an oversight in the raw data sheets, as no units were written with the values. In the future, we will ensure that all values are accompanied by their respective units.
	• Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Not submitted.
	• Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Not submitted.

Decision: Approved. Registration letter will be issued after submission of next time point data with raw data sheets as per analytical method and submission of fee for correction in form.

368.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Rasco Pharma, Plot No. 27, Holiday Park, Near Ali Raza Abad, 5.5 Km, Raiwind Road, Lahore.**
	Name, address of Manufacturing site.	M/s Rasco Pharma, Plot No. 27, Holiday Park, Near Ali Raza Abad, 5.5 Km, Raiwind Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 16712 dated 05-07-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 5577130027 dated 06-04-2023.
	The proposed proprietary name / brand name	**Docso 400mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet Contains: Doxofylline ……..…400mg
	Pharmacotherapeutic Group of (API)	Other Systemic Drugs for Obstructive Airway Diseases. R03DA11

	Reference to Finished product specifications	In-House/Manufacturer specifications.
	The status in reference regulatory authorities	Doxofillina ABC 400mg Uncoated Tablet AIFA (Italy) approved.
	For generic drugs (me-too status)	Fylod Tablets 400mg, M/s Sami Pharmaceuticals, Reg. No. 092697.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per Rule.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply submitted by the firm.
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	
2.	3.2.S.4.3	Analytical method verification studies of the drug product performed by the drug product manufacturer shall be submitted.	
3.	3.2.S.4.4	Certificate of Analysis (COA) of the same batch from both the Drug Substance / API manufacturer and drug product manufacturer used in the development of trial batches shall be submitted	
4.	3.2.P.2.2	Justification shall be submitted for not performing the dissolution test in pharmaceutical equivalence studies.	
5.	3.2.P.5.2	Justify the concentration of standard solution and sample solution in the submitted analytical procedures for finished drug product as both the concentrations are completely different from each other.	
6.	3.2.P.8	• Stability data sheets as per decision of Registration Board in its 293rd meeting with inclusion of API lot number shall be submitted. • Justify the concentration of sample solution in submitted raw data sheets with respect to provided analytical method in 3.2.P.5.2. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	

Decision of 340th meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Reason for deferment	Reply submitted by the firm
1.	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. 6115784 dated 19-10-2023 issued by FDA Maharashtra State, India valid till 18-10-2024. Firm has further submitted that the drug substance manufacturer has also applied for new GMP certificate and they also provided draft for reference.
2.	Analytical method verification studies of the drug product performed by the drug product manufacturer shall be submitted.	Submitted.
3.	Certificate of Analysis (COA) of the same batch from both the Drug Substance / API	Submitted.

	manufacturer and drug product manufacturer used in the development of trial batches shall be submitted	
4.	Justification shall be submitted for not performing the dissolution test in pharmaceutical equivalence studies.	Firm has submitted that the dissolution test is performed for pharmaceutical equivalence. The pharmaceutical equivalence is assessed against the Fylod 400mg tablets with batch number 005H from Sami pharma. They submitted COA. However, results of the comparator product are not provided.
5.	Justify the concentration of standard solution and sample solution in the submitted analytical procedures for finished drug product as both the concentrations are completely different from each other.	Firm has submitted that there was a writing mistake in the analytical procedure. The actual details of the analytical methods are as follows; **Standard stock solution:** • Weigh 40mg of Doxofylline WS. • Transfer to a 100ml volumetric flask. • Add diluent and shake to dissolve. **Standard Solution:** • Take 2ml of the stock solution. • Transfer to a 50ml volumetric flask. • Dilute to volume with diluent, shaking well. **Sample Solution:** • Weight the compressed material equivalent 400mg of Doxofylline. • Transfer to a 250ml volumetric flask. • Transfer 1ml of the stock solution to a 100ml volumetric flask.
6.	• Stability data sheets as per decision of Registration Board in its 293rd meeting with inclusion of API lot number shall be submitted. • Justify the concentration of sample solution in submitted raw data sheets with respect to provided analytical method in 3.2.P.5.2. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Stability data sheets as per decision of the Registration Board with inclusion of API lot No. DOX/22137 are submitted. As submitted in query No. 5. Not submitted. Not submitted.

Decision: Approved. Registration letter will be issued after submission of next time point data with raw data sheets as per analytical method and submission of fee for corrections.

369.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.**
	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 21412 dated 30-08-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 819116344469 dated 09-08-2023.
	The proposed proprietary name / brand name	**Finone 10mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Finerenone …… 10mg
	Pharmacotherapeutic Group of (API)	Mineralocorticoid Receptor (MR) Antagonist (C03D) Aldosterone Antagonists and other Potassium-Sparing Agents.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Kerendia 10mg & 20mg tablets by Bayer Healthcare, USFDA Approved.
	For generic drugs (me-too status)	N/A.
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	3.2.S.4.1	Specifications of the drug substance from drug substance manufacturer shall be submitted.	
2.	3.2.S.4.2	Analytical procedures of the drug substance from drug substance manufacturer shall be submitted.	
3.	3.2.S.4.2	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
4.	3.2.P.1	This section has mentioned 5% of overages. Scientific justification of overages shall be submitted.	
5.	3.2.P.2.2.1	Pictorial evidence of the innovator product, against which PE & CDP studies are performed, with visible information of batch number, manufacturing date etc. shall be submitted.	
6.	3.2.P.5.1	Justification shall be submitted for assay limit of 90% - 110% while the innovator product has shelf life assay limit of 95% - 105%.	
7.	3.2.P.5.2	Justification shall be submitted for difference in assay test parameters i.e. injection volume (10µl), Detector wavelength (225nm) & Column (C18, 4.6 x 250mm 5 micron or equivalent) to that of the innovator product i.e. injection volume (5µl), Detector wavelength (251nm) & Column (Steel, length 150 mm, inner diameter 3.0 mm).	

Decision of 340th meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Observation	Reply by the firm
1.	Specifications of the drug substance from drug substance manufacturer shall be submitted.	Submitted.
2.	Analytical procedures of the drug substance from drug substance manufacturer shall be submitted.	Submitted.
3.	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Firm has submitted analytical method verification studies of the drug substance performed by the finished product manufacturer.
4.	This section has mentioned 5% of overages. Scientific justification of overages shall be submitted.	Firm has submitted that Finerenone is BCS class II drug. In the batch manufacturing process (Confirmatory trial), overage of 5% API was added for potential losses during Micronization and screening. This adjustment was necessary to ensure that the final quantity of API in each tablet was precisely 10mg and 20mg, as per the label claim. Without this overage, shortfall in the API recovery observed during trial stage, compromising the product's efficacy and compliance with the batch manufacturing record. Stability studies of the final product have confirmed that it meets all physical and chemical quality targets, demonstrating the effectiveness and necessity of 5% overage in maintaining consistent and accurate dosing after Micronization losses.
5.	Pictorial evidence of the innovator product, against which PE & CDP studies are performed, with visible information of batch number, manufacturing date etc. shall be submitted.	Firm has submitted picture of the innovator product i.e. Kerendia 10mg Tablets, B. No. 757025, Mfg. date of 08-2024 manufactured by Bayer Zydus Pharma.
6.	Justification shall be submitted for assay limit of 90% - 110% while the innovator product has shelf life assay limit of 95% - 105%.	Firm has revised their assay specifications limits to 95% - 105% with submission of 9000/- as pre-registration variation vide challan No. 2841936996 dated 30-10-2024.
7.	Justification shall be submitted for difference in assay test parameters i.e. injection volume (10µl), Detector wavelength (225nm) & Column (C18, 4.6 x 250mm 5 micron or equivalent) to that of the innovator product i.e. injection volume (5µl), Detector wavelength (251nm) & Column (Steel, length 150 mm, inner diameter 3.0 mm).	Firm has submitted that during literature review, due to restricted access to the analytical testing conditions of the innovator's product, we adopted the parameters specified in the product standard operating procedure (SOP). Additionally, we have conducted a comprehensive analytical method validation, demonstrating that the method is specific, robust and suitable for its intended purpose. Product validation ensures this testing method is scientifically sound and both applied and reference product are pharmaceutically equivalent.
Decision: Approved. Registration Board further directed the firm to not use any overage in the commercial batches of the formulation.		
370.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.**

	Name, address of Manufacturing site.	M/s Genix Pharma (Pvt.) Ltd., Plot No. 44-45-B, Korangi Creek Road, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 19980 dated 11-08-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 375803527777 dated 02-08-2023.
	The proposed proprietary name / brand name	**Imeglin 500mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Imeglimin Hydrochloride …… 500mg
	Pharmacotherapeutic Group of (API)	Other Anti-diabetic. ATC code; A10BX15.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Twmeeg tablets 500mg, PMDA Japan approved.
	For generic drugs (me-too status)	N/A.
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	
2.	3.2.S.4.1	Specifications of the drug substance from drug product manufacturer shall be submitted.	
3.	3.2.S.4.2	Analytical procedures of the drug substance from drug product manufacturer shall be submitted.	
4.	3.2.S.4.2	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
5.	3.2.P.2.2.1	Pictorial evidence of the innovator product, against which PE & CDP studies are performed, with visible information of batch number, manufacturing date etc. shall be submitted.	
6.	3.2.P.8	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	

Decision of 340th meeting of Registration Board**:** Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Observation	Reply by the firm
1.	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Firm has submitted copy of certificate No. E-2242912/DD/DCA/VSP/2023 dated 01.12.2023 issued by Drug Control Administration Andhra Pradesh valid till 30.11.2024 is submitted.

2.	Specifications of the drug substance from drug product manufacturer shall be submitted.	Submitted.
3.	Analytical procedures of the drug substance from drug product manufacturer shall be submitted.	Submitted.
4.	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted.
5.	Pictorial evidence of the innovator product, against which PE & CDP studies are performed, with visible information of batch number, manufacturing date etc. shall be submitted.	Firm has submitted pictorial evidence of the innovator product with visible details.
6.	Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	Firm has submitted copy of Form 6 No. K-987780628765 dated 15-09-2022 mentioning 4.50 kg of Imeglimin HCl attested by Assistant Director, I&E, DRAP, Karachi.

Decision: Approved.

371.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Macter International Ltd., F-216, S.I.T.E., Karachi.**
	Name, address of Manufacturing site.	M/s Macter International Ltd., F-216, S.I.T.E., Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 7091 dated 10-03-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 081730065862 dated 30-08-2022.
	The proposed proprietary name / brand name	**Tamlomac 0.4mg Capsule.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Tamsulosin hydrochloride as modified release pellets ……..……..0.4mg
	Pharmacotherapeutic Group of (API)	Alpha-adrenoreceptor antagonists. ATC code G04CA02
	Reference to Finished product specifications	USP specifications.
	The status in reference regulatory authorities	FLOMAX® (Tamsulosin hydrochloride, USP) Capsules, USFDA approved.
	For generic drugs (me-too status)	Sintam 0.4mg Capsule, Hilton Pharma, Reg. No. 061842.
	Proposed Pack size	10's, 20's & 30's.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	**Section**	**Observation**	**Reply by the firm**

1.	1.3.5	Evidence of approval of manufacturing facility/section approval from Licensing Authority shall be submitted.
2.	1.5.6	Pharmacopoeial reference / Status of applied formulation shall be submitted.
3.	1.6.5	Valid copy of GMP certificate for the drug substance manufacturer shall be submitted.
4.	2.3	Table for literature references shall be submitted.
5.	3.2.S.4.1	Specifications of the drug substance from drug product manufacturer shall be submitted.
6.	3.2.S.4.2	Analytical procedures of the drug substances from drug product manufacturer shall be submitted.
7.	3.2.S.4.3	Verification studies of the drug substances from drug product manufacturer shall be submitted.
8.	3.2.S.4.4	COA of the drug substances i.e. with same batch number from both the drug substance and drug product manufacturer.
9.	3.2.P.8.3	• Stability data sheets as per decision of Registration Board with inclusion of API lot number, batch size etc. as per decision of 293rd meeting shall be submitted. • Documents for the procurement of API shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.

Decision of 339th meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Reason for deferment	Reply by the firm
1.	Evidence of approval of manufacturing facility/section approval from Licensing Authority shall be submitted.	Firm has submitted copy of letter No. F.2-13/95-Lic (Vol-VII) dated 26-10-2020 mentioning Capsule (General) section.
2.	Pharmacopoeial reference / Status of applied formulation shall be submitted.	USP specifications.
3.	Valid copy of GMP certificate for the drug substance manufacturer shall be submitted.	Copy of GMP certificate No. F. 3-26/2019-Addl. Dir. (QA&LT-I)-9 dated 02-02-2023 issued on the basis of inspection conducted on 13-01-2023 is submitted by the firm.
4.	Table for literature references shall be submitted.	Firm has submitted corrected table for literature references.
5.	Specifications of the drug substance from drug product manufacturer shall be submitted.	Submitted.
6.	Analytical procedures of the drug substances from drug product manufacturer shall be submitted.	Submitted.
7.	Verification studies of the drug substances from drug product manufacturer shall be submitted.	Submitted.

8.	COA of the drug substances i.e. with same batch number from both the drug substance and drug product manufacturer.	Firm has submitted COA of the drug substance with same batch number as that of the drug substance manufacturer i.e. TMS338.
9.	• Stability data sheets as per decision of Registration Board with inclusion of API lot number, batch size etc. as per decision of 293rd meeting shall be submitted. • Documents for the procurement of API shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Submitted. Firm has submitted Local purchase order from M/s Vision Pharma. Submitted.

Decision: Approved.

372.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 7697 dated 17-03-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 30810134648 dated 27-01-2023.
	The proposed proprietary name / brand name	**Thiofold 4mg/2ml Injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml ampoule contains: Thiocolchicoside …… 4mg
	Pharmacotherapeutic Group of (API)	Muscle relaxant.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	ANSM France approved.
	For generic drugs (me-too status)	Chicowin 4mg/2ml Injection, Wnsfield Pharmaceuticals, Reg. No. 093890.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	**Section**	**Observation**	**Reply by the firm**
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	
2.	1.3.4	Valid copy of DML of the applicant shall be submitted.	
3.	3.2.S.4.1	Specifications of the drug substance from drug substance manufacturer shall be submitted.	
4.	3.2.S.4.2	Analytical procedures of the drug substance from drug substance manufacturer shall be submitted.	
5.	3.2.S.4.3	Complete verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	

6.	3.2.S.4.4	Analytical record submitted has shown run time of 6 minutes and retention time of 3 minutes while analytical procedure for assay and potential impurities has mentioned approximate retention time of 15.4 minutes. Clarification shall be submitted.
7.	3.2.S.7.3	Complete real time stability data as per Zone Iva shall be submitted.
8.	3.2.P.2.2.1	• Details of the manufacturer of the product against which PE studies are performed shall be submitted. • Justification shall be submitted for not performing PE & CDP studies against the innovator product.
9.	3.2.P.3.3	Justification shall be submitted for not performing terminal sterilization of the applied formulation.
10.	3.2.P.5.2	Analytical procedures for the finished product shall be submitted.
11.		Batch No. L-01 & L-03 at 0-month time point has volume variation test out of specification. Limit is 1.8 to 2.2 while the results are 2.3ml. clarification shall be submitted.
12.	3.2.P.8.3	• Chromatograms does not reveal any wavelength. Clarification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)shall be submitted.

Decision of 339th meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	**Observation**	**Reply by the firm**
1.	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Firm has once again submitted copy of GMP certificate No. 17P/1/175/2008/1210 dated 22-01-2019 issued by Drug Controlling & Licensing Authority Uttarakhand valid for 03 years. Not valid.
2.	Valid copy of DML of the applicant shall be submitted.	Firm has once again submitted copy of DML w.e.f. 27-09-2013. They also submitted copy of receiving for renewal of DML dated 21-09-2023.
3.	Specifications of the drug substance from drug substance manufacturer shall be submitted.	Firm has submitted specifications of the drug substance from drug product manufacturer. Specifications by the drug substance manufacturer are still not provided.
4.	Analytical procedures of the drug substance from drug substance manufacturer shall be submitted.	Submitted. *However, pH limit mentioned in analytical procedures are different from that provided in the specifications.*

5.	Complete verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted. *However, the initially submitted results of system suitability, specificity, accuracy etc. are completely different from that of the newly submitted results.*
6.	Analytical record submitted has shown run time of 6 minutes and retention time of 3 minutes while analytical procedure for assay and potential impurities has mentioned approximate retention time of 15.4 minutes. Clarification shall be submitted.	Firm has submitted that test performed on API manufacturer testing specs two injections injected up to 30 minute. No extra peak found. *No such test results are submitted by the firm.*
7.	Complete real time stability data as per Zone Ivb shall be submitted.	Firm has submitted both real time and accelerated stability studies for the drug substance for three batches.
8.	• Details of the manufacturer of the product against which PE studies are performed shall be submitted. • Justification shall be submitted for not performing PE studies against the innovator product.	Muscoril Injection, B. No. JY011, Mfg. date 09-2020 manufactured by Sanofi Winthrop Industrie, France. firm has submitted PE studies against innovator product.
9.	Justification shall be submitted for not performing terminal sterilization of the applied formulation.	Firm has submitted that they perform terminal sterilization. However, in the initially submitted dossier, there was no terminal sterilization.
10.	Analytical procedures for the finished product shall be submitted.	Firm has submitted analytical procedures for the applied formulations and it has mentioned UV method for the assay test. *However, the data provided by the firm is through HPLC and they also submitted audit trial for the applied formulation.*
11.	Batch No. L-01 & L-03 at 0-month time point has volume variation test out of specification. Limit is 1.8 to 2.2 while the results are 2.3ml. clarification shall be submitted.	Firm has submitted that it was a typo error and submitted revised COAs for the applied formulations.
12.	• Chromatograms does not reveal any wavelength. Clarification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)shall be submitted.	Firm has submitted that at the time of stability not added, now in all working added. Submitted. Submitted.

Submitted.

Decision: Deferred for following;

- **Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.**
- **Specifications of the drug substance from drug substance manufacturer shall be submitted.**
- **Justification shall be submitted for provision of changed method verification results from that of the initially submitted in the dossier.**
- **Justification shall be submitted regarding method of analysis provided and raw data sheets submitted for the applied formulation as both are in contrast to each other.**

3.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 7698 dated 17-03-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 8064730870 dated 27-01-2023.
	The proposed proprietary name / brand name	**Thiofold 4mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Thiocolchicoside …… 4mg
	Pharmacotherapeutic Group of (API)	Muscle relaxant.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	ANSM France approved.
	For generic drugs (me-too status)	Wodlink 4mg tablets, Martin Dow, Reg. No. 081138.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per SRO.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	
2.	1.3.4	Valid copy of DML of the applicant shall be submitted.	
3.	3.2.S.4.1	Specifications of the drug substance from drug product manufacturer shall be submitted.	
4.	3.2.S.4.2	Analytical procedures of the drug substance from drug product manufacturer shall be submitted.	
5.	3.2.S.4.3	Complete verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	
6.	3.2.S.4.4	• Specifications provided by the drug substance manufacturer for drug substance has mentioned assay limit of 98.0% - 102% while COA provided by the drug substance manufacturer for drug substance has mentioned NLT 95%. Clarification shall be submitted. • Value of sulphated Ash in specification is NMT 0.1% while COA has mentioned NMT 0.2%. Clarification shall be submitted.	

7.	3.2.S.7.3	Stability data sheets for the drug substance are from Sarv Biolabs while the drug substance manufacturer in all the three modules is M/s India Glycols. Clarification shall be submitted.
8.	3.2.P.1	Qualitative composition of the applied formulation is different from the innovator product. Justification shall be submitted.
9.	3.2.P.2.2.1	• Details of the manufacturer of the product against which PE studies are performed shall be submitted. • Justification shall be submitted for not performing PE & CDP studies against the innovator product.
10.	3.2.P.8.3	• Stability data sheets with inclusion of API lot number as per decision of registration Board in its 293 shall be submitted. • Raw data sheets for calculation of assay and dissolution as per calculation formula shall be submitted. • Chromatograms also does not reveal any wavelength. Clarification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)shall be submitted.

Decision of 339th meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply Submitted by the firm:

Sr. No.	Observation	Reply by the firm
1.	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Firm has once again submitted copy of GMP certificate No. 17P/1/175/2008/1210 dated 22-01-2019 issued by Drug Controlling & Licensing Authority Uttarakhand valid for 03 years. *Not valid.*
2.	Valid copy of DML of the applicant shall be submitted.	Firm has once again submitted copy of DML w.e.f. 27-09-2013. They also submitted copy of receiving for renewal of DML dated 21-09-2023.
3.	Specifications of the drug substance from drug product manufacturer shall be submitted.	Submitted. However, pH limit submitted is different from drug substance manufacturer.
4.	Analytical procedures of the drug substance from drug product manufacturer shall be submitted.	Not submitted.
5.	Complete verification studies of the drug substance performed by the drug product manufacturer shall be submitted.	Submitted. *However, the initially submitted results of system suitability, specificity, accuracy etc. are completely different from that of the newly submitted results.*
6.	• Specifications provided by the drug substance manufacturer for drug substance has mentioned assay limit of 98.0% - 102%	Firm has submitted that it was a typo error and corrected COA is attached.

	while COA provided by the drug substance manufacturer for drug substance has mentioned NLT 95%. Clarification shall be submitted. • Value of sulphated Ash in specification is NMT 0.1% while COA has mentioned NMT 0.2%. Clarification shall be submitted.	However, they once again submitted the same COA wherein NLT 95% is mentioned. Firm has submitted that value of sulphated ash is mentioned in specification is 0.2%. COA of API manufacturer is attached.
7.	Stability data sheets for the drug substance are from Sarv Biolabs while the drug substance manufacturer in all the three modules is M/s India Glycols. Clarification shall be submitted.	Firm has submitted drug substance stability data from M/s India Glycols Limited both at real time and accelerated conditions for three batches.
8.	Qualitative composition of the applied formulation is different from the innovator product. Justification shall be submitted.	Firm has submitted revised their formulation. *In the initially submitted dossier, the qualitative composition of the applied formulation was completely different from the innovator product. Now they provided different composition from the initial dossier.*
9.	• Details of the manufacturer of the product against which PE studies are performed shall be submitted. • Justification shall be submitted for not performing PE & CDP studies against the innovator product.	Not submitted. Firm has submitted that they perform against innovator product.
10.	• Stability data sheets with inclusion of API lot number as per decision of registration Board in its 293 shall be submitted. • Raw data sheets for calculation of assay and dissolution as per calculation formula shall be submitted. • Chromatograms also does not reveal any wavelength. Clarification shall be submitted. • Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)shall be submitted.	Submitted with inclusion of API lot No. M022100040. Not submitted. Firm has submitted that at the time of stability not added, now in all working added. Submitted. Submitted.

Submitted.

Decision: Deferred for following;

- **Submission of Rs. 9000/- fee for pre-registration variations as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.**
- **Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.**
- **Specifications of the drug substance from drug substance manufacturer shall be submitted.**
- **Justification shall be submitted for changing the qualitative composition of the applied formulation as initially at the time of submission of dossier it was different from innovator and after shortcoming it is align with the innovator product.**
- **Justification shall be submitted regarding method of analysis provided and raw data sheets submitted for the applied formulation as both are in contrast to each other.**
- **Raw data sheets for calculation of assay and dissolution as per calculation formula for each time interval shall be submitted.**

374.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted inspection report dated 20-02-2019. Not valid.
	Evidence of approval of manufacturing facility	Firm has submitted approval of layout plan instead of section approval letter.
	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. 29325 dated 17-10-2022.
	Details of fee submitted	PKR 30,000/-, vide slip No. 8013542500 Dated 28/09/2022.
	The proposed proprietary name / brand name	**Salefo 5mg tablets.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Solifenacin succinate ……. 5mg
	Pharmacotherapeutic Group of (API)	Drugs for urinary frequency and incontinence (G04BD)
	Pharmaceutical form of applied drug	Oral tablet.
	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	VESICARE (solifenacin succinate) 5mg & 10mg tablets, USFDA approved.
	For generic drugs (me-too status)	Solifen Tablets 5mg, Getz Pharma, Registration No. 061202.

	Name and address of API manufacturer.	Union Quimico Farmaceutica, S.A. (Uquifa) Poligon Industrial Moli de les Planes Font de Bocs S/N C-35, Km. 57 08470 Sant Celoni (Barcelona) Spain.
	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, 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 details of the drug substance related to its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (15001825003, mfg. date 26-11-2021) 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. Batch No. 15001328001, 15001329003, 15001429001.
	Module-III Drug Product:	Firm has submitted details of the 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	Pharmaceutical Equivalence has been established against the comparator product i.e. Solifen 5mg tablets, B. No. 090F52, mfg. date 10-2021 manufactured by M/s Getz pharma by performing quality tests (Identification, Average weight & Comparative Dissolution). CDP has been performed against the same brand in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). in all the three mediums both the applied formulation and comparator product has more than 85% release within 15 minutes.
	Analytical method validation/verification of product	Not Submitted.

STABILITY STUDY DATA

Manufacturer of API	Union Quimico Farmaceutica, S.A. (Uquifa) Poligon Industrial Moli de les Planes Font de Bocs S/N C-35, Km. 57 08470 Sant Celoni (Barcelona) Spain.
API Lot No.	15001825003.
Description of Pack (Container closure system)	Alu Alu blister of 3 x 10's further packed in bleech card unit carton along with 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.	T-01	T-02	T-03
Batch Size	1200 Tablets.	1200 Tablets.	1200 Tablets.
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	05-03-2022	05-03-2022	05-03-2022
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)	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. NCF-II/1827/001/CAT dated 13-07-2018 issued by Ministry of Health of Government of Catalonia – Spain issued on the basis of inspection conducted on 25, 26, 27 & 28 July, 2016 valid for a period three years from the date of inspection 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. 00148/2022-DRAP(P)/394 dated 28-01-2022 mentioning Solifenacin Succinate EP attested by Assistant Drug Controller, DRAP, Peshawar. Firm has also submitted commercial invoice and copies of form 3 and form 7.
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:

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. 27-09-2013. Valid copy of GMP certificate/last inspection report conducted within last three years shall be submitted.	
2.	1.3.5	Evidence of approval of manufacturing facility/section approval from licensing division shall be submitted.	
3.	1.5.2	This section has mentioned Solifenacin succinate USP (drug substance) while official pharmacopoeia of USP has no monograph for Solifenacin succinate. Clarification shall be submitted.	
4.	1.5.5	Revised Pharmacotherapeutic group with applicable fee as per WHO ATC classification shall be submitted.	
5.	1.6.5	Valid copy of GMP certificate of drug substance manufacturer shall be submitted.	
6.	2.3	Table for literature references with correct information regarding the drug substance shall be submitted.	

7.	3.2.S.4.1	Specification of the drug substance from the drug substance manufacturer shall be submitted.
8.	3.2.S.4.2	• Analytical procedures of the drug substance from the drug substance manufacturer with details of complete test shall be submitted. • Analytical procedures of the drug substance from the drug product manufacturer shall be submitted.
9.	3.2.S.4.3	• Analytical method verification protocol shall be submitted. • Clear and visible details of the analytical method verification shall be submitted.
10.	3.2.S.5	• COA and details of the reference/working standard used in the development studies shall be submitted.
11.	3.2.S.7.3	• Specifications has mentioned assay limits of 99% - 101% on titration while the stability studies have mentioned 98% - 102% on HPLC. Clarification shall be submitted.
12.	3.2.P.2.2	• Justification for not performing CDP & PE against the innovator product shall be submitted. • Justification shall be submitted for submitting same results of CDP for both the strengths of the same formulation. • Justification shall be submitted for not performing assay and dissolution test in the PE studies shall be submitted.
13.	3.2.P.5.1	Specification for dissolution test has not mentioned any time limit. Justification shall be submitted.
14.	3.2.P.5.2	• Complete analytical procedures for all the tests of the finished product shall be submitted. • Justification shall be submitted for assay test on UV method instead of HPLC in the analytical procedures..
15.	3.2.P.5.3	Analytical method verification protocol along with complete results of the analytical method as per the submitted analytical method shall be submitted.
16.	3.2.P.6	COA and details of the reference standard used in the development studies shall be submitted.
17.	3.2.P.8	• Justification shall be submitted regarding the raw data and chromatograms as HPLC method is used while analytical procedures has mentioned UV method for assay test. • Justification shall be submitted regarding the submitted chromatograms as the analytical method has mentioned UV method for the analysis of assay test while the submitted chromatograms are of HPLC. • Content uniformity test has not been performed in the stability studies. Clarification shall be submitted. • Submitted chromatograms has not mentioned any wavelength. Clarification shall be submitted. • Raw data sheets for calculation of assay and dissolution as per submitted formula in the analytical procedures at each time interval 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.

- Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.

Decision of 336th meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm;

Sr. No.	Observation	Reply by the firm.
1.	Valid copy of DML of the applicant shall be submitted as the submitted one is w.e.f. 27-09-2013.	Firm has once again submitted copy of DML w.e.f. 27-09-2013. They also submitted copy of receiving for renewal of DML dated 21-09-2023.
	Valid copy of GMP certificate/last inspection report conducted within last three years shall be submitted.	Firm has submitted copy of GMP certificate No. F.3-12/2022-DRAP-179 dated 28-10-2022 issued on the basis of inspection conducted on 12-10-2022.
2.	Evidence of approval of manufacturing facility/section approval from licensing division shall be submitted.	Firm has submitted copy of letter No. F. 3-8/2007-Lic dated 05-05-2007mentioning approval for change of Tablet (Psychotropic) Section into Tablet (General) section.
3.	This section has mentioned Solifenacin succinate USP (drug substance) while official pharmacopoeia of USP has no monograph for Solifenacin succinate. Clarification shall be submitted.	Firm has submitted rectified label claim as follows; Each film coated tablet contains: Solifenacin succinate ……. 5mg (Product complies BP specifications)
4.	Revised Pharmacotherapeutic group with applicable fee as per WHO ATC classification shall be submitted.	*Submitted without any fee.*
5.	Valid copy of GMP certificate of drug substance manufacturer shall be submitted.	*Firm has submitted GMP certificate of M/s India Glycols instead of the actual drug substance manufacturer.*
6.	Table for literature references with correct information regarding the drug substance shall be submitted.	Table for literature references with correct information regarding the drug substance is submitted by the firm.
7.	Specification of the drug substance from the drug substance manufacturer shall be submitted.	Submitted.
8.	• Analytical procedures of the drug substance from the drug substance manufacturer with details of complete test shall be submitted. • Analytical procedures of the drug substance from the drug product manufacturer shall be submitted.	Submitted. Submitted.
9.	• Analytical method verification protocol shall be submitted. • Clear and visible details of the analytical method verification shall be submitted.	Submitted. Submitted.

10.	• COA and details of the reference/working standard used in the development studies shall be submitted.	Submitted.
11.	• Specifications has mentioned assay limits of 99% - 101% on titration while the stability studies have mentioned 98% - 102% on HPLC. Clarification shall be submitted.	Firm has submitted new stability data for the drug substance with assay limit of 99% - 101% by titration method.
12.	• Justification for not performing CDP & PE against the innovator product shall be submitted.	Firm has submitted that they perform PE & CDP against innovator product i.e. Vesicare 5mg, B. No. VT053J1. *However, neither any details of the manufacturer is provided nor any pictorial evidence is submitted.*
	• Justification shall be submitted for submitting same results of CDP for both the strengths of the same formulation. • Justification shall be submitted for not performing assay and dissolution test in the PE studies shall be submitted.	*No justification is provided by the firm. They only submitted revised results.* Firm has submitted revised PE & CDP studies wherein they included results for both the tests.
13.	Specification for dissolution test has not mentioned any time limit. Justification shall be submitted.	Revised SAP with inclusion of time limit dissolution test is submitted by the firm.
14.	• Complete analytical procedures for all the tests of the finished product shall be submitted. • Justification shall be submitted for assay test on UV method instead of HPLC in the analytical procedures..	Submitted. Revised SAP has mentioned HPLC method for the finished product.
15.	Analytical method verification protocol along with complete results of the analytical method as per the submitted analytical method shall be submitted.	Only results submitted while no protocol is submitted.
16.	COA and details of the reference standard used in the development studies shall be submitted.	Submitted.
17.	• Justification shall be submitted regarding the raw data and chromatograms as HPLC method is used while analytical procedures has mentioned UV method for assay test. • Content uniformity test has not been performed in the stability studies. Clarification shall be submitted. • Submitted chromatograms has not mentioned any wavelength. Clarification shall be submitted. • Raw data sheets for calculation of assay and dissolution as per submitted formula in the	No justification is submitted by the firm. Firm has submitted revised stability data sheets wherein they provided content uniformity test. No justification is submitted.

	analytical procedures at each time interval 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. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	Not submitted as per calculation formula. Submitted. Submitted. Submitted.

Decision: Deferred for following;

- **Submission of Rs. 9000/- fee for pre-registration variations as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.**
- **Valid copy of GMP certificate of drug substance manufacturer provided in Module I and Module III shall be submitted.**
- **Pictorial evidence of the innovator product i.e. Vesicare 5mg against which CDP and PE studies are performed with clear and visible detail shall be submitted.**
- **Justification shall be submitted regarding the raw data and chromatograms as HPLC method is used while analytical procedures has mentioned UV method for assay test.**
- **Raw data sheets for calculation of assay and dissolution as per submitted formula in the analytical procedures at each time interval shall be submitted.**

375.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals, Plot # 69/2, Phase-II, Industrial Area, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm has submitted inspection report dated 20-02-2019. Not valid.
	Evidence of approval of manufacturing facility	Firm has submitted approval of layout plan instead of section approval letter.
	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. 29841 dated 21-10-2022.
	Details of fee submitted	PKR 30,000/-, vide slip No. 46716000 Dated 28/09/2022.
	The proposed proprietary name / brand	**Salefo 10mg tablets.**

	name	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Solifenacin succinate ……. 10mg
	Pharmacotherapeutic Group of (API)	Drugs for urinary frequency and incontinence (G04BD)
	Pharmaceutical form of applied drug	Oral tablet.
	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	VESICARE (solifenacin succinate) 5mg & 10mg tablets, USFDA approved.
	For generic drugs (me-too status)	Solifen Tablets 10mg, Getz Pharma, Registration No. 061203.
	Name and address of API manufacturer.	Union Quimico Farmaceutica, S.A. (Uquifa) Poligon Industrial Moli de les Planes Font de Bocs S/N C-35, Km. 57 08470 Sant Celoni (Barcelona) Spain.
	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, 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 details of the drug substance related to its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its validation, batch analysis (15001825003, mfg. date 26-11-2021) 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. Batch No. 15001328001, 15001329003, 15001429001.
	Module-III Drug Product:	Firm has submitted details of the 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	Pharmaceutical Equivalence has been established against the comparator product i.e. Solifen 10mg tablets, B. No. 100F84, mfg. date 10-2021 manufactured by M/s Getz pharma by performing quality tests (Identification, Average weight & Comparative Dissolution). CDP has been performed against the same brand in Acid media (pH 1.2), Acetate buffer (pH 4.5) & Phosphate Buffer

		(pH 6.8). in all the three mediums both the applied formulation and comparator product has more than 85% release within 15 minutes.
	Analytical method validation/verification of product	Not Submitted.

STABILITY STUDY DATA			
Manufacturer of API	Union Quimico Farmaceutica, S.A. (Uquifa) Poligon Industrial Moli de les Planes Font de Bocs S/N C-35, Km. 57 08470 Sant Celoni (Barcelona) Spain.		
API Lot No.	15001825003.		
Description of Pack (Container closure system)	Alu Alu blister of 3 x 10's further packed in bleech card unit carton along with 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.	T-04	T-05	T-06
Batch Size	1200 Tablets.	1200 Tablets.	1200 Tablets.
Manufacturing Date	03-2022	03-2022	03-2022
Date of Initiation	05-03-2022	05-03-2022	05-03-2022
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)	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. NCF-II/1827/001/CAT dated 13-07-2018 issued by Ministry of Health of Government of Catalonia – Spain issued on the basis of inspection conducted on 25, 26, 27 & 28 July, 2016 valid for a period three years from the date of inspection 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. 00148/2022-DRAP(P)/394 dated 28-01-2022 mentioning Solifenacin Succinate EP attested by Assistant Drug Controller, DRAP, Peshawar. Firm has also submitted commercial invoice and copies of form 3 and form 7.
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:

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. 27-09-2013.	

		Valid copy of GMP certificate/last inspection report conducted within last three years shall be submitted.
2.	1.3.5	Evidence of approval of manufacturing facility/section approval from licensing division shall be submitted.
3.	1.5.2	This section has mentioned Solifenacin succinate USP (drug substance) while official pharmacopoeia of USP has no monograph for Solifenacin succinate. Clarification shall be submitted.
4.	1.5.5	Revised Pharmacotherapeutic group with applicable fee as per WHO ATC classification shall be submitted.
5.	1.6.5	Valid copy of GMP certificate of drug substance manufacturer shall be submitted.
6.	2.3	Table for literature references with correct information regarding the drug substance shall be submitted.
7.	3.2.S.4.1	Specification of the drug substance from the drug substance manufacturer shall be submitted.
8.	3.2.S.4.2	• Analytical procedures of the drug substance from the drug substance manufacturer with details of complete test shall be submitted. • Analytical procedures of the drug substance from the drug product manufacturer shall be submitted.
9.	3.2.S.4.3	• Analytical method verification protocol shall be submitted. • Clear and visible details of the analytical method verification shall be submitted.
10.	3.2.S.5	• COA and details of the reference/working standard used in the development studies shall be submitted.
11.	3.2.S.7.3	• Specifications has mentioned assay limits of 99% - 101% on titration while the stability studies have mentioned 98% - 102% on HPLC. Clarification shall be submitted.
12.	3.2.P.2.2	• Justification for not performing CDP & PE against the innovator product shall be submitted. • Justification shall be submitted for submitting same results of CDP for both the strengths of the same formulation. • Justification shall be submitted for not performing assay and dissolution test in the PE studies shall be submitted.
13.	3.2.P.5.1	Specification for dissolution test has not mentioned any time limit. Justification shall be submitted.
14.	3.2.P.5.2	• Complete analytical procedures for all the tests of the finished product shall be submitted. • Justification shall be submitted for performing assay test on UV method instead of HPLC.
15.	3.2.P.5.3	Analytical method verification protocol along with complete results of the analytical method as per the submitted analytical method shall be submitted.
16.	3.2.P.6	COA and details of the reference standard used in the development studies shall be submitted.
17.	3.2.P.8	• Justification shall be submitted regarding the raw data and chromatograms as HPLC method is used while analytical procedures has mentioned UV method for assay test. • Content uniformity test has not been performed in the stability studies. Clarification shall be submitted.

- Submitted chromatograms has not mentioned any wavelength. Clarification shall be submitted.
- Raw data sheets for calculation of assay and dissolution as per submitted formula in the analytical procedures at each time interval 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.
- Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.

Decision of 336th meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Observation	Reply by the firm.
1.	Valid copy of DML of the applicant shall be submitted as the submitted one is w.e.f. 27-09-2013.	Firm has once again submitted copy of DML w.e.f. 27-09-2013. They also submitted copy of receiving for renewal of DML dated 21-09-2023.
	Valid copy of GMP certificate/last inspection report conducted within last three years shall be submitted.	Firm has submitted copy of GMP certificate No. F.3-12/2022-DRAP-179 dated 28-10-2022 issued on the basis of inspection conducted on 12-10-2022.
2.	Evidence of approval of manufacturing facility/section approval from licensing division shall be submitted.	Firm has submitted copy of letter No. F. 3-8/2007-Lic dated 05-05-2007mentioning approval for change of Tablet (Psychotropic) Section into Tablet (General) section.
3.	This section has mentioned Solifenacin succinate USP (drug substance) while official pharmacopoeia of USP has no monograph for Solifenacin succinate. Clarification shall be submitted.	Firm has submitted rectified label claim as follows; Each film coated tablet contains: Solifenacin succinate ……. 10mg (Product complies BP specifications)
4.	Revised Pharmacotherapeutic group with applicable fee as per WHO ATC classification shall be submitted.	*Submitted without any fee.*
5.	Valid copy of GMP certificate of drug substance manufacturer shall be submitted.	*Firm has submitted GMP certificate of M/s India Glycols instead of the actual drug substance manufacturer.*
6.	Table for literature references with correct information regarding the drug substance shall be submitted.	Table for literature references with correct information regarding the drug substance is submitted by the firm.
7.	Specification of the drug substance from the drug substance manufacturer shall be submitted.	Submitted.
8.	• Analytical procedures of the drug substance from the drug substance manufacturer with details of complete test shall be submitted.	Submitted.

	• Analytical procedures of the drug substance from the drug product manufacturer shall be submitted.	Submitted.
9.	• Analytical method verification protocol shall be submitted. • Clear and visible details of the analytical method verification shall be submitted.	Submitted. Submitted.
10.	• COA and details of the reference/working standard used in the development studies shall be submitted.	Submitted.
11.	• Specifications has mentioned assay limits of 99% - 101% on titration while the stability studies have mentioned 98% - 102% on HPLC. Clarification shall be submitted.	Firm has submitted new stability data for the drug substance with assay limit of 99% - 101% by titration method.
12.	• Justification for not performing CDP & PE against the innovator product shall be submitted.	Firm has submitted that they perform PE & CDP against innovator product i.e. Vesicare 5mg, B. No. VT053J1. *However, neither any details of the manufacturer is provided nor any pictorial evidence is submitted.*
	• Justification shall be submitted for submitting same results of CDP for both the strengths of the same formulation. • Justification shall be submitted for not performing assay and dissolution test in the PE studies shall be submitted.	*No justification is provided by the firm. They only submitted revised results.* Firm has submitted revised PE & CDP studies wherein they included results for both the tests.
13.	Specification for dissolution test has not mentioned any time limit. Justification shall be submitted.	Revised SAP with inclusion of time limit dissolution test is submitted by the firm.
14.	• Complete analytical procedures for all the tests of the finished product shall be submitted. • Justification shall be submitted for assay test on UV method instead of HPLC in the analytical procedures..	Submitted. Revised SAP has mentioned HPLC method for the finished product.
15.	Analytical method verification protocol along with complete results of the analytical method as per the submitted analytical method shall be submitted.	Only results submitted while no protocol is submitted.
16.	COA and details of the reference standard used in the development studies shall be submitted.	Submitted.
17.	• Justification shall be submitted regarding the raw data and chromatograms as HPLC	No justification is submitted by the firm.

	method is used while analytical procedures has mentioned UV method for assay test. • Content uniformity test has not been performed in the stability studies. Clarification shall be submitted. • Submitted chromatograms has not mentioned any wavelength. Clarification shall be submitted. • Raw data sheets for calculation of assay and dissolution as per submitted formula in the analytical procedures at each time interval 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. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted.	Firm has submitted revised stability data sheets wherein they provided content uniformity test. No justification is submitted. Not submitted as per calculation formula. Submitted. Submitted. Submitted.
Decision: Deferred for following; • **Submission of Rs. 9000/- fee for pre-registration variations as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.** • **Valid copy of GMP certificate of drug substance manufacturer provided in Module I and Module III shall be submitted.** • **Pictorial evidence of the innovator product i.e. Vesicare 5mg against which CDP and PE studies are performed with clear and visible detail shall be submitted.** • **Justification shall be submitted regarding the raw data and chromatograms as HPLC method is used while analytical procedures has mentioned UV method for assay test.** • **Raw data sheets for calculation of assay and dissolution as per submitted formula in the analytical procedures at each time interval shall be submitted.**		
376.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fynk Pharmaceuticals, 19 km, G.T. Road, Kalashah Kaku, Lahore.**
	Name, address of Manufacturing site.	M/s Fynk Pharmaceuticals, 19 km, G.T. Road, Kalashah Kaku, Lahore.
	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 No. 198/2022-DRAP (AD-9405944056-789) dated 17-11-2022 issued on the basis of inspection 14/11/2022.

	Evidence of approval of manufacturing facility	Capsule (Penicillin) – New section approved vide letter No. F. 1-63/84-Lic (Vol III) dated 27-12-2021 is submitted.
	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 16406 dated 27-06-2023.
	Details of fee submitted	PKR 30,000/- vide slip No. 96593694 Dated 17-05-2023.
	The proposed proprietary name / brand name	**Ampiwell 500mg Capsule.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Ampicillin as trihydrate …… 500mg
	Pharmacotherapeutic Group of (API)	Beta-Lactam Antibacterial, Penicillin.
	Pharmaceutical form of applied drug	Oral capsule.
	Reference to Finished product specifications	BP specifications.
	Proposed Pack size	100's capsules.
	Proposed unit price	As per SRO.
	The status in reference regulatory authorities	Ampicillin Capsules BP 500 mg, Crescent Pharma Limited, MHRA approved.
	For generic drugs (me-too status)	Penbritin 500mg Capsule, GSK Pakistan, Reg. No. 000189.
	Name and address of API manufacturer.	M/s Pharmagen Limited, Kot Nabi buksh wala, 34 K.M. Ferozpur Road, Lahore. Copy of GMP certificate No. 06/2019-DRAP (AD/607409-530) dated 11-01-2019 on the basis of inspection conducted on 08-01-2019 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, 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 detail of the drug substance including its nomenclature, structure, general properties, solubility, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. 00003/093/2021, mfg. date 11-2021) and justification of specification, working 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 sheets of three batches for the drug substance. Real time stability conducted at 30˚C ± 2˚C / 65% ± 5% RH for 60months. Accelerated stability conducted at 40˚C ± 2˚C / 75% ± 5% RH for 06 months. B. No. (00003/001/2015, 00003/002/2015 & 00003/003/2015)
	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 of their product against the Penbritin 500mg capsule, B. No. UH2X, mfg. date 06-2021manufactured by GSK, Pakistan by performing quality tests od identification, average filled weight, dissolution and assay. Firm has also submitted comparative dissolution of their applied formulation with Penbritin 500mg capsule B. No. UH2X, mfg. date 06-2021manufactured by GSK, Pakistan in three different mediums of pH 1.2, 4.5 & 6.8. values of the F_2 are in acceptable range.
	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	M/s Pharmagen Limited, Kot Nabi buksh wala, 34 K.M. Ferozpur Road, Lahore.		
API Lot No.	00003/093/2021.		
Description of Pack (Container closure system)	Almost white granular powder filled in purple and white capsule packed in printed Alu - Alu blister of 20 capsules further 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.	A	B	C
Batch Size	2000 Capsules	2000 Capsules	2000 Capsules
Manufacturing Date	02-2022	02-2022	02-2022
Date of Initiation	08-02-2022	08-02-2022	08-02-2022
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.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP certificate No. 06/2019-DRAP (AD/607409-530) dated 11-01-2019 on the basis of inspection conducted on 08-01-2019 is submitted.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Proforma invoice No. PL/P-INV/HO/866 dated 03-01-2022 wherein they have purchased 1kg of Ampicillin trihydrate from M/s Pharmagen Limited. However, the invoice has not mentioned any batch number and manufacturing date of the drug substance.
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	Response by the firm
1.	1.6.5	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	
2.	2.3	Table for literature references with correct information with applicable fee shall be submitted.	
3.	3.2.S.6	Details/COA of the working standard used in the trial batches shall be submitted.	
4.	3.2.S.7	Justification shall be submitted for not performing all the test in stability data sheets as required by monograph.	
5.	3.2.P.2.2	Justification shall be submitted for providing exact same results for dissolution and assay test in pharmaceutical equivalence studies of two different strengths of Ampicillin 250mg and 500mg.	
6.	3.2.P.5.1	Justification shall be submitted for adopting all the specifications for the finished product from BP while only dissolution test is adopted from USP.	
7.	3.2.P.5.3	• Justification shall be submitted for providing analytical method verification studies of 250mg capsule for 500mg capsule. • Justification shall be submitted regarding the submitted chromatograms as they have mentioned 200mg, 250mg and 300mg ampicillin capsules.	
8.	3.2.P.8	• Proforma invoice provided by the firm has not mentioned any batch number and mfg. date. Clarify. • Justification shall be submitted regarding the submitted quantity of 1kg with respect to manufactured batches of 2000 capsule each of three batches.	

Decision of 335th meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Observation	Response by the firm
1.	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Firm has submitted copy of GMP certificate No. 204/2022-DRAP (AD/159531263130/538) dated 22-11-2022 on the basis of inspection conducted on 18-11-2022.
2.	Table for literature references with correct information with applicable fee shall be submitted.	Submitted with applicable fee of 9000/- vide slip No. 6600920147 dated 02-10-2024.
3.	Details/COA of the working standard used in the trial batches shall be submitted.	Submitted.
4.	Justification shall be submitted for not performing all the test in stability data sheets as required by monograph.	Firm has submitted updated stability data sheets for the drug substance wherein following stability indicating parameters are included as per monograph;

		• General appearance. • Moisture. • pH. • Optical rotation. • Assay. • Related substances.
5.	Justification shall be submitted for providing exact same results for dissolution and assay test in pharmaceutical equivalence studies of two different strengths of Ampicillin 250mg and 500mg.	Firm has submitted that during compilation of pharmaceutical equivalence, same results were mistakenly entered, it was typographic error. They further submitted revised pharmaceutical equivalence studies.
6.	Justification shall be submitted for adopting all the specifications for the finished product from BP while only dissolution test is adopted from USP.	Firm has submitted that in BP monograph of Ampicillin capsules, dissolution test has not been given, so they adopted dissolution test from USP.
7.	• Justification shall be submitted for providing analytical method verification studies of 250mg capsule for 500mg capsule.	Firm has submitted that analytical method is adopted from BP, and method is same for ampicillin capsule 250mg and 500mg. However, they have revised it for 500mg capsules.
	• Justification shall be submitted regarding the submitted chromatograms as they have mentioned 200mg, 250mg and 300mg ampicillin capsules.	Firm has submitted that since same method was used for different strengths, so during testing all available SKUs were mentioned.
8.	• Proforma invoice provided by the firm has not mentioned any batch number and mfg. date. Clarify.	Firm has submitted commercial invoice which mentioned the batch number.
	• Justification shall be submitted regarding the submitted quantity of 1kg with respect to manufactured batches of 2000 capsule each of three batches.	Firm has submitted that total of 11kg API was ordered which was delivered in two parts on dated 10-01-2022 (1kg) and 22-02-2022 (10kg). (587mg of Ampicillin trihydrate equivalent to 500mg of Ampicillin). 587 x 2000 x 3 = 3.52kg.

Decision: Approved.

377.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Aptcure (Pvt.) Ltd, 8- Pharma City, 30 km, Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s Aptcure (Pvt.) Ltd, 8- Pharma City, 30 km, Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 16596 dated 04-07-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 29214587840 dated 14-06-2023.
	The proposed proprietary name / brand name	**Aptin 1mg Tablet.**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Pitavastatin calcium eq. to Pitavastatin ……..…1mg
	Pharmacotherapeutic Group of (API)	HMG CoA reductase inhibitors. C10AA08.
	Reference to Finished product specifications	Innovator specifications.
	The status in reference regulatory authorities	Alipza 1mg film-coated tablets MHRA Approved.
	For generic drugs (me-too status)	Pitalo 1mg Tablets, M/s Genix pharma, Reg. No. 073684.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per Rule.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply submitted by the firm.
1.	1.3.4	Valid copy of DML of the applicant shall be submitted.	
2.	1.5.6	This section has mentioned innovator specification while official monograph is available in Japanese pharmacopoeia. Clarification shall be submitted.	
3.	3.2.S.4.1	Specifications of the drug substance by the drug product manufacturer shall be submitted.	
4.	3.2.S.4.2	• Assay method in the analytical procedure submitted by drug substance manufacturer shall be submitted as the submitted one is clearly different from that of the drug substance manufacturer. • Analytical procedures of the drug substance by the drug product manufacturer shall be submitted.	
5.	3.2.S.4.3	Analytical method verification studies performed by the drug product manufacturer shall be submitted.	
6.	3.2.P.2.2	• Justification shall be submitted for not considering 15-minute time point in CDP studies. • Calculation and values of F_2 shall be submitted for each medium.	
7.	3.2.P.5.3	Justification shall be submitted for providing same results for linearity of both drug substance and drug product.	
8.	3.2.P.8	• Raw data sheets for calculation of assay and dissolution at each time interval shall be submitted. • Analytical method has mentioned injection volume of 25µl while submitted chromatograms has mentioned 10 µl injection volume. Clarification shall be submitted. • Some of the chromatograms have mentioned date of 09-05-2022 while the stability data sheets and BMR is having manufacturing date of 01-06-2022. Clarification shall be submitted. • Submitted chromatograms has mentioned 0.03gm or 30mg of Pitavastatin calcium. Justify the quantity imported against 3 developed formulations of Aptin 1mg, 2mg & 4mg tablets. • 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.	

Decision of 340th meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Observation	Reply submitted by the firm.
1.	Valid copy of DML of the applicant shall be submitted.	Firm has submitted copy of DML No. 000648 renewed w.e.f. 24-10-2023.
2.	This section has mentioned innovator specification while official monograph is available in Japanese pharmacopoeia. Clarification shall be submitted.	Firm has revised their specifications from innovator to JP specifications and submitted that testing specifications will now be aligned with JP. They also attached 09th, 12th, 18th & 24th month real time stability. However requisite fee is not submitted by the firm.
3.	Specifications of the drug substance by the drug product manufacturer shall be submitted.	Submitted.
4.	• Assay method in the analytical procedure submitted by drug substance manufacturer shall be submitted as the submitted one is clearly different from that of the drug substance manufacturer. • Analytical procedures of the drug substance by the drug product manufacturer shall be submitted.	Submitted. Submitted.
5.	Analytical method verification studies performed by the drug product manufacturer shall be submitted.	*Only linearity is submitted by the firm. Rest of the parameters of method verification are not submitted by the firm.*
6.	• Justification shall be submitted for not considering 15-minute time point in CDP studies. • Calculation and values of F_2 shall be submitted for each medium.	Firm has submitted that slow drug release was observed for Aptin 1mg & 4mg tablets Vs reference in pH 4.5 and 6.8 buffers. Consequently, dissolution testing utilized expanded 10-minute interval: 10, 20, 30, 45, and 60 minutes, to ensure comprehensive comparative CDP analysis. Firm has submitted F_2 values for all the three mediums and values are in acceptable ranges.
7.	Justification shall be submitted for providing same results for linearity of both drug substance and drug product.	Firm has submitted revised linearity for drug substance.
8.	• Raw data sheets for calculation of assay and dissolution at each time interval shall be submitted. • Analytical method has mentioned injection volume of 25µl while submitted chromatograms has mentioned 10 µl injection volume. Clarification shall be submitted. • Some of the chromatograms have mentioned date of 09-05-2022 while the stability data sheets and BMR is having manufacturing	Submitted. Firm has submitted that Analytical method validation for the product is now performed again and assay method is as per JP, utilizing a 10 µl injection quantity. *Firm was asked about the analytical method they submitted validation method.*

	date of 01-06-2022. Clarification shall be submitted. • Submitted clearance certificate has mentioned 0.03gm or 30mg of Pitavastatin calcium. Justify the quantity imported against 3 developed formulations of Aptin 1mg, 2mg & 4mg tablets. • 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 that HPLC chromatograms date pattern is MM/DD/YY. Therefore 09-05-2022 corresponds to September 5, 2022. While the date pattern in BMR was DD/MM/YY. Firm has submitted that it was a typo mistake and the original imported quantity of the material is 0.30kg or 30grams which was written by mistake. They also submitted commercial invoice wherein 0.03kg quantity is mentioned. Not submitted. Submitted.

Decision: Approved. Registration letter will be issued after submission of Rs. 9000/- fee for pre-registration variations as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.

- **Firm will also submit analytical method verification studies for both drug substance and drug product performed by the drug product manufacturer.**

378.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Aptcure (Pvt.) Ltd, 8- Pharma City, 30 km, Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s Aptcure (Pvt.) Ltd, 8- Pharma City, 30 km, Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 16595 dated 04-07-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 0201381859 dated 14-06-2023.
	The proposed proprietary name / brand name	**Aptin 2mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Pitavastatin calcium eq. to Pitavastatin ……..…2mg
	Pharmacotherapeutic Group of (API)	HMG CoA reductase inhibitors. C10AA08.
	Reference to Finished product specifications	Innovator specifications.
	The status in reference regulatory authorities	Alipza 2mg film-coated tablets MHRA Approved.
	For generic drugs (me-too status)	Pitalo 2mg Tablets, M/s Genix pharma, Reg. No. 070457.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per Rule.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply submitted by the firm.
1.	1.3.4	Valid copy of DML of the applicant shall be submitted.	
2.	1.5.2	Label claim has mentioned 1mg of Pitavastatin. Clarification shall be submitted.	

3.	1.5.6	This section has mentioned innovator specification while official monograph is available in Japanese pharmacopoeia. Clarification shall be submitted.
4.	3.2.S.4.1	Specifications of the drug substance by the drug product manufacturer shall be submitted.
5.	3.2.S.4.2	• Assay method in the analytical procedure submitted by drug substance manufacturer shall be submitted as the submitted one is clearly different from that of the drug substance manufacturer. • Analytical procedures of the drug substance by the drug product manufacturer shall be submitted.
6.	3.2.S.4.3	Analytical method verification studies performed by the drug product manufacturer shall be submitted.
7.	3.2.P.2.2	• Justification shall be submitted for not considering 15-minute time point in CDP studies. • Calculation and values of F_2 shall be submitted for each medium.
8.	3.2.P.5.3	Justification shall be submitted for providing same results for linearity of both drug substance and drug product.
9.	3.2.P.8	• Raw data sheets for calculation of assay and dissolution at each time interval shall be submitted. • Analytical method has mentioned injection volume of 25µl while submitted chromatograms has mentioned 10 µl injection volume. Clarification shall be submitted. • Some of the chromatograms have mentioned date of 09-05-2022 while the stability data sheets and BMR is having manufacturing date of 01-06-2022. Clarification shall be submitted. • Submitted chromatograms has mentioned 0.03gm or 30mg of Pitavastatin calcium. Justify the quantity imported against 3 developed formulations of Aptin 1mg, 2mg & 4mg tablets. • 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.

Decision of 340th meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm;

Sr. No.	**Observation**	**Reply submitted by the firm.**
1.	Valid copy of DML of the applicant shall be submitted.	Firm has submitted copy of DML No. 000648 renewed w.e.f. 24-10-2023.
2.	Label claim has mentioned 1mg of Pitavastatin. Clarification shall be submitted.	Firm has submitted that it was a typographic error. Correct label claim is as under: Each film coated tablet Contains: Pitavastatin calcium eq. to Pitavastatin ……..…2mg
3.	This section has mentioned innovator specification while official monograph is available in Japanese pharmacopoeia. Clarification shall be submitted.	Firm has revised their specifications from innovator to JP specifications and submitted that testing specifications will now be aligned with JP.

		They also attached 09th, 12th, 18th & 24th month real time stability. However requisite fee is not submitted by the firm.
4.	Specifications of the drug substance by the drug product manufacturer shall be submitted.	Submitted.
5.	• Assay method in the analytical procedure submitted by drug substance manufacturer shall be submitted as the submitted one is clearly different from that of the drug substance manufacturer. • Analytical procedures of the drug substance by the drug product manufacturer shall be submitted.	Submitted. Submitted.
6.	Analytical method verification studies performed by the drug product manufacturer shall be submitted.	*Only linearity is submitted by the firm. Rest of the parameters of method verification are not submitted by the firm.*
7.	• Justification shall be submitted for not considering 15-minute time point in CDP studies. • Calculation and values of F_2 shall be submitted for each medium.	Firm has submitted that slow drug release was observed for Aptin 1mg & 4mg tablets Vs reference in pH 4.5 and 6.8 buffers. Consequently, dissolution testing utilized expanded 10-minute interval: 10, 20, 30, 45, and 60 minutes, to ensure comprehensive comparative CDP analysis. Firm has submitted F_2 values for all the three mediums and values are in acceptable ranges.
8.	Justification shall be submitted for providing same results for linearity of both drug substance and drug product.	Firm has submitted revised linearity for drug substance.
9.	• Raw data sheets for calculation of assay and dissolution at each time interval shall be submitted. • Analytical method has mentioned injection volume of 25µl while submitted chromatograms has mentioned 10 µl injection volume. Clarification shall be submitted. • Some of the chromatograms have mentioned date of 09-05-2022 while the stability data sheets and BMR is having manufacturing date of 01-06-2022. Clarification shall be submitted. • Submitted chromatograms has mentioned 0.03gm or 30mg of Pitavastatin calcium. Justify the quantity imported against 3 developed formulations of Aptin 1mg, 2mg & 4mg tablets. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Submitted. Firm has submitted that Analytical method validation for the product is now performed again and assay method is as per JP, utilizing a 10 µl injection quantity. *Firm was asked about the analytical method they submitted validation method.* Firm has submitted that HPLC chromatograms date pattern is MM/DD/YY. Therefore 09-05-2022 corresponds to September 5, 2022. While the date pattern in BMR was DD/MM/YY. Firm has submitted that it was a typo mistake and the original imported quantity of the material is 0.30kg or 30grams which was written by mistake.

	• Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	They also submitted commercial invoice wherein 0.03kg quantity is mentioned. Not submitted. Submitted.

Decision: Approved. Registration letter will be issued after submission of Rs.9000/- fee for pre-registration variations as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.

- **Firm will also submit analytical method verification studies for both drug substance and drug product performed by the drug product manufacturer.**

379.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Aptcure (Pvt.) Ltd, 8- Pharma City, 30 km, Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s Aptcure (Pvt.) Ltd, 8- Pharma City, 30 km, Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 16594 dated 04-07-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 674572805 dated 14-06-2023.
	The proposed proprietary name / brand name	**Aptin 4mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Pitavastatin calcium eq. to Pitavastatin ……..…4mg
	Pharmacotherapeutic Group of (API)	HMG CoA reductase inhibitors. C10AA08.
	Reference to Finished product specifications	Innovator specifications.
	The status in reference regulatory authorities	Alipza 4mg film-coated tablets MHRA Approved.
	For generic drugs (me-too status)	Pitalo 4mg Tablets, M/s Genix pharma, Reg. No. 073687.
	Proposed Pack size	As per SRO.
	Proposed unit price	As per Rule.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply submitted by the firm.
1.	1.3.4	Valid copy of DML of the applicant shall be submitted.	
2.	1.5.6	This section has mentioned innovator specification while official monograph is available in Japanese pharmacopoeia. Clarification shall be submitted.	
3.	3.2.S.4.1	Specifications of the drug substance by the drug product manufacturer shall be submitted.	
4.	3.2.S.4.2	• Assay method in the analytical procedure submitted by drug substance manufacturer shall be submitted as the submitted one is clearly different from that of the drug substance manufacturer. • Analytical procedures of the drug substance by the drug product manufacturer shall be submitted.	

5.	3.2.S.4.3	Analytical method verification studies performed by the drug product manufacturer shall be submitted.
6.	3.2.P.2.2	• Justification shall be submitted for not considering 15-minute time point in CDP studies. • Calculation and values of F_2 shall be submitted for each medium.
7.	3.2.P.5.3	Justification shall be submitted for providing same results for linearity of both drug substance and drug product.
8.	3.2.P.8	• Raw data sheets for calculation of assay and dissolution at each time interval shall be submitted. • Analytical method has mentioned injection volume of 25µl while submitted chromatograms has mentioned 10 µl injection volume. Clarification shall be submitted. • Some of the chromatograms have mentioned date of 09-05-2022 while the stability data sheets and BMR is having manufacturing date of 01-06-2022. Clarification shall be submitted. • Submitted chromatograms has mentioned 0.03gm or 30mg of Pitavastatin calcium. Justify the quantity imported against 3 developed formulations of Aptin 1mg, 2mg & 4mg tablets. • 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.

Decision of 340th meeting of Registration Board: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the Firm:

Sr. No.	**Observation**	**Reply submitted by the firm.**
1.	Valid copy of DML of the applicant shall be submitted.	Firm has submitted copy of DML No. 000648 renewed w.e.f. 24-10-2023.
2.	This section has mentioned innovator specification while official monograph is available in Japanese pharmacopoeia. Clarification shall be submitted.	Firm has revised their specifications from innovator to JP specifications and submitted that testing specifications will now be aligned with JP. They also attached 09th, 12th, 18th & 24th month real time stability. However requisite fee is not submitted by the firm.
3.	Specifications of the drug substance by the drug product manufacturer shall be submitted.	Submitted.
4.	• Assay method in the analytical procedure submitted by drug substance manufacturer shall be submitted as the submitted one is clearly different from that of the drug substance manufacturer. • Analytical procedures of the drug substance by the drug product manufacturer shall be submitted.	Submitted. Submitted.

5.	Analytical method verification studies performed by the drug product manufacturer shall be submitted.	*Only linearity is submitted by the firm. Rest of the parameters of method verification are not submitted by the firm.*
6.	• Justification shall be submitted for not considering 15-minute time point in CDP studies. • Calculation and values of F_2 shall be submitted for each medium.	Firm has submitted that slow drug release was observed for Aptin 1mg & 4mg tablets Vs reference in pH 4.5 and 6.8 buffers. Consequently, dissolution testing utilized expanded 10-minute interval: 10, 20, 30, 45, and 60 minutes, to ensure comprehensive comparative CDP analysis. Firm has submitted F_2 values for all the three mediums and values are in acceptable ranges.
7.	Justification shall be submitted for providing same results for linearity of both drug substance and drug product.	Firm has submitted revised linearity for drug substance.
8.	• Raw data sheets for calculation of assay and dissolution at each time interval shall be submitted.	Submitted.
	• Analytical method has mentioned injection volume of 25µl while submitted chromatograms has mentioned 10 µl injection volume. Clarification shall be submitted.	Firm has submitted that Analytical method validation for the product is now performed again and assay method is as per JP, utilizing a 10 µl injection quantity. *Firm was asked about the analytical method they submitted validation method.*
	• Some of the chromatograms have mentioned date of 09-05-2022 while the stability data sheets and BMR is having manufacturing date of 01-06-2022. Clarification shall be submitted.	Firm has submitted that HPLC chromatograms date pattern is MM/DD/YY. Therefore 09-05-2022 corresponds to September 5, 2022. While the date pattern in BMR was DD/MM/YY.
	• Submitted chromatograms has mentioned 0.03gm or 30mg of Pitavastatin calcium. Justify the quantity imported against 3 developed formulations of Aptin 1mg, 2mg & 4mg tablets.	Firm has submitted that it was a typo mistake and the original imported quantity of the material is 0.30kg or 30grams which was written by mistake. They also submitted commercial invoice wherein 0.03kg quantity is mentioned.
	• 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.	Submitted.

Decision: Approved. Registration letter will be issued after submission of Rs. 9000/- fee for pre-registration variations as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.

- **Firm will also submit analytical method verification studies for both drug substance and drug product performed by the drug product manufacturer.**

380.	Name, address of Applicant / Marketing Authorization Holder	**M/s Inventor Pharma, Plot No. K/196, S.I.T.E (SHW) Phase-II, Karachi.**
	Name, address of Manufacturing site.	M/s Inventor Pharma, Plot No. K/196, S.I.T.E (SHW) Phase-II, Karachi.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Not submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter No. F. 2-4/2013-Lic dated 13/07/2017 specifying 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. 29839 dated 21-10-2022.
	Details of fee submitted	PKR 30,000/- vide slip No. 5363423303 dated: 14/04/2022.
	The proposed proprietary name / brand name	**Ledenzo-Lid 600mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Linezolid ……. …… 600mg
	Pharmacotherapeutic Group of (API)	Other antibacterial (J01XX)
	Pharmaceutical form of applied drug	Film coated tablet.
	Reference to Finished product specifications	USP specification.
	Proposed Pack size	1 x 10's.
	Proposed unit price	As per SRO/DPC.
	The status in reference regulatory authorities	ZYVOX® (linezolid) 600mg tablets, USFDA approved.
	For generic drugs (me-too status)	Lyzon 600mg Tablet, Getz Pharma, Reg. No. 055439.
	Name and address of API manufacturer.	M/s Cipla Ltd., plot D-22, MIDC Industrial Area Kurkumbh Village, Taluka Daund District Pune (Maharashtra) 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, 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 details of the drug substance including its nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, specifications, analytical procedures and its verification, batch analysis (B. No. LDX180026, Mfg. date 05-2018) and justification of specification, reference standard, container closure system and stability studies of drug substance.
	Stability studies (Conditions & duration of 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 06 months Batches: (LDX180021, LDX180025 & LDX180026)
	Module-III (Drug Product):	Firm has submitted details of the drug product including its

		description, composition, pharmaceutical development, manufacture, batch formula, 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.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence is established against the comparator product i.e. Zolrest 600mg tablets, by performing quality tests average weight, Dissolution & Assay. Results of both the test product and comparator product are comparable. Comparative Dissolution is also performed against the same product i.e. Zolrest 600mg tablets, B. No. 210582, Exp. date 03-2023 manufactured by M/s Bosch Pharmaceuticals. *However, only details of the product is submitted while no data for CDP studies is submitted by the firm.*
	Analytical method validation/verification of product	Method verification studies are submitted including System suitability, specificity, accuracy, precision.

STABILITY STUDY DATA

Manufacturer of API	M/s Cipla Ltd., plot D-22, MIDC Industrial Area Kurkumbh Village, Taluka Daund District Pune (Maharashtra) India.		
API Lot No.	Not submitted.		
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.	001	002	003
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	07/2021	07/2021	07/2021
Date of Initiation	07-2021	07-2021	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)	Not Submitted.
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not 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 of evaluator:

Sr. No.	Section	Observation	Reply by the firm
1.	1.3.4	• Valid copy of DML of the applicant shall be submitted. • Valid copy of GMP certificate/last inspection report conducted within last three years shall be submitted.	
2.	1.5.6	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	
3.	2.3	Copies of executed BMR's shall be submitted.	
4.	3.2.S.2 & 3.2.S.3	Detailed information of these sections for both the drug substances shall be submitted.	
5.	3.2.S.4.1	Specifications of the drug substance from both drug substance manufacturer and drug product manufacturer shall be submitted.	
6.	3.2.S.4.2	Analytical procedures of the drug substance from both drug substance manufacturer and drug product manufacturer shall be submitted	
7.	3.2.S.4.4	• Clear and readable copy of COA of the drug substance from drug substance manufacturer shall be submitted. • COAs of the drug substance from both drug substance manufacturer and drug product manufacturer with same batch number shall be submitted.	
8.	3.2.S.4.5	Readable copy of Justification of specification shall be submitted.	
9.	3.2.S.6	Readable copy of container closure system for the drug substance shall be submitted	
10.	3.2.P.1	Qualitative composition of the applied formulation is different from the innovator product. Justification shall be submitted.	
11.	3.2.P.2.2	• Justification shall be submitted for not performing PE & CDP against the innovator product. • Details of the product i.e. name of manufacturer, batch number, manufacturing date and expiry date etc. against which PE is performed shall be submitted. • Results of the CDP studies in all the three mediums with calculation of F_2 value shall be submitted.	
12.	3.2.P.5.1	This section has mentioned In-House specification. Justification shall be submitted.	
13.	3.2.P.8	• Stability data sheets as per decision of 293rd meeting of Registration Board with inclusion of APLI lot number, initiation date etc. shall be submitted. • Justification shall be submitted for not performing uniformity of dosage units of the finished as required by the official monograph. • Justification shall be submitted regarding the initial time results of dissolution test as they are out of specification. • Justification shall be submitted regarding the concentration of standard solution in raw data sheets (0.049 mg/ml) as it is different from that given in the formula (0.06mg/ml). • 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. • Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	

Decision of 336th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply submitted by the firm:

Sr. No.	Observation	Reply by the firm
1.	• Valid copy of DML of the applicant shall be submitted. • Valid copy of GMP certificate/last inspection report conducted within last three years shall be submitted.	Copy of DML No. 000866 w.e.f. 22-06-2022 is submitted. Copy of GMP certificate No. 164/2022-DRAP (K) dated 15-09-2022issued on the basis of inspection conducted on 13-09-2022.
2.	Valid copy of GMP certificate of the drug substance manufacturer shall be submitted.	Copy of GMP certificate No. New-WHO-GMP/CERT/PD/105447/2022/11/39339 dated 28-02-2022 valid till 27-02-2025 is submitted.
3.	Copies of executed BMR's shall be submitted.	Submitted.
4.	Detailed information of these sections for both the drug substances shall be submitted.	Submitted.
5.	Specifications of the drug substance from both drug substance manufacturer and drug product manufacturer shall be submitted.	Submitted.
6.	Analytical procedures of the drug substance from both drug substance manufacturer and drug product manufacturer shall be submitted	Submitted.
7.	• Clear and readable copy of COA of the drug substance from drug substance manufacturer shall be submitted. • COAs of the drug substance from both drug substance manufacturer and drug product manufacturer with same batch number shall be submitted.	Firm has submitted clear and readable copy of COA of the drug substance from drug substance manufacturer along with COA of the drug substance from drug product manufacturer having same batch number and manufacturing date etc.
8.	Readable copy of Justification of specification shall be submitted.	Submitted.
9.	Readable copy of container closure system for the drug substance shall be submitted	Submitted.
10.	Qualitative composition of the applied formulation is different from the innovator product. Justification shall be submitted.	Firm has submitted that at the time of submission of application there was a typographical error in entering formulation ingredients. However, we hereby undertake that our applied formulation strictly followed the formulation of innovator product.
11.	• Justification shall be submitted for not performing PE & CDP against the innovator product. • Details of the product i.e. name of manufacturer, batch number, manufacturing date and expiry date etc.	Firm has submitted that initially due to unavailability of the innovator product in the market, they performed PE and CDP with comparator product. Now they arranged the innovator and submitted PE and CDP with Zyvox

	against which PE is performed shall be submitted. • Results of the CDP studies in all the three mediums with calculation of F_2 value shall be submitted.	600mg tablet, B. No. TLT-2915, Mfg. date 06-2021 manufactured by Pfizer Limited. They submitted new CDP and PE studies.
12.	This section has mentioned In-House specification. Justification shall be submitted.	Firm has submitted that it was a typographic error.
13.	• Stability data sheets as per decision of 293rd meeting of Registration Board with inclusion of APLI lot number, initiation date etc. shall be submitted.	Submitted.
	• Justification shall be submitted for not performing uniformity of dosage units of the finished as required by the official monograph.	Firm has submitted that at the time of submission of application, they were unable to perform the said test, however they now revised the analytical procedures as per USP and added the said test in finished product specifications too.
	• Justification shall be submitted regarding the initial time results of dissolution test as they are out of specification.	Firm has submitted that they accept that there was a typographical error in preparation and compilation of stability data. However, now we were submitting the correct data in the relevant section.
	• Justification shall be submitted regarding the concentration of standard solution in raw data sheets (0.049 mg/ml) as it is different from that given in the formula (0.06mg/ml).	Firm has submitted that they accept that there was a typographical error in preparation and compilation of stability data. However, now we were submitting the correct data in the relevant section.
	• Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted.	Firm has submitted copy of Form 6 mentioning 4kg of linezolid attested by Assistant Director, DRAP, Karachi.
	• Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted.	Submitted.
	• Reference of previous approval of applications with stability study data of the firm (if any) shall be submitted.	Submitted.

Decision of 340th meeting of Registration Board: Registration Board deferred the case for verification of authenticity of submitted data by the panel constituted by the Chairman Registration Board in which one member will be Dr. Saif Ur Rehman Khattak.

Reply submitted by the firm:
Firm vide their letter No. IP/DRAP-Reg/10/2024-001 dated 22-10-2024 submitted a request for withdrawing their previously submitted application namely Ledenzo-lid 600mg tablets dated 21-10-2022. Firm has further stated that due to significant changes in the formulation and testing methodologies of said product, we strongly believe that it is necessary to reevaluate our development strategies to ensure alignment with the latest regulatory standards.

Decision: Registration Board acceded the request of the firm and also decided to reject the instant application of the firm.

Case 03: Registration applications imported (Human) drugs Deferred cases on Form 5F.

381.	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	Firm has submitted original and legalized sole agency

	agency agreement	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 25ºC ± 2º 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 of 329th 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.

Reply submitted 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 a declaration from the manufacturer wherein they have declared that the batches of "Exopio 380mg powder for suspension for injection" (Naltrexone extended release) manufactured for territory of Pakistan will not have 12.9% excess of active ingredient "Naltrexone base" as base.
2.	Justification for use of Naltrexone Hydrochloride as working standard in the analysis while USP monograph recommends Naltrexone base as reference standard.	Firm has submitted a declaration from the manufacturer wherein they have declared that they have resolved the matter related to "Reference Standard" and now we are using the same reference standard in the analysis of API and finished product, as the one used by USP.

Furthermore, they also submitted Bioequivalence studies against the innovator product.

Conclusion:

According to the results obtained from the present study, it is concluded that EXOPIO (380mg naltrexone) manufactured by NanoDaru Pajuhan Pardis, Iran, is bioequivalent to Vivitrol® (380mg naltrexone), manufactured by Alkermis, USA, following a single IM dose of 380mg naltrexone to healthy male adults and

thus equal therapeutic efficacy can be concluded. Adverse events were limited and subjects have tolerated the treatments well.
Decision: Approved as per policy of Inspection of Manufacturer abroad. • **Firm will not use any overage of the active ingredient in the applied formulation.** • **Registration letter will be issued after submission of COA of the drug substance after testing the drug substance as per USP method.**

Case 04: Registration applications Locally manufactured (Human) drugs deferred cases on Form 5.

382.	Name and address of manufacturer/ Applicant	M/s Scotmann Pharmaceuticals 5-D, I-10/3 Islamabad. (DML No. 000498) Tablet (General) Section.
	Brand Name + Dosage Form + Strength	JADE Flash 10mg Tablets
	Composition	Each tablet contains; Loratadine……10mg
	Diary No. Date of R & I & fee	Initial dossier submission: Dy. No. 6981 dated 22.07.2010 R&I verified. Initial fee Rs. 8000/- paid on 16.07.2010, endorsed on 22.07.2010. Differential fee: Dy. No. 76 dated 3.02.2020. Fee paid Rs. 12000/- vide Slip No. 1927667 dated 31-01-2020, endorsed on 31.01.2020. Duplicate Dossier: Submitted along with differential fee.
	Pharmacological Group	Other antihistamines for systemic use ATC Code: R06AX13
	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	LORATADINE 10MG TABLETS PL 00142/0479 MHRA Approved.
	Me-too status	Jade Tablet Reg. No. 028265 M/s Scotmann Pharmaceuticals
	GMP status	Inspection conducted on 19.11.2021. GMP status is good.
	Remarks of the Evaluator	i. Applied formulation is already registered vide Reg. No. 028265 (jade 10mg tablet). Clarification is required why again is applied. ii. No reference of finished product specifications is given. The monograph of applied product is available in JP. Revision of specs along with fee of Rs.7500/- is required.
	Decision of 326th meeting of Registration Board: Deferred for clarification for applying already registered formulation with different name.	
	Reply submitted by the firm: Firm has submitted that they are submitting the required documents as per decision of 326th meeting and stability data in order to comply with your letter No. 320-DRB/2022 (PE&R) dated 17-10-2022. The details of the submission are as follows; Sr. No. / Brand Name / Composition / Submitted date 1 / Jade Flash tablet 10mg. / Each Oral Dispersible tablet contains; / 16-10-2010	

	Loratadine …….. 10mg 31-01/2020 (JP Specifications) They also submitted 7500/- vide slip No. 31802818 dated 15-03-2023.	
	Evaluation by PEC: • Firm has neither submitted any stability data as mentioned in the above submission. • Loratadine 10 mg Orodispersible Tablets is approved by MHRA, however me too could not be confirmed. • Furthermore, initially submitted label claim was for tablet rather than Orodispersible tablet. • Qualitative composition of the applied formulation is totally different from that of the approved product. • If me too is not available, then full fee for new product along with stability data shall be submitted.	
	Decision: Registration Board deliberated that both formulations (applied and proposed) have the approval status from reference regulatory authiries and the Board did not condsider such requests in past. Accordingly, the Board decided to advise firm to complete the shortcomings of instant application or submit a fresh application for the prodposed revised formulation.	
383.	Name and address of manufacturer/ Applicant	M/s Semos Pharmaceuticals (Pvt.) Ltd., Plot No. 11, Sector 12-A, North Karachi, Karachi (Cream/Ointment).
	Brand Name + Dosage Form + Strength	Mysin 10000 units/ 500 units ointment.
	Composition	Each gram Contains: Polymyxin B sulphate …….. 10,000 units. Bacitracin zinc ……500 units.
	Diary No. Date of R & I & fee	Dy. No 9761 dated 04-03-2019; Rs.20,000 Dated 25-02-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form-5.
	Finished product Specification	Manufacturer's Specifications.
	Pack size & Demanded Price	1's (10gm) & as per SRO.
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed.
	Me-too status	Polyaid Ointment, Trigon Pharmaceutical, Reg. No. 042765.
	GMP status	The firm was inspected on 04-07-2018 by the FID, DRAP, Karachi and concluded that "Based on above observations their current GMP compliance level is rated as GOOD".
	Previous Remarks of the Evaluator	• Applied formulation is Ointment while fee challan is for Mysin 1000/500 units Cream. • Approval status of product in Reference Regulatory Authorities is missing. • The firm has claimed manufacturer's specification, while the official monograph of applied formulation is available in USP & BP.
	Decision of 297th meeting of Registration Board:	Deferred for the following reasons: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Clarification regarding applied formulation as the applied formulation is Ointment while fee challan is for Mysin 1000/500 units Cream.

	Submission of the firm:	Firm submitted following reference product; Bacitracin Zinc and Polymyxin B Sulfate, (500 Units/Gm;10,000 Units/Gm,) Ointment; Ophthalmic, USFDA Approved. • They further clarified that applied formulation is ointment and cream was mistakenly written on fee challan.
	Remarks of the Evaluator PEC-XIII	Submitted reference product is ophthalmic ointment while the firm is having Cream/Ointment general section.
	Decision of 307th meeting of Registration Board: Deferred for following: • Clarification regarding the applied formulation whether ophthalmic ointment or otherwise.	
	Reply submitted by the firm; Firm has clarified that the applied formulation is topical ointment. Firm has also submitted RRA evidence from HPRA, Ireland. Polyfax Ointment, 10,000 IU Polymyxin B Sulphate + 500 IU Bacitracin Zinc. https://www.hpra.ie/img/uploaded/swedocuments/LicenseSPC_PA0585-013-001_29072015115036.pdf	
	Remarks of PEC: Firm has submitted the above mentioned link which shows SPC of the said product (Last updated 2015 Revision of text). However, official database of HPRA does not show this product.	
	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 as the submitted evidence could not be verified from the official website of HPRA, Ireland.	

Agenda of Ms. Maham Misbah

I. New cases of Form 5F

384.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sundar Industrial Estate, Raiwind Road Lahore.**
	Name, address of Manufacturing site.	M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sundar Industrial Estate, Raiwind Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 23768: 27-09-2023
	Details of fee submitted	PKR 30,000/- : 11417511
	The proposed proprietary name / brand name	**GenLin-CR 82.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Extended Release Tablet Contains: Pregabalin…82.5mg
	Pharmacotherapeutic Group of (API)	Analgesics; Gabapentinoids
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	LYRICA CR Tablet (USFDA Approved)
	For generic drugs (me-too status)	Gablin 82.5mg Tablet by CCL

		Pharmaceuticals (Pvt) Ltd. (Reg.No. 123862).
	Proposed Pack size	As per SRO
385.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sundar Industrial Estate, Raiwind Road Lahore.**
	Name, address of Manufacturing site.	M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sundar Industrial Estate, Raiwind Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 23769: 27-09-2023
	Details of fee submitted	PKR 30,000/- : DS No. 76956985602
	The proposed proprietary name / brand name	**GenLin-CR 165mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Extended Release Tablet Contains: Pregabalin…165mg
	Pharmacotherapeutic Group of (API)	Analgesics; Gabapentinoids
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	LYRICA CR Tablet (USFDA Approved)
	For generic drugs (me-too status)	Gablin 165mg Tablet by CCL Pharmaceuticals (Pvt) Ltd. (Reg.No. 123863).
	Proposed Pack size	As per SRO
386.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sundar Industrial Estate, Raiwind Road Lahore.**
	Name, address of Manufacturing site.	M/s Genetics Pharmaceuticals (Pvt) Ltd. 539-A, Sundar Industrial Estate, Raiwind Road Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 23770: 27-09-2023
	Details of fee submitted	PKR 30,000/- : 054840941
	The proposed proprietary name / brand name	**GenLin-CR 330mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Extended Release Tablet Contains: Pregabalin…330mg
	Pharmacotherapeutic Group of (API)	Analgesics; Gabapentinoids
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	LYRICA CR Tablet (USFDA Approved)
	For generic drugs (me-too status)	Gablin 330mg Tablet by CCL

		Pharmaceuticals (Pvt) Ltd. (Reg.No. 123864).
	Proposed Pack size	As per SRO

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings	Response of Applicant and Evaluator's remarks (if any)
1.	2.3.R.2	Executed BMRs of stability batches shall be submitted.	Submitted for both batches.
2.	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.	Submitted.
3.	3.2.P.5.3	In accordance with USP General Chapter 1225 and ICH Q2(R1) guidelines, the results and associated data of following parameters shall be submitted for Analytical method validation: Robustness and intermediate precision (ruggedness).	Submitted.
4.	----------	Clearance documents for imported API(s) shall be submitted.	Applicant has submitted clearance certificate From DRAP, Lahore office No. E-3035761712657 dated 16-10-2022 specifying the import of 100kg Pregabalin from M/s CTX Laboratories, India.

Remarks of Evaluator:

Decision: Approved.

387.	**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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 23478: 22-09-2023
	Details of fee submitted	PKR 75,000/- : 71825174905
	The proposed proprietary name / brand name	**BemPulse 180mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Bempedoic acid…180mg
	Pharmacotherapeutic Group of (API)	Lipid modifying agent
	Reference to Finished product specifications	Innovator's Specifications

	The status in reference regulatory authorities	NEXLETOL Tablet (USFDA Approved)
	For generic drugs (me-too status)	New drug, hence not applicable.
	Proposed Pack size	As per SRO

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings	Response of Applicant and Evaluator's remarks (if any)
1.	2.3.R.2	Executed BMRs of stability batches shall be submitted.	Submitted for batches T-177, T-178 and T-179 having batch size 1000 tablets each.
2.	3.2.P.2.2.1	i. Submit details of reference product including manufacturer's name, batch number etc. ii. According to the Innovator's report, the drug product has low solubility below pH6and high solubility above pH 6. In CDP summary, you have stated that release of test and reference product is more than 90% in pH1.2 and pH 4.5. Justify.	i. Nextletol by Esperion Therapeutics Inc. Batch no. 1850842. Expiry 02-2023. ii. Applicant has submitted that API is a BCS Class II drug. We have perfomed CDP as per guidelines in three different media. Actual results are mentioned in CDP report. Practically it is expected to achieve more than 90% with respect to time in dissolution. *Not justified.*
3.	3.2.P.5.3	In accordance with ICH Q2(R1) guidelines, the robustness of the analytical procedure shall be measured by variation in several parameters. Your protocol and report only describes variation in flow rate. Justify why other parameters were not considered.	Guidelines do not state that we need to cover all the robustness parameters so we

			have covered only one parameter.
4.	3.2.P.7	In the attached CoAs of Aluminium foil, microbial testing results shall also be submitted.	In-house test reports are submitted.

Remarks of Evaluator:

Decision: Registration Board was apprised that the dissolution profile of applied formulation, submitted by firm, in pH 1.2 & pH 4.5 buffer is not as per the solubility profile declard in the innovator drug product literature approved by US FDA. Hence Registration Board decided to defer the application for following:

- **Submission of revised product development to achieve the dissolution profile with reference the innovator drug product literature.**
- **Fee for pre-registration variation, as per SRO as per SRO1324 (I)/2024 dated 30-08-2024.**

388.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura**
	Name, address of Manufacturing site.	M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22606: 14-09-2023
	Details of fee submitted	PKR 30,000/- : 540353890444
	The proposed proprietary name / brand name	**Hydralazine Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml Ampoule Contains: Hydralazine…20mg
	Pharmacotherapeutic Group of (API)	Vasodilator and antihypertensive agent
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Hydralazine HCl 20mg/ml Injection by Zafa Pharmaceutical Lab (Pvt) Ltd (Reg.No. 42157).
	Proposed Pack size	1's, 5's, 10's, 25's

Evaluation by PEC (No.XXIII):

Serial No.	**Module/ Section**	**Shortcomings**
1.	1.5.2	Revise label claim to include salt form as per reference product along with submission of requisite fee.
2.	3.2.S.4.3	Report of Analytical method verification studies conducted by drug product manufacturer shall be submitted.
3.	3.2.P.2.2.1	Pharmaceutical equivalence shall be submitted against all parameters given in USP monograph.

4.	3.2.P.5.3	Analytical method verification report and associated data shall be submitted.
5.	3.2.P.7	The reference product approved by USFDA is supplied in single dose vials whereas the applied product is to be supplied in amber glass ampules. Justify the container used along with evidence.
6.	3.2.P.8	Results and associated data of six-month time point stability studies shall be submitted.

Remarks of Evaluator:

Decision: Deferred for sucmission of response to afore-mentioned shortcomings.

389.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s BJ Pharmaceuticals. 18 Km, Mandialai Stop, Lahore-Sheikhupura Road, Lahore**
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals. 18 Km, Mandialai Stop, Lahore-Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26550 : 03-11-2023
	Details of fee submitted	PKR 30,000/- : Deposit Slip No. 934697469
	The proposed proprietary name / brand name	Levo-Citral 2.5mg/5ml Syrup
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Syrup Contains: Levocetirizine Dihydrochloride…2.5mg
	Pharmacotherapeutic Group of (API)	Antihistamine for systemic use
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Xyzal Oral solution (USFDA Approved)
	For generic drugs (me-too status)	Leviva Syrup 2.5mg/5ml of M/s Titlis Pharmaceuticals Pvt Ltd (Reg No. 078819)
	Proposed Pack size	Needs clarification

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings
1.	**1.3.4**	Copy of valid Drug Manufacturing License (DML) issued by Licensing Division, DRAP shall be submitted along with section approval letter.
2.	**1.3.5**	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.
3.	**3.2.S.4.3**	Analytical method verification report along with associated raw data shall be submitted under the relevant module.
4.	**3.2.S.5.1**	Complete details of reference standard shall be provided.
5.	**3.2.P.8**	Documents for procurement and import of API shall be submitted.
6.	---------	Executed BMRs shall be submitted.

Decision: Deferred for satisfactory response to afore-mentioned shortcomings and restoration of production by QA&LT Division.

390.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s BJ Pharmaceuticals. 18 Km, Mandialai Stop, Lahore-Sheikhupura Road, Lahore**
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals. 18 Km, Mandialai Stop, Lahore-

		Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26551 : 03-11-2023
	Details of fee submitted	PKR 30,000/- : Deposit Slip No. 83406445944
	The proposed proprietary name / brand name	Levo-Citral 5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Levocetirizine Dihydrochloride…5mg
	Pharmacotherapeutic Group of (API)	Antihistamine for systemic use
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	AVCI 5mg Tablet of M/s Biomark (Reg No. 106968)
	Proposed Pack size	As per SRO.

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings
1.	**1.3.4**	Copy of valid Drug Manufacturing License (DML) issued by Licensing Division, DRAP shall be submitted along with section approval letter.
2.	**1.3.5**	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.
3.	**3.2.S.4.3**	Analytical method verification report along with associated raw data shall be submitted under the relevant module.
4.	**3.2.S.5.1**	Complete details of reference standard shall be provided.
5.	**3.2.P.2.2.1**	i. CDP protocol shall be submitted as only results and spectra are submitted. ii. It is noted that you have run 12 samples at 5 minute time point in pH1.2. However, on the spectra provided, only six values have been plotted. Submit complete spectra. iii. Absorbance of each sample shall be submitted. iv. Complete calculations to measure the concentration of each sample shall be submitted.
6.	----------	System suitability testing shall be conducted for finished product testing.
7.	**3.2.P.8**	Documents for procurement and import of API shall be submitted.

Decision: Deferred for submission of response to afore-mentioned shortcomings and restoration of production activities.

391.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above

		(contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25428: 19-10-2023
	Details of fee submitted	PKR 30,000/- : 695348587095
	The proposed proprietary name / brand name	**Tydol IR 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tapentadol Hcl Eq. to Tapentadol…100mg
	Pharmacotherapeutic Group of (API)	Opioid Analgesics
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Tapento IR Tablet by SAMI Pharmaceuticals (Pvt) Ltd. (Reg.No. 109990).
	Proposed Pack size	As per SRO
392.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals (Pvt.) Ltd.** **Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25427: 19-10-2023
	Details of fee submitted	PKR 30,000/- : 4479961498
	The proposed proprietary name / brand name	**Tydol IR 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tapentadol Hcl Eq. to Tapentadol…50mg
	Pharmacotherapeutic Group of (API)	Opioid Analgesics
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Tapento IR Tablet by SAMI Pharmaceuticals (Pvt) Ltd. (Reg.No. 109989).
	Proposed Pack size	As per SRO

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings	Response of applicant/ Remarks of evaluator
1.		Latest GMP inspection report conducted within the last three years shall be submitted.	Applicant has submitted GMP certificate No. 188/2023-DRAP (AD-3489860170) dated 14-11-2023 issued on the basis of evaluation conducted on 03-04-2023 specifying Tablet (General) (Human) section.

2.	3.2.P.5.3	Only one parameter i.e. flow rate is changed during robustness testing in analytical method validation of drug product. Justify.	Guidelines do not state that we need to cover all the robustness parameters so we have covered only one parameter.

Remarks of Evaluator:

Decision: Approved.

393.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat,Lahore**
	Name, address of Manufacturing site.	M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat,Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No. 24350 : 05-10-2023
	Details of fee submitted	PKR 75,000/- : 852380276308
	The proposed proprietary name / brand name	LAMOLIN 600mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Lefamulin as Acetate……..600mg
	Pharmacotherapeutic Group of (API)	Antibacterial
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Xenleta 600mg tablet (USFDA Approved)
	For generic drugs (me-too status)	Not available
	Proposed Pack size	As per SRO

Evaluation by PEC (No.XXIII):

Decision: Approved.

394.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fortune Pharmaceuticals. Plot No K/201, S.I.T.E (SHW) Phase II, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Fortune Pharmaceuticals. Plot No K/201, S.I.T.E (SHW) Phase II, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26383: 01-11-2023
	Details of fee submitted	PKR 30,000/- : 961773622

	The proposed proprietary name / brand name	**Formeco 500mcg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sugar Coated Tablet Contains: Mecobalamin…500µg
	Pharmacotherapeutic Group of (API)	Vitamin B12 (cyanocobalamin and analogues)
	Reference to Finished product specifications	JP Specifications
	The status in reference regulatory authorities	Neumethecol 500mcg Tablet (PMDA Approved)
	For generic drugs (me-too status)	Vitobal 500mcg Tablet by Xenon Pharma. (Reg.No. 113718).
	Proposed Pack size	As per SRO

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings
1.	1.3.5	GMP report of applicant generated against inspection conducted in the last three years shall be submitted.
2.	3.2.P.8	Valid GMP and DML of API manufacturer (M/s Mahima Life Sciences, India) shall be submitted.
3.	---	Executed BMRs of stability batches shall be submitted.

Remarks of Evaluator:

Decision: Deferred for submission of response to afore-mentioned shortcomings.

395.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi.**
	Name, address of Manufacturing site.	M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22604: 14-09-2023
	Details of fee submitted	PKR 75,000/- : 71269415097
	The proposed proprietary name / brand name	**Bepmed 180mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Bempedoic acid…180mg
	Pharmacotherapeutic Group of (API)	Lipid modifying agent
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	NEXLETOL Tablet (USFDA Approved)
	For generic drugs (me-too status)	New drug, hence not applicable.
	Proposed Pack size	As per SRO

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings	Response of applicant/ Remarks of evaluator
1.		Analytical method verification report and associated data of drug substance conducted by drug product manufacturer shall be submitted.	Submitted.
2.	3.2.S.7	Real time stability studies results of 18 month time point of drug substance shall be submitted.	Submitted.
3.	2.3.R.2	Executed BMRs of stability batches shall be submitted.	Submitted.
4.	3.2.P.8	The batch number of drug substance used in the manufacturing of stability studies shall be submitted along with CoA of that batch from drug substance and drug product manufacturer.	COA of Batch No HAN-PM/22002 is submitted from drug substance and drug product manufacturer.

Remarks of Evaluator:

Decision: Approved.

396.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25887: 26-10-2023
	Details of fee submitted	PKR 75,000/- : 2872953616
	The proposed proprietary name / brand name	**Zeegap 20mg/ml Oral Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml oral solution contains: Pregabalin…20mg
	Pharmacotherapeutic Group of (API)	Analgesics; Gabapentinoids
	Reference to Finished product specifications	BP Specifications
	The status in reference regulatory authorities	LYRICA ORAL SOLUTION 20mg/ml (USFDA Approved)
	For generic drugs (me-too status)	New drug, hence not applicable.
	Proposed Pack size	60ml, 100ml, 120ml

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings	Response of applicant
1.	1.3	DML renewal of applicant due in 10-2024 shall be submitted.	DML renewal submitted in Licensing division of DRAP on 01-07-2024 having Tracking ID. GUZ-GJY-EDRP.

2.	3.2.P.8	DRAP attested invoice for clearance of imported raw materials shall be submitted.	Firm has submitted clearance certifcate dated 21-01-2021 from DRAP field office specifying the import of 435kg material imported from M/s Kopran Laboratories, India.
3.	3.2.P.8	Stability studies summary sheets shall be submitted for real time and accelerated stability studies for 6 months.	Submitted for three batches, having batch size 5L each and pack size 60mL.

Remarks of Evaluator:

Decision: Approved.

397.		
	Name, address of Applicant / Marketing Authorization Holder	**M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan**
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22955: 19-09-2023
	Details of fee submitted	PKR 75,000/- : 61683672
	The proposed proprietary name / brand name	**Seipil Oral Solution 20mg/ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml oral solution contains: Pregabalin…20mg
	Pharmacotherapeutic Group of (API)	Analgesics; Gabapentinoids
	Reference to Finished product specifications	BP Specifications
	The status in reference regulatory authorities	LYRICA ORAL SOLUTION 20mg/ml (USFDA Approved)
	For generic drugs (me-too status)	New drug, hence not applicable.
	Proposed Pack size	120ml

Evaluation by PEC (No.XXIII):

Serial No.	**Module/ Section**	**Shortcomings**	**Response of applicant**
1.	3.2.P.8	DRAP attested invoice for clearance of imported raw materials shall be submitted.	Submitted. Details of batch imported are as follows: Batch No. PRGH/P2205039. Mfg 05-22, Expiry 05-26 Manufcaturer: M/s Kopran Laboratories, India.
2.	3.2.P.8	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	Submitted.

Remarks of Evaluator:

Decision: Approved.

398.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan**
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26506: 02-11-2023
	Details of fee submitted	PKR 30,000/- : 646404493296
	The proposed proprietary name / brand name	**Seipil 25mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Pregabalin…25mg
	Pharmacotherapeutic Group of (API)	Analgesics; Gabapentinoids
	Reference to Finished product specifications	BP Specifications
	The status in reference regulatory authorities	LYRICA CAPSULE 25mg (USFDA Approved)
	For generic drugs (me-too status)	Gabica Capsules 25mg by Getz Pharma. (Reg.No. 104290).
	Proposed Pack size	7's, 10's, 14's, 20's, 28's, 30's
Evaluation by PEC (No.XXIII):		
Decision: Approved.		
399.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ipram International. Plot No. 26, S.S 3, National Industrial Zone, Rawat, Rawalpindi**
	Name, address of Manufacturing site.	M/s Ipram International. Plot No. 26, S.S 3, National Industrial Zone, Rawat, Rawalpindi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 27665: 27-11-2023
	Details of fee submitted	PKR 30,000/- : 769133967033
	The proposed proprietary name / brand name	**Ipramol Capsules**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Paracetamol BP…500mg
	Pharmacotherapeutic Group of (API)	Analgesic, Antipyretic
	Reference to Finished product specifications	BP Specifications
	The status in reference regulatory authorities	Paracetamol hard gel capsule (TGA Australia and MHRA Approved)

	For generic drugs (me-too status)	Complete details not submitted.
	Proposed Pack size	12's, 24's, 36's, 102's, 204's

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings
1.	1.3.4	DML renewal of applicant was due from 26-08-2024. Submit copy of valid DML or receiving of DML renewal application submitted in Licensing Division of DRAP.
2.	1.3.5	Copy of GMP certificate or GMP compliance report of applicant issued against inspection conducted within the last three years shall be submitted.
3.	1.5.8	Brand name, Registration number, manufacturer's name of me-too product shall be submitted.
4.	1.5.2 & 1.5.9	Me-too is submitted for gel coated tablets and RRA reference is for hard gelatin capsules (TGA Approved). Dosage form in 1.5.2. is given as hard capsules. Clarify the dosage form and submit RRA reference accordingly.
5.	3.2.S.7	Real time stability studies results of 60 month time point of drug substance shall be submitted.
6.	3.2.S.4.4.	The CoA of drug substance used in the manufacturing of stability studies shall be submitted, from drug substance and drug product manufacturer.
7.	3.2.P.2.2.1	Pharmaceutical Equivalence is submitted against "Panadol Capsule". Details of reference product, including brand name, batch number, manufacturer and DRAP registration number (if applicable), shall be submitted.
8.	--------	Clarify the batch size of the stability batches of drug product. According to BP monograph, system suitability test shall be performed for assay of paracetamol capsule. Submit results of system suitability testing along with daw rata.
9.	2.3.R.2	Executed BMRs of stability batches shall be submitted.

Remarks of Evaluator:

Decision:Deferred for submission of response to afore-mentioned shortcomings.

400.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan.**
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22435: 12-09-2023
	Details of fee submitted	PKR 30,000/- : 09505030227
	The proposed proprietary name / brand name	**Ozerta 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Losartan Potassium…100mg
	Pharmacotherapeutic Group of (API)	Angiotensin II receptor blockers (ARBs), plain
	Reference to Finished product specifications	USP Specifications

	The status in reference regulatory authorities	Losartan Potassium film coated tablet (MHRA Approved)
	For generic drugs (me-too status)	Acozar 100mg Tablet by AGP Limited (Reg.No. 82246).
	Proposed Pack size	As per SRO
401.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winbrains Research Laboratories.** **Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan.**
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22443: 12-09-2023
	Details of fee submitted	PKR 30,000/- : 3045106159
	The proposed proprietary name / brand name	**Ozerta 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Losartan Potassium…50mg
	Pharmacotherapeutic Group of (API)	Angiotensin II receptor blockers (ARBs), plain
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	Losartan Potassium film coated tablet (MHRA Approved)
	For generic drugs (me-too status)	Sartan Tablets 50mg by Barrett Hodgson Pakistan (Pvt) Ltd. (Reg.No. 24251).
	Proposed Pack size	As per SRO

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings
1.	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.
2.	3.2.P.2.2.1	CDP and Pharmaceutical Equivalence is submitted against "Tansin tablets". Details of comparator/reference product, including brand name, batch number, manufacturer and DRAP registration number (if applicable), shall be submitted.
3.	3.2.P.5.3	Summary of results and raw data of analytical method validation is submitted only. The protocol for analytical method validation of drug product shall be submitted.
4.	--------	According to USP monograph, system suitability test shall be performed for assay of losartan potassium tablets. Submit results of system suitability testing along with daw rata.
5.	3.2.P.8	According to the raw data of dissolution of stability batches, it is seen that maximum absorbance is not being achieved at the wavelength specified in USP monograph. Justify.

6.	2.3.R.2	Incomplete BMRs of stability batches are submitted. Complete BMRs shall be submitted along with batch reconciliation and details of steps followed i.e. wet granulation, drying, final mixing, compression, coating, blistering and packing.

Remarks of Evaluator:

Decision: Deferred for submission of response to afore-mentioned shortcomings.

402.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nabi Qasim Industries (Pvt) Ltd 17/24 Korangi Industrial Area, Karachi-Pakistan.**
	Name, address of Manufacturing site.	M/s Nabi Qasim 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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22147 : 08-09-2023
	Details of fee submitted	PKR 75,000/- :
	The proposed proprietary name / brand name	**Gloza 600mg Lyophilized Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Glutathione…600mg
	Pharmacotherapeutic Group of (API)	Antidote
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	TAD 600mg/4ml Powder and solvent for solution for injection Tationil 600 mg/4 ml powder and solvent for solution for injection
	For generic drugs (me-too status)	New drug hence not applicable.
	Proposed Pack size	1's

Evaluation by PEC (No.XXIII):
Label claim shall be revised to include salt form as per reference product along with submission of requisite fee.

Proceedings: The Board was apprised with the innovator's product manufacturing method wherein reduced glutathione is neutralized by sodium bicarbonate until desired pH is achieved. The drug product specifications of innovator drug product include test of sodium content also, the limits of which depends upon the amount of NaHCO3 used during the freeze-drying process in order to have required pH value.

Decision: Registration Board considered the fact that the firm has applied Sodium hydroxide (NaOH) instead of Sodium bicarbonate during formulation process, which is in deviation to the innovator drug product literature and also firm has not provided any reference for the applied manufacturing method, hence the Board decided to approve the above application while firm shall submit following before issuance of registration letter:

- **Full fee for pre-registration variation of change of label claim, as per SRO as per SRO1324 (I)/2024 dated 30-08-2024, according to innovator drug product i.e., *"Each Vial Contains: Glutathione as Sodium (powder for solution for injection)……600mg"***

- **Revised product development studies wherein manufacturing method shall include neutralisation of L-Glutathione reduced by sodium bicarbonate, for conversion into Glutathione sodium along with drug product stability studies data for newly manufactured stability batches till 3rd month time point at both accelerated and long term stability conditions.**
- **Drug product specifications including test of "Sodium content".**

403.	**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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 23860 : 28-09-2023
	Details of fee submitted	PKR 45,000/- : PKR 30,000/- :
	The proposed proprietary name / brand name	Siti-Gluta 600mg Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Glutathione as Sodium…600mg
	Pharmacotherapeutic Group of (API)	Antidote
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	TAD 600mg/4ml Powder and solvent for solution for injection Tationil 600 mg/4 ml powder and solvent for solution for injection (AIFA Italy approved)
	For generic drugs (me-too status)	New drug hence not applicable.
	Proposed Pack size	10ml glass vial x1's, 10ml glass vial x 10's

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings
1.	1.3.5	DML renewal of applicant was due in 10-24. Submit copy of valid DML.
2.	3.2.S	You are importing lyophilized material. Clarify the section in which the applied product shall be manufactured and submit its approval from Licensing Division, DRAP.
3.	3.2.S.7	Long term stability data shall be submitted as per zone Iva conditions.
4.	3.2.P.8	Results and associated data of real time and accelerated stability studies for six-month time point shall be submitted.
5.	3.2.R.1	Filled BMRs of stability batches shall be submitted.

Decision: Deferred for submission of response to afore-mentioned shortcomings.

404.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Nabi Qasim Industries (Pvt) Ltd 17/24 Korangi Industrial Area, Karachi-Pakistan.**

	Name, address of Manufacturing site.	M/s Nabi Qasim 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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26554 : 03-11-2023
	Details of fee submitted	PKR 75,000/- : 99375817992
	The proposed proprietary name / brand name	Reline 25mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Sertraline Hcl Eq. to Sertraline…25mg
	Pharmacotherapeutic Group of (API)	Antidepressant
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	New drug hence not applicable.
	Proposed Pack size	10's, 20's, 28's, 30's

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings	Response of applicant
1.	3.2.S.7	Accelerated stability studies data of drug substance shall be submitted.	Submitted.
2.	3.2.P.8	Results of long term and accelerated stability studies shall be submitted for six-month time point.	Submitted.

Decision: Approved.

405.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Name, address of Manufacturing site.	M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25299 : 18-10-2023
	Details of fee submitted	PKR 30,000/- : 04035253
	The proposed proprietary name / brand name	ARZENA 30mg Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Artesunate…30mg
	Pharmacotherapeutic Group of (API)	Antimalarial
	Reference to Finished product specifications	International Pharmacopoeial Specifications

	The status in reference regulatory authorities	WHO approved formulation
	For generic drugs (me-too status)	GEN-M 30MG INJECTION By M/s Genix (Reg. No. 76072)
	Proposed Pack size	As per SRO
406.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan**
	Name, address of Manufacturing site.	M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25300 : 18-10-2023
	Details of fee submitted	PKR 30,000/- : 91952782
	The proposed proprietary name / brand name	ARZENA 60mg Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Artesunate (Intl Pharmacopeia)…60mg
	Pharmacotherapeutic Group of (API)	Antimalarial
	Reference to Finished product specifications	International Pharmacopoeia Specifications
	The status in reference regulatory authorities	WHO approved formulation
	For generic drugs (me-too status)	GEN-M 60MG INJECTION By M/s Genix (Reg. No. 47630)
	Proposed Pack size	As per SRO

Evaluation by PEC (No.XXIII):

Serial No.	Shortcomings
1.	API manufacturer stated in S part is Arihantham whereas material is procured from Metro Chem, India. Clarify and submit S part accordingly.
2.	Analytical method verification report of API by drug product manufacturer shall be submitted
3.	Clarify the batch of API used in manufacturing of stability batches and submit its CoA from drug substance and drug product manufacturer.
4.	What measures were adopted during manufacturing to ensure that if tested, the product shall comply with the limits of water content as given in the drug product monograph.
5.	Give details of the reference standard used for product testing

Decision: Deferred for submission of response to afore-mentioned shortcomings.

407.	**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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26372: 31-10-2023
	Details of fee submitted	PKR.75,000/-: 114970085 PKR.75,000/-: 185424586560
	The proposed proprietary name / brand name	**Difectro 240mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Dimethyl Fumarate Delayed Release Pellets Eq. to Dimethyl Fumarate…240mg
	Pharmacotherapeutic Group of (API)	Immunosuppressant
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Tecfidera (USFDA Approved)
	For generic drugs (me-too status)	New drug product, hence not applicable.
	Proposed Pack size	As per SRO
408.	**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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 26371: 31-10-2023
	Details of fee submitted	PKR.150,000/-: 640668807795 PKR.75,000/-: 97738399060
	The proposed proprietary name / brand name	**Difectro 120mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Dimethyl Fumarate Delayed Release Pellets Eq. to Dimethyl Fumarate…120mg
	Pharmacotherapeutic Group of (API)	Immunosuppressant
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Tecfidera (USFDA Approved)
	For generic drugs (me-too status)	New drug product, hence not applicable.
	Proposed Pack size	As per SRO
Evaluation by PEC (No.XXIII):		

Serial No.	Module/ Section	Shortcomings	Response of applicant
1.	1.3.4	DML renewal of applicant was due from 02-02-2024. Submit copy of valid DML or receiving of DML renewal application submitted in Licensing Division of DRAP.	Application for renewal of DML has been sumitted in Licenisng Division having Tracking ID 8Y3-7UJ-9ZMU in 12-2023.
2.	1.3.5	Copy of GMP certificate or GMP compliance report of applicant issued against inspection conducted within the last three years shall be submitted.	Applicant has submitted DML renewal report. Inspection was conducted ion 14-10-2021. *Copy of GMP certificate or GMP compliance report of applicant issued against inspection conducted* ***within the last three years*** *shall be submitted.*
3.	3.2.P.5.2	For assay and dissolution testing, innovator has specified UV-PDA detection at 223nm. In chromatographic conditions submitted by applicant, the detector is written as "210nm". Clarify the detector used, give evidence of its availability and justify the difference in wavelength from innovator's data.	We have taken the wavelength 210nm from manufacturer's method and have performed the validation studies which provided the reliable results and peak purity at PDA detector.
4.	3.2.P.5.3	Analytical method verification report is submitted for product. As the applicant has claimed innovator's specifications, analytical method validation studies report of drug product shall be submitted.	Submitted.
5.	3.2.P.8	Documents for procurement of API and clearance certificate issued by DRAP shall be submitted.	Applicant has submitted clearance certificate dated 21-06-23 issued by DRAP field office specifying import of dimethyl fumarate pellets.
6.	3.2.P.8	Results of long term and accelerated stability studies shall be submitted for six-month time point.	Submitted.
7.	2.3.R.2	According to the submitted BMRs of stability batches, in process tests for disintegration has not been conducted whereas it has been recommended in the innovator's literature. Justify.	Our product is delayed release pellets filled in capsule shells. So we have performed the dissolution test while we have performed the disintegration test of empty shells during in-process testing.

Remarks of Evaluator: Source of pellets:
M/s Sionc Pharmceutical Pvt Ltd. Plot No. 34A, Road 1, JN Pharma City, Parwada, Thanam (V), Vishakhapatnam-5310211, Andhra Pradesh, India.

Decision: Approved. Firm shall submit following before issuance of registration letter:

- **IQ, OQ & PQ reports of HPLC equipped with PDA detector.**
- **Differential fee for import of pellets as per SRO 1324(I)/2024 dated 30-08-2024.**

Manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of this drug.

409.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No. 25416: 19-10-2023
	Details of fee submitted	PKR 30,000/- : 71069490
	The proposed proprietary name / brand name	CLOZZA 25mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Uncoated Tablet Contains: Clozapine…25mg
	Pharmacotherapeutic Group of (API)	Antipsycotic
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Ekloz 25 mg Tablets by M/s Wnsfeild (Reg. No. 78444)
	Proposed Pack size	As per SRO
410.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No. 26274 : 31-10-2023
	Details of fee submitted	PKR 30,000/- : 0312690979
	The proposed proprietary name / brand name	CLOZZA 50mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Uncoated Tablet Contains: Clozapine…50mg
	Pharmacotherapeutic Group of (API)	Antipsycotic
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Cannot be verified from database
	Proposed Pack size	As per SRO

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings
1.	1.5.9	Submit me-too status of 50mg strength
2.	3.2.S.7	Long term stability data is submitted for 2 batches only. Submit long term stability data for at least three batches.

Decision: Deferred for satisfactory response to afore-mentioned shortcomings.

411.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No. 25303: 18-10-2023
	Details of fee submitted	PKR 30,000/- : 7675026282
	The proposed proprietary name / brand name	Clozin 25mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Uncoated Tablet Contains: Clozapine…25mg
	Pharmacotherapeutic Group of (API)	Antipsycotic
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Ekloz 25 mg Tablets by M/s Wnsfeild (Reg. No. 78444)
	Proposed Pack size	As per SRO
412.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan**
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No. 25304: 18-10-2023
	Details of fee submitted	PKR 30,000/- : 94072495235
	The proposed proprietary name / brand name	Clozin 50mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Uncoated Tablet Contains: Clozapine…50mg
	Pharmacotherapeutic Group of (API)	Antipsycotic
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Cannot be verified from database

	Proposed Pack size	As per SRO

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings
1.	1.5.9	Submit me-too status of 50mg strength
2.	3.2.S.7	Long term stability data is submitted for 2 batches only. Submit long term stability data for at least three batches.
3.	3.2.P.8	Documents for procurement of API shall be submitted.

Decision: Deferred for satisfactory response to afore-mentioned shortcomings.

413.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25294: 18-10-2023
	Details of fee submitted	PKR 30,000/- : 3894189016
	The proposed proprietary name / brand name	Tofocib 5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tofacitinib Citrate Eq. to Tofacitinib…5mg
	Pharmacotherapeutic Group of (API)	Immunosuppressant
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Xeljanz 5mg tablet, Manufactured by apf Prism CV. USFDA Approved.
	For generic drugs (me-too status)	Tofajak Tablet by M/s Hiranis Pharmaceuticals (Reg No. 110057)
	Proposed Pack size	As per SRO

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings	Response of applicant
1.	2.3.S.1.3	Which Polymorphic form of Tofacitinib Citrate is used.	Only one polymorph exists. Polymorphic Form A is used.
2.	3.2.S.4	Detailed analytical procedures from drug substance manufacturer shall be provided for the testing of drug substance.	Submitted.
3.	3.2.S.7	Stability studies data shall be submitted for at least three batches according to Zone Iva conditions.	Submitted.
4.	3.2.P.5.1	US FDA review document of the Innovator product, specifies the dissolution limit as "NLT Q in 15 minutes" whereas submitted specifications declare the dissolution limits as "NLT 80% in 30 minutes". Clarification is required.	Limit is revised as per innovator. *Applicant shall submit testing results at next time interval of stability testing.*

5.	3.2.P.5.2	Analytical procedure is submitted for assay only. Complete analytical procedure of finished product shall be submitted.	Submitted.
6.	3.2.P.5.3	All parameters of method validation shall be included in the method validation report.	Submitted.
7.	3.2.P.8	Results and associated data of real time and accelerated stability studies for six-month time point shall be submitted.	Submitted.
8.	----------	Filled BMRs of stability batches shall be submitted.	Submitted.

Decision: Approved. Applicant shall submit satisfactory dissolution testing results at next time interval of stability testing, before issuance of registration letter.

Firm shall submit following before issuance of registration letter:

- **Stability studies of next time point of long term stability studies wherein performance of dissolution test must be performed as per the innovator drug product limits.**
- **Fee of Rs. 9000/- for pre-approval variation in drug product specifications as per SRO 1324(I)/2024 dated 30-08-2024**

Manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of this drug.

414.	**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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 23856: 28-09-2023
	Details of fee submitted	PKR 75,000/- : 9932505792
	The proposed proprietary name / brand name	Lulican 1% Cream
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram Contains: Luliconazole…1%
	Pharmacotherapeutic Group of (API)	Anti fungal
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	LUZU (luliconazole) Cream, 1% for topical use USFDA Approved.
	For generic drugs (me-too status)	Not applicable
	Proposed Pack size	30gm, 60gm; As per SRO

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings	Response of applicant
1.	3.2.P.2.2.1	Pharmaceutical equivalence report shall be submitted.	Submitted against Luzu Cream 1% manufactured by Bausch Health Companies Inc, Cananda.

2.	3.2.P.8	Documents for procurement of API shall be submitted.	Applicant has submitted Form 6 dated 04-08-2022 for import of API. The license is issued by relevant field office of DRAP.
3.	3.2.P.5.1	Viscosity and Particulate Matter is not given in product specifications. Justify.	EXPLANATION FOR VISCOSITY TEST: Luliconazole Cream is local-action, formulated to deliver active ingredients to a specific site rather than for systemic or cosmetic purposes. Local-action creams do not need to meet user preferences for texture or feel, which viscosity often influences. Furthermore, FDA literature for Luzu (Luliconazole) cream, 1%, summary of CMC assessment & stability data does not define viscosity test. Although reviewer addressed to post submission but not concluded. USP General chapter EXPLANATION FOR PARTICULATE MATTER: Local-action creams are applied externally to the skin, where the presence of particulate matter does not pose the same risks as in injectable or ophthalmic products. Furthermore, USP defined this test only in "(1) INJECTIONS AND IMPLANTED DRUG PRODUCTS (PARENTERALS PRODUCT QUALITY TESTS". **Remarks of evaluator:** *According to USP General Chapter (3) TOPICAL AND TRANSDERMAL DRUG PRODUCTS—PRODUCT QUALITY TESTS, "SPECIFIC TESTS FOR TOPICALLY APPLIED SEMISOLID DRUG PRODUCTS" include test for apparent viscosity.*
Decision: Approved. Applicant shall revise finished product specifications to include viscosity, along with submittion of prescribed fee, prior to issuance of registration letter.			

II. Deferred cases of Form 5F-CTD

415.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Neutro Pharma (Pvt) Ltd. 9.5km Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd. 9.5km Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 29851: 21-10-2022
	Details of fee submitted	PKR 30,000/- : DS No. 89201210
	The proposed proprietary name / brand name	SINCALCET 30mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet Contains: Cinacalcet Hydrochloride ……30mg
	Pharmacotherapeutic Group of (API)	Other anti-parathyroid agents
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	14's, 28's, 84's
	The status in reference regulatory authorities	Sensipar (USFDA Approved)
	For generic drugs (me-too status)	Not available
416.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Neutro Pharma (Pvt) Ltd. 9.5km Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd. 9.5km Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 29850: 21-10-2022
	Details of fee submitted	PKR 30,000/- : DS No. 45011133195
	The proposed proprietary name / brand name	SINCALCET 60mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet Contains: Cinacalcet Hydrochloride ……60mg
	Pharmacotherapeutic Group of (API)	Other anti-parathyroid agents
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	14's, 28's, 84's
	The status in reference regulatory authorities	Sensipar (USFDA Approved)
	For generic drugs (me-too status)	Not available
417.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Neutro Pharma (Pvt) Ltd. 9.5km Sheikhupura Road, Lahore.**

	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd. 9.5km Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 29851: 21-10-2022
	Details of fee submitted	PKR 30,000/- : DS No. 4237851354
	The proposed proprietary name / brand name	SINCALCET 90mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet Contains: Cinacalcet Hydrochloride ……90mg
	Pharmacotherapeutic Group of (API)	Other anti-parathyroid agents
	Reference to Finished product specifications	Innovator's specification
	Proposed Pack size	14's, 28's, 84's
	The status in reference regulatory authorities	Sensipar (USFDA Approved)
	For generic drugs (me-too status)	Not available

Evaluation by PEC (No. XXIII):

Sections	Observations/Deficiencies/ Short-comings
----------	Clarify the enantiomer of API.
1.5.2	The reference product contains 30mg, 60mg, 90mg equivalent base of Cinacalcet HCl. The label claim shall be changed according to the reference product along with full fee of registration.
1.5.8	Me-too for Cinacalcet 90mg is not available. It shall be applied as a new drug product and differential fee of Rs. 45000/- shall be submitted.
----------	The yield of stability batches given in BMRs is as low as 48% percent. E.g. 16 packs of 30's were placed for stability studies of Cinacalcet 30mg. Justify. Also justify how this quantity is sufficient to conduct testing of stability batches throughout the proposed shelf life of the drug product.
3.2.S.4.3	Raw data and chromatograms of Analytical method verification of API conducted by drug product manufacturer shall be submitted.
3.2.P.5	The dissolution specifications are given as NLT 70 % after 15 minutes and NLT 80% (Q) after 45minutes. Justification shall be submitted. The method of analysis must be validated according to ICH guidelines and report and *associated data* of validation shall be submitted.
3.2.P.2.2.1	CDP is performed using UV Visible spectrophotometer instead of HPLC. Justify. Provide complete details of the product (including brand name, strength, manufacturer's name) against which pharmaceutical equivalence and CDP is conducted.
3.2.P.8	Material imported against clearance certificate issued by DRAP dated 18-07-18 specifying 2kg API has previously been utilized in stability batches and data of the same was presented in 296th meeting of RB. Complete consumption details of the imported material shall be submitted as it has been used in the manufacturing of current and previous stability batches for all three strengths.

Decision of 336th meeting: Deferred for submission of satisfactory response to above-cited shortcomings.

Remarks of Evaluator:

Serial No.	Sections	Observations/Deficiencies/ Short-comings	Response of applicant
1.	----------	Clarify the enantiomer of API.	R enantiomer is used which is same as innovator.
1.	**1.5.2**	The reference product contains 30mg, 60mg, 90mg equivalent base of Cinacalcet HCl. The label claim shall be changed according to the reference product along with full fee of registration.	*Fee for change of label claim shall be submitted for all three products.*
2.	**1.5.8**	Me-too for Cinacalcet 90mg is not available. It shall be applied as a new drug product and differential fee of Rs. 45000/- shall be submitted.	Submitted. DS No. 69369068.
3.	----------	The yield of stability batches given in BMRs is as low as 48% percent. E.g. 16 packs of 30's were placed for stability studies of Cinacalcet 30mg. Justify. Also justify how this quantity is sufficient to conduct testing of stability batches throughout the proposed shelf life of the drug product.	Low yield is due to compression machine adjustments. Reconciliation of 480tablets for stability studies is submitted.
4.	**3.2.S.4.3**	Raw data and chromatograms of Analytical method verification of API conducted by drug product manufacturer shall be submitted.	Submitted
5.	**3.2.P.5**	The dissolution specifications are given as NLT 70 % after 15 minutes and NLT 80% (Q) after 45minutes. Justification shall be submitted. The method of analysis must be validated according to ICH guidelines and report and *associated data* of validation shall be submitted.	Dissolution specifications are revised to single point (Q=75%). *Dissolution time shall also be included in the limit.* *Validation of the assay method for finished product is not submitted.*
6.	**3.2.P.2.2.1**	CDP is performed using UV Visible spectrophotometer instead of HPLC. Justify. Provide complete details of the product (including brand name, strength, manufacturer's name) against which pharmaceutical equivalence and CDP is conducted.	As product is Innovator's specifications so we performed dissolution on UV using a validated method. Firm has committed to using HPLC method in case of commercial batches.
7.	**3.2.P.8**	Material imported against clearance certificate issued by DRAP dated 18-07-18 specifying 2kg API has previously been utilized in stability batches and data of the same was presented in 296th meeting of RB. Complete consumption details of the imported material shall be submitted as it has been used in the manufacturing of current and previous stability batches for all three strengths.	Submitted.

Decision of 340th meeting of RB: Deferred for submission of following:

- Pre-registration fee for change of label claim for all three strengths,
- Limit of dissolution and,
- validation protocol, associated data and report of assay method for finished product as per HPLC method.

Response of applicant

Serial No.	Observations/Deficiencies/ Short-comings	Response of applicant
1.	Pre-registration fee for change of label claim for all three strengths	*Not submitted*
2.	Limit of dissolution	Revised.
3.	Validation protocol, associated data and report of assay method for finished product as per HPLC method	Submitted

Decision: Approved. Applicant shall submit following prior to issuance of registration letter:

- **Prescribed fee for change of label claim of all three strengths a as per SRO 1324(I)/2024 dated 30-08-2024.**
- **Dissolution test resuts at next time interval of long term stability studies.**

418.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No. 19392 : 04-08-2023
	Details of fee submitted	PKR 30,000/- : 689688645138
	The proposed proprietary name / brand name	**MIZTA 30mg tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Mirtazipine ……30 mg
	Pharmacotherapeutic Group of (API)	Anti-depressant
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	Mirtazapine 30mg Tablets Wockhardt UK (MHRA Approved)
	For generic drugs (me-too status)	Mirtazameron Tablet 30mg by M/s Akson Pharmaceuticals (Pvt) Ltd (Reg. No. 81646)
	Proposed Pack size	As per SRO
419.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No. 19393 : 04-08-2023
	Details of fee submitted	PKR 30,000/- : 34894790721
	The proposed proprietary name / brand name	**MIZTA 45mg tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Mirtazipine ……45 mg
	Pharmacotherapeutic Group of (API)	Anti-depressant
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	Mirtazapine 45mg Tablets Wockhardt UK (MHRA Approved)
	For generic drugs (me-too status)	Mirtazep 45mg Tablet by M/s Zafa Pharmaceuticals (Pvt) Ltd (Reg. No. 110105)
	Proposed Pack size	As per SRO

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings
1.	3.2.S.7	According to CoA of raw material Batch No. MZI0520025 (Mfg date 10-21, Expiry date 10-26) submitted in 3.2.S.4.4, the shelf life assigned to the API is 5 years. Real time stability studies data of three batches of API are submitted for 18 months only. Stability studies results and data of API shall be submitted for the complete assigned shelf life (5 years).
2.	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.
3.	3.2.P.8	DRAP attested invoice for clearance of imported raw material shall be submitted.

Decision of 340th meeting of RB: Deferred for submission of satisfactory response to afore-mentioned shortcomings.

Response of applicant:

Serial No.	Module/ Section	Shortcomings	Response of applicant
1.	3.2.S.7	According to CoA of raw material Batch No. MZI0520025 (Mfg date 10-21, Expiry date 10-26) submitted in 3.2.S.4.4, the shelf life assigned to the API is 5 years. Real time stability studies data of three batches of API are submitted for 18 months only. Stability studies results and data of API shall be submitted for the complete assigned shelf life (5 years).	Submitted.
2.	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.	Revised master formulation is submitted.
3.	3.2.P.8	DRAP attested invoice for clearance of imported raw material shall be submitted.	Form 6 is submitted. *Clearance*

		certificate is not submitted
Decision: Deferred for confirmation / provisionof import invoice and goods declaration document as evidence of import of raw material.		
420.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No. 16613 : 04-07-2023
	Details of fee submitted	PKR 75,000/- : 859909619
	The proposed proprietary name / brand name	LAMOLIN 600mg tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Lefamulin as Acetate……..600mg
	Pharmacotherapeutic Group of (API)	Antibacterial
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Xenleta 600mg tablet (USFDA Approved)
	For generic drugs (me-too status)	Not available
	Proposed Pack size	As per SRO

Evaluation by PEC (No.XXIII):

Serial No.	Module/ Section	Shortcomings
1.	3.2.S.7	According to CoA of raw material submitted in 3.2.S.4.4, the shelf life assigned to the API is 3 years. Real time stability studies data of three batches of API are submitted for 2 years only. Stability studies results and data of API shall be submitted for the complete assigned shelf life (3 years).
2.	3.2.P.5.1	Justify with evidence the limit of dissolution as NLT Q in 75 minutes whereas the innovator's limit is set at NLT Q in 60 minutes.
3.	3.2.P.8	DRAP attested invoice for clearance of imported raw material shall be submitted.

Decision of 340th meeting of RB: Deferred for submission of satisfactory response to afore-mentioned shortcomings.

Response of applicant:

Serial No.	Module/ Section	Shortcomings	Response of applicant
1.	3.2.S.7	According to CoA of raw material submitted in 3.2.S.4.4, the shelf life assigned to the API is 3 years. Real time stability studies data of three batches of API are submitted for 2 years	Submitted.

		only. Stability studies results and data of API shall be submitted for the complete assigned shelf life (3 years).	
2.	3.2.P.5.1	Justify with evidence the limit of dissolution as NLT Q in 75 minutes whereas the innovator's limit is set at NLT Q in 60 minutes.	It was a typographical error. Revised SAP is submitted.
3.	3.2.P.8	DRAP attested invoice for clearance of imported raw material shall be submitted.	Not submitted.

Decision: Deferred for confirmation of following documents: DRAP attested invoice for clearance of imported raw material or any other document as proof of import of raw material;

- **Dissolution test resuts at next time interval of stability studies.**

421.	**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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 19525: 07-08-2023
	Details of fee submitted	PKR 30,000/- : 191633990
	The proposed proprietary name / brand name	IROSAC 100mg/ 5mL
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Polysaccharide Iron Complex Eq. to Elemental Iron…100mg
	Pharmacotherapeutic Group of (API)	Anti anaemic
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Not applicable
	For generic drugs (me-too status)	Irotit 100mg/5ml Syrup By M/s Titlis Pharma (Reg. No. 110606)
	Proposed Pack size	As per SRO

Evaluation by PEC (No.XXIII):

Serial No.	**Module/ Section**	**Shortcomings**
1.		DML of applicant was issued wef 03-02-2019. Valid DML shall be submitted along with approval from DRAP to manufacture iron polysaccharide complex raw material.
2.	3.2.P.1	Sorbitol Solution is used in the formulation. Submit COA of Sorbitol solution mentioning test results for EG, DEG impurities from excipient manufacturer and from drug product manufacturer.
3.	3.2.S.4	Detailed analytical procedures from drug substance manufacturer shall be provided for the testing of drug substance.
4.	3.2.P.8	Results and associated data of real time and accelerated stability studies for six-month time point shall be submitted.
5.	3.2.R.1	Filled BMRs of stability batches shall be submitted.

Decision of 340th meeting of RB: Deferred for submission of satisfactory response to afore-mentioned shortcomings.

Response of applicant:

Serial No.	Module/ Section	Shortcomings	Response of applicant
1.		DML of API manufacturer was issued wef 03-02-2019. Valid DML shall be submitted along with approval from DRAP to manufacture iron polysaccharide complex raw material.	*Not submitted*
2.	3.2.P.1	Sorbitol Solution is used in the formulation. Submit COA of Sorbitol solution mentioning test results for EG, DEG impurities from excipient manufacturer and from drug product manufacturer.	*Test report of Sorbitol solution from CDL has been submitted.*
3.	3.2.S.4	Detailed analytical procedures from drug substance manufacturer shall be provided for the testing of drug substance.	Submitted.
4.	3.2.P.8	Results and associated data of real time and accelerated stability studies for six-month time point shall be submitted.	Submitted.
5.	3.2.R.1	Filled BMRs of stability batches shall be submitted.	Submitted for following two batches manufactured on 12-22 having batch size 2000 bottles each: IPSC-01, IPSC-02

Decision: Approved.

422.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s News Pharma, 42-Sundar Industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s News Pharma, 42-Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 2103: 23-01-2023
	Details of fee submitted	PKR 30,000/- : DS No.: 652192266025
	The proposed proprietary name / brand name	**NEWS-GOR Syrup 0.25mg/5mL**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Syrup Contains: Pizotifen (as Hydrogen Malate)…0.25mg
	Pharmacotherapeutic Group of (API)	Analgesics (Anti migraine)
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	60ml, 90ml, 120ml
	The status in reference regulatory authorities	Sanomigran Elixir (MHRA Approved)

	For generic drugs (me-too status)	Pizosrch 0.25mg/5ml Syrup of M/s Medisearch Pharmacal (Pvt) Ltd (Reg. No. 113334)

Evaluation by PEC (No.XXIII):

Sr. No.	Module/Section	Observations/Deficiencies/ Short-comings
1.		DML of applicant was issued/renewed on 18-02-2018. DML renewal due in 2023 shall be submitted.
2.	3.2.P.1	The reference product is an *elixir* with the following excipients: Raspberry flavour 50969, maraschino flavour, methyl hydroxybenzoate, propyl hydroxybenzoate, citric acid (anhydrous), disodium phosphate (anhydrous), maltitol liquid, ethanol 96% and purified water. However, the master formulation of applied product contains the following excipients and applicant has claimed that it is a syrup: Sorbitol solution at 70 % (non-crystallizing), Glycerol, Propylene glycol (PG), Saccharin sodium, Methyl Paraben sodium, Propyl Paraben sodium, Chocolate Liquid flavor, Sodium Citrate and Purified water. i. Justify the use of qualitatively different excipients than the reference product and submit excipient compatibility studies. ii. Also clarify whether the applied and reference products are syrups or elixirs with clear scientific rationale. iii. Composition of the Drug Product includes Glycerine/Glycerol, Sorbitol and Propylene Glycol. In light of DRAP's letter/advisory No.F.3-41/2023-QC dated 01-12-2023, applicant shall submit following details for the three excipients: • Vendor name, specifications, CoAs by respective vendor(s) as well as in-house batch analysis results, including test results for EG and DEG impurities.
3.	3.2.R.1 & 3.2.P.1	Submit data in section 3.2.P.1 and BMRs as per the guidance document approved by Registration Board and available on DRAP website which specifies that "If the Drug product is formulated using an active moiety, then the composition for the active ingredient shall be clearly indicated (e.g. "1 mg of active ingredient base = 1.075 mg active ingredient hydrochloride)".
4.	3.2.P.5.3	Analytical Method Validation report of drug product with results and associated data of "Robustness" shall be submitted.

Decision in 336th meeting of RB: Deferred for submission of satisfactory response to above-cited shortcomings.

Reply of applicant

Sr. No.	Module/Section	Observations/Deficiencies/ Short-comings	Response of applicant
1.		DML of applicant was issued/renewed on 18-02-2018. DML renewal due in 2023 shall be submitted.	Copy of valid DML is submitted.
2.	3.2.P.1	The reference product is an *elixir* with the following excipients:	Reference product is also approved as syrup by AEMPS, Spain. Developed

		Raspberry flavour 50969, maraschino flavour, methyl hydroxybenzoate, propyl hydroxybenzoate, citric acid (anhydrous), disodium phosphate (anhydrous), maltitol liquid, ethanol 96% and purified water. However, the master formulation of applied product contains the following excipients and applicant has claimed that it is a syrup: Sorbitol solution at 70 % (non-crystallizing), Glycerol, Propylene glycol (PG), Saccharin sodium, Methyl Paraben sodium, Propyl Paraben sodium, Chocolate Liquid flavor, Sodium Citrate and Purified water. iv. Justify the use of qualitatively different excipients than the reference product and submit excipient compatibility studies. v. Also clarify whether the applied and reference products are syrups or elixirs with clear scientific rationale. vi. Composition of the Drug Product includes Glycerine/Glycerol, Sorbitol and Propylene Glycol. In light of DRAP's letter/advisory No.F.3-41/2023-QC dated 01-12-2023, applicant shall submit following details for the three excipients: • Vendor name, specifications, CoAs by respective vendor(s) as well as in-house batch analysis results, including test results for EG and DEG impurities.	product has same excipients as the reference product approved in Spain. Details of Glycerine/Glycerol, Sorbitol and Propylene Glycol are submitted.
3.	3.2.R.1 & 3.2.P.1	Submit data in section 3.2.P.1 and BMRs as per the guidance document approved by Registration Board and available on DRAP website which specifies that "If the Drug product is formulated using an active moiety, then the composition for the active ingredient shall be clearly indicated (e.g. "1 mg of active ingredient base = 1.075 mg active ingredient hydrochloride)".	Submitted
4.	3.2.P.5.3	Analytical Method Validation report of drug product with results and associated data of "Robustness" shall be submitted.	Submitted

Decision: Approved.

423.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Fassgen Pharmaceuticals Plot # 67/1 Block-A Phase III, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	M/s Winlet Pharmaceuticals Pvt Ltd, 30km Lahore Sargodha Road, Sargodha.
	Status of the applicant	☐ Manufacturer ☐ Importer

		☒ Is involved in none of the above (contract giver) (Contract manufacturing agreement between both firms dated 10-04-2022 is provided)
	GMP status of the firm	GMP certificate of the contract acceptor is not submitted.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 26-02-2018 specifying Liquid 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 32010 dated 07-11-2022
	Details of fee submitted	PKR 75,000/- Deposit Slip No. 7727370183
	The proposed proprietary name / brand name	**VENSET 4mg/5ml Syrup**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml syrup contains: Ondensetron Hydrochloride equivalent to Ondensetron …… ……4mg
	Pharmacotherapeutic Group of (API)	Anti-emetics and Anti-nauseants
	Pharmaceutical form of applied drug	Transparent Syrup
	Reference to Finished product specifications	USP Specifications
	Proposed Pack size	30ml & 60ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ondensetron Syrup (MHRA Approved)
	For generic drugs (me-too status)	Dantron Oral Solution of M/s Shrooq Pharmaceuticals (Pvt) Ltd, Lahore. (Reg. No. 77076)
	Name and address of API manufacturer.	Aungraha Chemicals, No. D-47 to 50, C-62 & C-63, KSSIDC, Industrial Esate, Doddaballapur, Bengaluru, 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, 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, solubilities, physical form, 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.
	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, verification 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 reference product Onseron Syrup. CDP is not applicable.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for drug product.

STABILITY STUDY DATA

Manufacturer of API	Anugraha Chemicals, No. D-47 to 50, C-62 & C-63, KSSIDC, Industrial Esate, Doddaballapur, Bengaluru, India.		
API Lot No.	AR/078/19 in Batch No.s 003 & 004. AR/149/20 in Batch No. 005		
Description of Pack (Container closure system)	Amber coloured glass bottle with aluminium cap		
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.	003	004	005
Batch Size	10000 packs	10000 packs	10000 packs
Manufacturing Date	11-2020	03-2021	05-2021
Date of Initiation	17-11-2020	11-03-2021	28-05-2021

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)	Not submitted.
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.CI-I/CR-1884/18-19 dated 16-02-2019 issued by Drugs Control Department, Government of Karnataka. The certificate specifies that the firm is operating at satisfactory level of GMP compliance. The certificate was valid for one year from the date of issue.
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 analytical record for product testing.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm has not submitted certificate of 21 CFR compliance for the HPLC system and audit trail report for 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 and humidity monitoring of real time and accelerated stability chambers.

Remarks of Evaluator[xxiii]:

Sr. No.	**Sections**	**Observations/Deficiencies/ Short-comings**
1.	**1.3.4**	DML of M/s Winlet Pharmaceuticals (Pvt) Ltd is dated 21-02-2018. Copy of valid DML issued by Licensing Division of DRAP shall be submitted.
2.	**1.3.5**	GMP inspection report/ GMP certificate of the manufacturing unit/ contract acceptor issued within the last three years shall be submitted.
3.	**3.2.S.4**	Analytical method verification of drug substance conducted by drug product manufacturer shall be submitted.
4.	**3.2.S.7**	Real time stability studies report is submitted for 36 months at 30C and 65% RH. The shelf life assigned to the commercial batches of Ondansetron hydrochloride is 5 years. Real time stability studies data shall be submitted for the complete shelf life of the drug substance.
5.	**3.2.P.1**	According to the submitted composition, the quantity of Ondensteron as HCl is 50mg/25ml whereas the label claim is 4mg/5ml. Clarify and submit requisite fee in case of any change in quantity of API.
6.	**3.2.P.1**	Applicant shall submit adjustment of salt factor and water content.
7.	**3.2.P.2.2.1**	Manufacturer's name and registration number of reference product (Onseron Syrup) shall be submitted.
8.	**3.2.P.2.2.1**	Applicant shall submit and discuss results of Identification test, microbial enumeration tests and tests for specified microorganisms for applied and reference/comparator product.

9.	**3.2.P.2**	Provide details of formulation of reference/innovator product approved in RRA against which applicant has conducted formulation development. If excipients of applied formulation are different from reference product, provide drug-excipient compatibility studies.
10.	**3.2.P.4**	The drug product composition includes glycerine. Applicant shall submit analysis report/CoA of glycerine which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol in compliance to DRAP's notification No. F.6-30/2022-QA dated 21-10-2022.
11.	**3.2.P.5.1**	Specifications of drug product shall include test for absence of E.coli and test for Enterobacteriaceae as given in USP monograph.
12.	**1.6.5, 3.2.P.8**	Approval of API/ *valid DML/ valid GMP certificate* of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.
13.	**3.2.P.8**	Documents for the procurement of API with approval from DRAP along with CoA(s) of relevant batches shall be submitted.
14.	**3.2.P.8**	Applicant shall submit results and supporting documents of Identification test, microbial enumeration tests and tests for specified microorganisms conducted during stability studies of drug product.
15.	**3.2.P.8**	Applicant shall submit certificate of 21 CFR compliance for the HPLC system and audit trail report for product testing.

Decision of 331st meeting of RB: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response of applicant:

Sr. No.	Sections	Observations/Deficiencies/ Short-comings	Reply of applicant
1.	**1.3.4**	DML of M/s Winlet Pharmaceuticals (Pvt) Ltd is dated 21-02-2018. Copy of valid DML issued by Licensing Division of DRAP shall be submitted.	Receiving of DML renewal application submitted in Licensing Division of DRAP dated 06-02-2023 is submitted.
2.	**1.3.5**	GMP inspection report/ GMP certificate of the manufacturing unit/ contract acceptor issued within the last three years shall be submitted.	GMP certificate No. 248/2022-DRAP (AD-0835218-1099) issued on the basis of evaluation conducted on 25-11-2022 is submitted.
3.	**3.2.S.4**	Analytical method verification of drug substance conducted by drug product manufacturer shall be submitted.	Submitted
4.	**3.2.S.7**	Real time stability studies report is submitted for 36 months at 30C and 65% RH. The shelf life assigned to the commercial batches of Ondansetron hydrochloride is 5 years. Real time stability studies data shall be submitted for the complete shelf life of the drug substance.	Submitted
5.	**3.2.P.1**	According to the submitted composition, the quantity of Ondensteron as HCl is 50mg/25ml whereas the label claim is 4mg/5ml. Clarify and submit requisite fee in case of any change in quantity of API.	Applicant has submitted complete calculations including adjustment of salt factor. Applicant has also clarified that the fill weight is 50mL in 60mL bottle. API quantity is not changed. The applied label claim is correct.

6.	**3.2.P.1**	Applicant shall submit adjustment of salt factor and water content.	Submitted
7.	**3.2.P.2.2.1**	Manufacturer's name and registration number of reference product (Onseron Syrup) shall be submitted.	M/s Indus Pharma Pvt Ltd, Karachi. Reg. No. 058677
8.	**3.2.P.2.2.1**	Applicant shall submit and discuss results of Identification test, microbial enumeration tests and tests for specified microorganisms for applied and reference/comparator product.	Submitted
9.	**3.2.P.2**	Provide details of formulation of reference/innovator product approved in RRA against which applicant has conducted formulation development. If excipients of applied formulation are different from reference product, provide drug-excipient compatibility studies.	*PL/ Marketing Authorization number of MHRA approved product used as reference shall be submitted along with composition of the applied product.*
10.	**3.2.P.4**	The drug product composition includes glycerine. Applicant shall submit analysis report/CoA of glycerine which includes the results of impurity testing related to the presence of ethylene glycol and diethylene glycol in compliance to DRAP's notification No. F.6-30/2022-QA dated 21-10-2022.	CoA of glycerine Batch No. 0800, Mfg dtae 23-09-2022, Expiry 24-09-2024 from vendor (OleoCorp) is submitted. This batch was manufactured after the manufacturing of stability batches. CoA/test report generated by manufacturer is also not submitted. ***Reply is not satisfactory***
11.	**3.2.P.5.1**	Specifications of drug product shall include test for absence of E.coli and test for Enterobacteriaceae as given in USP monograph.	Submitted
12.	**1.6.5, 3.2.P.8**	Approval of API/ *valid DML/ valid GMP certificate* of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted.	GMP certificate dated 10/04/2023 and valid till one year from the date of issue is submitted.
13.	**3.2.P.8**	Documents for the procurement of API with approval from DRAP along with CoA(s) of relevant batches shall be submitted.	Firm has submitted clearance certificate dated 22-10-2020 specifying import of 5kg Ondensetron HCl by M/s Winlet. The clearance certificate is issued by AD (I&E) DRAP, Lahore. Batch No. of imported batch is AOND-20013, Mfg 09-2020, Exp 08-2025. Batch No. of API used for manufacturing of stability batches is different. ***Clarification shall be submitted by the applicant.***

14.	**3.2.P.8**	Applicant shall submit results and supporting documents of Identification test, microbial enumeration tests and tests for specified microorganisms conducted during stability studies of drug product.	Submitted
15.	**3.2.P.8**	Applicant shall submit certificate of 21 CFR compliance for the HPLC system and audit trail report for product testing.	Submitted

Remarks of Evaluator[xxiii]: Response of applicant is not satisfactory.

Decision of 336th meeting of RB: Registration Board decided to defer the application for the following reasons:

i. Submission of CoA/test report of relevant batch of Glycerin generated by manufacturer,
ii. Clarification regarding the batch of glycerin used in the manufacturing of stability batches,
iii. Clarification regarding the batch of API used in the manufacturing of stability batches,
iv. Marketing Authorization number of MHRA approved product used as reference shall be submitted along with composition of the applied product. If excipients of applied formulation are different from reference product, drug-excipient compatibility studies shall also be submitted.

Reply of applicant:

Serial No.	Reason for deferment	Reply of applicant
1.	Submission of CoA/test report of relevant batch of Glycerin generated by manufacturer	Submitted for two batches**.** ***However, in the in-house CoA's the results for DEG and EG impurities are stated as " As per CoA" so in-house testing of these impurities has not been conducted.***
2.	Clarification regarding the batch of glycerin used in the manufacturing of stability batches	Glycerin Lot No. 7920DMS3L used in the manufacturing of Batches 003 and 004. Glycerin Lot No. 3200KMS3L used in the manufacturing of Batch 005.
3.	Clarification regarding the batch of API used in the manufacturing of stability batches	API Lot No. AOND-19017 used in the manufacturing of Batches 003 and 004. API Lot No. AOND-20013 used in the manufacturing of Batch 005. ***Submit CoA's of these batches of API by drug product manufacturer.***
4.	Marketing Authorization number of MHRA approved product used as reference shall be submitted along with composition of the applied product. If excipients of applied formulation are different from reference product, drug-excipient compatibility studies shall also be submitted.	Marketing Authorization number is not submitted. However, drug excipient compatibility studies have been submitted.

Remarks of evaluator:

Decision of 339th meeting of RB: Deferred for submission of following:

CoA/test report of relevant batch of Glycerin generated by applicant mentioning test results for EG and DEG impurities.

CoAs of the batches of API by drug product manufacturer, used in the manufacturing of stability batches.

Reply of applicant/Remarks of evaluator: Firm has provided the relevant CoAs.
Decision: Approved. Firm shall submit fee for pre-approval variation/correction to include complete salt form of drug substance i.e., Ondansetron hydrochloride dihydrate as per SRO 1324(I)/2024 dated 30-08-2024, before issuance of registration letter.

Agenda of Mr. Hafiz Asif Iqbal

424.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 27480 dated 23-11-2023
	Details of fee submitted	Rs 30,000/- dated 25-10-2023
	The proposed proprietary name / brand name	**Lesnop 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Uncoated Tablet Contains: Lisinopril as Dihydrate…5mg
	Pharmacotherapeutic Group of (API)	Angiotensin-Converting Enzyme (Ace) Inhibitors
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	MHRA approved.
	For generic drugs (me-too status)	Lis-BP 10mg Tablets (Reg.# 087618) of M/s Akson Pharmaceuticals
	Proposed Pack size & proposes price	As per SRO
Evaluation by PEC (XXIV):		
Decision: Approved.		
425.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 27579 dated 24-11-2023
	Details of fee submitted	Rs 30,000/- dated 25-10-2023
	The proposed proprietary name / brand name	**Lesnop-H 20/12.5 mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Uncoated Tablet Contains: Lisinopril as Dihydrate…20mg Hydrochlorothiazide…12.5mg
	Pharmacotherapeutic Group of (API)	Angiotensin-Converting Enzyme (Ace) Inhibitors & Diuretics
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	MHRA approved.
	For generic drugs (me-too status)	Corace plus 20/12.5mg Tablet (Reg.# 073529) of M/s Bosch Pharma
	Proposed Pack size & proposes price	As per SRO
Evaluation by PEC (XXIV): • Firm provided commercial invoice attested by D I&E Peshawar alongwith licesne to import issued by AD I&E Pesahwar		
Decision: Approved.		
426.	**Name, address of Applicant / Marketing Authorization Holder**	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22442: 12-09-2023
	Details of fee submitted	PKR 30,000/- :02-09-2023
	The proposed proprietary name / brand name	**Nebrain 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each Uncoated Tablet Contains:** Nabivolol as Hydrochloride…10mg
	Pharmacotherapeutic Group of (API)	Beta Blocker
	Reference to Finished product specifications	Innovator's specifications.
	The status in reference regulatory authorities	Nabivolol 10mg Tablet MHRA approved.
	For generic drugs (me-too status)	Nibovo 10mg Tablet of Ms/s Dyson Laboratories.
	Proposed Pack size & proposes price	As per SRO
Evaluation by PEC (XXIV):		
Decision: Approved.		
427.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22444: 12-09-2023
	Details of fee submitted	PKR 30,000/- :02-09-2023
	The proposed proprietary name / brand name	**Nebrain 2.5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each Uncoated Tablet Contains:** Nabivolol as Hydrochloride…2.5mg
	Pharmacotherapeutic Group of (API)	Beta Blocker
	Reference to Finished product specifications	Innovator's specifications.
	The status in reference regulatory authorities	Nabivolol 2.5mg Tablet MHRA approved.
	For generic drugs (me-too status)	Nibovo 2.5mg Tablet of Ms/s Dyson Laboratories.
	Proposed Pack size & proposes price	As per SRO
Evaluation by PEC (XXIV):		
Decision: Approved.		
428.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22441: 12-09-2023
	Details of fee submitted	PKR 30,000/- :02-09-2023
	The proposed proprietary name / brand name	**Nebrain 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each Uncoated Tablet Contains:** Nabivolol as Hydrochloride…5mg
	Pharmacotherapeutic Group of (API)	Beta Blocker
	Reference to Finished product specifications	Innovator's specifications.
	The status in reference regulatory authorities	Nabivolol 5mg Tablet MHRA approved.
	For generic drugs (me-too status)	Nibovo 5mg Tablet of Ms/s Dyson Laboratories.
	Proposed Pack size & proposes price	As per SRO
Evaluation by PEC (XXIV):		
Decision: Approved.		
429.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.

	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22445: 12-09-2023
	Details of fee submitted	PKR 30,000/- :10-07-2023
	The proposed proprietary name / brand name	**Telmiza 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each Tablet Contains:** Telmisartan…20mg
	Pharmacotherapeutic Group of (API)	Anti-Hypertensive
	Reference to Finished product specifications	USP specifications.
	The status in reference regulatory authorities	Telmisartan 20mg Tablet MHRA approved.
	For generic drugs (me-too status)	Misar 20mg Tablet of Ms/s Highnoon Laboratories.
	Proposed Pack size & proposes price	As per SRO
Evaluation by PEC (XXIV):		
Decision: Approved.		
430.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22440: 12-09-2023
	Details of fee submitted	PKR 30,000/- :10-07-2023
	The proposed proprietary name / brand name	**Telmiza 80mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each Tablet Contains:** Telmisartan…80mg
	Pharmacotherapeutic Group of (API)	Anti-Hypertensive
	Reference to Finished product specifications	USP specifications.
	The status in reference regulatory authorities	Telmisartan 80mg Tablet MHRA approved.
	For generic drugs (me-too status)	Misar 80mg Tablet of Ms/s Highnoon Laboratories.
	Proposed Pack size & proposes price	As per SRO

Evaluation by PEC (XXIV):		
Decision: Approved.		
431.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22439: 12-09-2023
	Details of fee submitted	PKR 30,000/- :10-07-2023
	The proposed proprietary name / brand name	**Telmiza 40mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Telmisartan…40mg
	Pharmacotherapeutic Group of (API)	Anti-Hypertensive
	Reference to Finished product specifications	USP specifications.
	The status in reference regulatory authorities	Telmisartan 40mg Tablet MHRA approved.
	For generic drugs (me-too status)	Misar 40mg Tablet of Ms/s Highnoon Laboratories.
	Proposed Pack size & proposes price	As per SRO
Evaluation by PEC (XXIV):		
Decision: Approved.		
432.	**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)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 26040 dated 27-10-2023
	Details of fee submitted	Rs.30,000/- dated 15-09-2023
	The proposed proprietary name / brand name	**Vonzan 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vonoprazan Fumarate Eq. to Vonoprazan…10mg
	Pharmacotherapeutic Group of (API)	Potassium-Competitive acid Blocker (P-CAB)
	Reference to Finished product specifications	Innovator's specifications

	The status in reference regulatory authorities	Approved by PMDA of Japan
	For generic drugs (me-too status)	Vonozan tablet of Getz Pharma
	Proposed Pack size & proposes price	As per SRO
Evaluation by PEC (XXIV):		
Decision: Approved.		
433.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore**
	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)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 26540 dated 03-11-2023
	Details of fee submitted	PKR 30,000/- dated 13-09-2023
	The proposed proprietary name / brand name	**Becetam 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Brivaracetam…10mg
	Pharmacotherapeutic Group of (API)	Antiepileptic
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	Brivatam tablet of M/s CCL
	Proposed Pack size & proposes price	As per SRO
Evaluation by PEC (XXIV):		
Decision: Approved.		
434.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 25004 dated 13-10-2023
	Details of fee submitted	PKR 30,000/- :13-08-2023
	The proposed proprietary name / brand name	**Vonozi 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vonoprazan as Fumarate…10mg
	Pharmacotherapeutic Group of (API)	Potassium-Competitive acid Blocker (P-CAB)

	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	Approved by PMDA of Japan
	For generic drugs (me-too status)	Vonozan tablet of Getz Pharma
	Proposed Pack size & proposes price	As per SRO

Evaluation by PEC (XXIV):

Sr.#	Observations	Firm's response
1.	Valid GMP certificate/DML of the drug substance manufacturer, issued by the relevant regulatory authority of country of origin, shall be submitted.	Firm has submitted copy of DML no. 20060459 issued by Zhejiang Province Drug Administration valid until 27-09-2025

Decision: Approved.

435.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan**
	Name, address of Manufacturing site.	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 25005 dated 13-10-2023
	Details of fee submitted	PKR 30,000/- :13-08-2023
	The proposed proprietary name / brand name	**Vonozi 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Vonoprazan as Fumarate…20mg
	Pharmacotherapeutic Group of (API)	Potassium-Competitive acid Blocker (P-CAB)
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	Approved by PMDA of Japan
	For generic drugs (me-too status)	Vonozan tablet of Getz Pharma
	Proposed Pack size & proposes price	As per SRO

Evaluation by PEC (XXIV):

Sr.#	Observations	Firm's response
1.	Valid GMP certificate/DML of the drug substance manufacturer, issued by the relevant regulatory authority of country of origin, shall be submitted.	Firm has submitted copy of DML no. 20060459 issued by Zhejiang Province Drug Administration valid until 27-09-2025

Decision: Approved.

436.	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)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 25796 dated 25-10-2023
	Details of fee submitted	PKR 30,000/- dated 12-10-2023
	The proposed proprietary name / brand name	**Bilaso 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each Tablet Contains:** Bilastine…20mg
	Pharmacotherapeutic Group of (API)	Antihistamines for systemic use WHO ATC Code: R06AX29
	Reference to Finished product specifications	As per Innovator's specifications
	The status in reference regulatory authorities	Approved by MHRA of UK
	For generic drugs (me-too status)	Bistavo 20mg Tablet of M/s Sami pharmaceuticals (Reg.#117980)
	Proposed Pack size & proposes price	As per SRO
Evaluation by PEC (XXIV): Bilastine is used in the treatment of symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria. It is also is indicated for the relief of the symptoms associated with Chronic Spontaneous Urticaria (CSU) (e.g. pruritus and hives), in patients 12 years of age and older. • Firm shall submit drug product stability studies data of 6th month time point. • Subsequent to above observation firm has submitted 6th month stability studies data for drug product.		
Decision: Approved.		
437.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No.35-A, Small Industrial Estate, Taxila, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 25005 dated 13-10-2023
	Details of fee submitted	Rs.30,000/- dated 26-10-2023
	The proposed proprietary name / brand name	**Cisanim 2mg/ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Cisatracurium as Besylate…2mg
	Pharmacotherapeutic Group of (API)	Neuromuscular blocking agents. (WHO ATC Code: M03AC11)
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	CIS- CURON Injection of M/s Brookes
	Proposed Pack size & proposes price	As per SRO

Evaluation by PEC (XXIV):

Sr.#	Observations	Firm's response
1.	Justification shall be submitted for use of preservative in the applied formulation	The nominal range of material is below the range of preservative hence preservative is not required because it is a single dose container. Benzene sulfonic acid is used as pH adjuster rather than preservative
2.	Drug product stability studies data of 6th month time point shall be submitted.	Submitted

Decision: Approved.

438.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 26132 dated 30-10-2023
	Details of fee submitted	Rs.75,000/- dated 06-10-2023
	The proposed proprietary name / brand name	**Bempido 180mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Bempedoic Acid…180mg
	Pharmacotherapeutic Group of (API)	Adenosine triphosphate-citrate lyase (ACL) inhibitors Indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	Approved by US FDA
	For generic drugs (me-too status)	--
	Proposed Pack size & proposes price	As per SRO

Evaluation by PEC (XXIV):

Sr.#	Observations	Firm's response
1.	Valid GMP certificate/DML of the drug substance manufacturer, issued by the relevant regulatory authority of country of origin, shall be submitted.	Firm ha ssubmitted cpyof GMP certificate issued by Drugs Control Administration Andhra Pradesh valid upto 08-06-2025.
2.	Reference shall be submitted for the dissolution parameters applied for the performance of dissolution test of drug product.	Firm has referred ot US FDA Dissolution database.
3.	Document confirming procurement/import of drug substance with approval of DRAP I&E Office shall be submitted.	Firm has submitted Drug import license issued by DRAP I&E office dated 20-10-2022

Decision: Approved.		
439.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 24574 dated 06-10-2023
	Details of fee submitted	Rs.30,000/- dated 27-09-2023
	The proposed proprietary name / brand name	**Peradol-D 500/25 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Paracetamol…500mg Diphenylhydramine HCl…25mg
	Pharmacotherapeutic Group of (API)	N02BE51 (Paracetamol, Combinations excluding Psycholeptics).
	Reference to Finished product specifications	Manufacturer's specifications
	The status in reference regulatory authorities	TYLENOL PM EXTRA STRENGTH, approved as Human OTC Drug in US
	For generic drugs (me-too status)	Panadol night tablets of M/s Haleon
	Proposed Pack size & proposes price	As per SRO
Evaluation by PEC (XXIV):		
Decision: Approved.		
440.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No 26548 dated 03-11-2023
	Details of fee submitted	Rs.30,000/- dated 20-10-2023
	The proposed proprietary name / brand name	**Tofamit 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tofacitinib Citrate Eq. to Tofacitinib…10mg

	Pharmacotherapeutic Group of (API)	Janus kinase (JAK) inhibitors
	Reference to Finished product specifications	Innovator specifications
	The status in reference regulatory authorities	Xeljanz tablet approved by US FDA
	For generic drugs (me-too status)	Actinib tablet of M/s Searle
	Proposed Pack size & proposes price	As per SRO

Evaluation by PEC (XXIV):

Sr.#	Observations	Firm's response
1.	Valid GMP certificate/DML of the drug substance manufacturer, issued by the relevant regulatory authority of country of origin, shall be submitted.	Submitted
2.	Details of the reference product against which CDP studies has been performed, shall be submitted.	Firm has referred to the Xeljanz tablet.
3.	Reference shall be submitted for the dissolution parameters applied for the performance of dissolution test of drug product.	Firm has referred to the US FDA literature review for innovator drug product.

Decision: Approved. Manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of this drug.

441.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 26547 dated 03-11-2023
	Details of fee submitted	Rs.30,000/- dated 20-10-2023
	The proposed proprietary name / brand name	**Tofamit 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tofacitinib Citrate Eq. to Tofacitinib…5mg
	Pharmacotherapeutic Group of (API)	Janus kinase (JAK) inhibitors
	Reference to Finished product specifications	Innovator specifications
	The status in reference regulatory authorities	Xeljanz tablet approved by US FDA
	For generic drugs (me-too status)	Actinib tablet of M/s Searle
	Proposed Pack size & proposes price	As per SRO

Evaluation by PEC (XXIV):

Sr.#	Observations	Firm's response

1.	Valid GMP certificate/DML of the drug substance manufacturer, issued by the relevant regulatory authority of country of origin, shall be submitted.	Submitted
2.	Details of the reference product against which CDP studies has been performed, shall be submitted.	Firm has referred to the Xeljanz tablet.
3.	Reference shall be submitted for the dissolution parameters applied for the performance of dissolution test of drug product.	Firm has referred to the US FDA literature review for innovator drug product.

Decision: Approved. Manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of this drug.

442.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 24574 dated 06-10-2023
	Details of fee submitted	Rs.30,000/- dated 27-09-2023
	The proposed proprietary name / brand name	**Peradol Extend 665mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Modified Release Tablet Contains: Paracetamol……665mg
	Pharmacotherapeutic Group of (API)	Antipyretic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Approved by TGA of Australia
	For generic drugs (me-too status)	Panadol Extend tablet of M/s GSK
	Proposed Pack size & proposes price	As per SRO

Evaluation by PEC (XXIV):

Sr.#	Observations	Firm's response
1.	Details of the reference product against which CDP studies has been performed, shall be submitted	Panadol Extend tablet 665mg of M/s GSK.
2.	Clarification shall be submitted regarding the Dissolution "Test type" adopted from the USP monograph of "Acetaminophen Extended release tablet".	Firm has referred to "Dissolution Test Type I" of USP monograph of "Acetaminophen Extended release tablet"

Decision: Approved. To mitigate the risk due to toxicity associated with overdose of Paracetamol Extend Tablet 665mg, registration letter will be issued with following additional conditions/ statements:

"Following conditions should appear on label of the product in bold and conspicuous manner:

- **For adults, the highest recommended dose of Paracetamol Extend Tablet 665mg 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).**
- **Paracetamol Extend Tablet 665mg should not be used as an alternative to Panadol/ Paracetamol Tablet 500mg without prior consultation with Physician/ Pharmacist."**
- **Above-mentioned conditions will also be included in advertisement of the product and for this purpose, recommendation will be forwarded to Pharmacy Services Division, DRAP.**
- **To ensure compliance with the above-mentioned conditions, the applicant will be advised to conduct training programmes for the health care providers and submit biannual compliance reports to PE&R Division subsequent to issuance of registration.**

Registration application of contract manufacturing:

443.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Asian Continental Pvt Ltd. Continental House, D-133, Tipu Sultan Road, Scheme-I, Karachi**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 26549 dated 03-11-2023
	Details of fee submitted	Rs.75,000/- dated 04-10-2023
	The proposed proprietary name / brand name	**Feveren-D 500/25 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Paracetamol…500mg Diphenylhydramine HCl…25mg
	Pharmacotherapeutic Group of (API)	N02BE51 (Paracetamol, Combinations excluding Psycholeptics).
	Reference to Finished product specifications	Manufacturer's specifications
	The status in reference regulatory authorities	TYLENOL PM EXTRA STRENGTH, approved as Human OTC Drug in US
	For generic drugs (me-too status)	Panadol night tablets of M/s Haleon
	Proposed Pack size & proposes price	As per SRO
Evaluation by PEC (XXIV):		
Decision: Approved.		

Deferred cases:

444.	Name, address of Applicant / Marketing Authorization Holder	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat
	Name, address of Manufacturing site.	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road,

		Rawat 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. 36503 dated 15/12/2022
	Details of fee submitted	PKR 30,000/-: dated 07/12/2022
	The proposed proprietary name / brand name	**Rosucare 10 mg film coated tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Rosuvastatin as Rosuvastatin calcium…10 mg
	Pharmaceutical form of applied drug	Film coated tablet
	Pharmacotherapeutic Group of (API)	Leukotriene Receptor Antagonist (wrongly mentioned)
	Reference to Finished product specifications	USP
	Proposed Pack size	10's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	CRESTOR Tablets 10 mg By M/s AstraZeneca Pharmaceutical USA. USFDA Approved
	For generic drugs (me-too status)	Rovista tablets 10mg by M/s Getz Pharma Reg No 044044
	GMP status of the Finished product manufacturer	New license granted on 18/03/2021 Tablet (General) section was approved.
	Name and address of API manufacturer.	CTX Lifesciences (P) Ltd Block No: 251-252, Sachin Magdalla Road GIDC- Sachin, Dist: -Surat (Gujrat) 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)	Official monograph of Rosuvastatin Calcium is available in USP. The firm as submitted detail of nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process and controls, tests for organic impurities, unspecified impurities and 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 36 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months Batches: SCT/ST/001/2015 SCT/ST/002/2015 SCT/ST/003/2015
	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 and comparative dissolution profile was performed against Rovista 10 mg Tablet by Getz Pharma. Quality parameters were studied such as identification, uniformity of dosage, dissolution test and Assay. CDP was performed against same brand in Acid media (pH 1.0-1.2), acetate buffer (pH 4.5) & Phosphate Buffer (pH 6.8). The values for f1 and f2 were 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	CTX Lifesciences (P) Ltd Block No: 251-252, Sachin Magdalla Road GIDC-Sachin, Dist: -Surat (Gujrat) India
API Lot No.	21RU000026
Description of Pack	Alu-Alu blister packed in unit carton (10'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: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	09-2021	09-2021	09-2021
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.	Not provided
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted Invoice No E1/3012100205 Dated 21.06.2021 confirming import of Rosuvastatin calcium 0.25gm Batch No 21RU000026. Approval from DRAP is required.
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)	Submitted

Remarks of Assessor (DD PEC-XX):

1.5.5 Provide correct Pharmacotherapeutic group of Drug Substance.

1.6.5 Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin

2.3.S.3.1& 3.2.S.3 Elucidation of Structure and other Characteristics of Drug Substance has not been Provided

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 Potency adjustment (salt factor) of Drug substance to be justified in Batch formula i.e 10.4mg of Rosuvastatin calcium eq to 10mg Rosuvastatin, since reference product (MHRA approved) is provided as:

46.36 mg Rosuvastatin calcium eq to 10mg Rosuvastatin.

3.P.2.1.1 Compatibility of the Drug Substance(s) with excipient (Calcium phosphate) is not provided.

3.2.P.2 Batch no of innovator product and test product has not been mentioned under CDP.

3.2.P.8 Documents for the procurement of API (approval from DRAP) to be submitted.

3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports is not submitted

Decision 326th 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.

Remarks of assessor:

Sr.#	Observation	Reply	Remarks
1.	Provide correct pharmacotherapeutic group of Drug Substance.	Pharmacotherapeutic group of Drug Substance has been corrected as HMG CoA reductase	Fee of Rs 7500/- is required as per SRO
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin	Copy of Retention of license No G/25/1723 is submitted valid till 23.01.2026 issued by Food and Drug Control Administration Gujrat state	Complied
3.	Elucidation of Structure and other Characteristics of Drug Substance has not been Provided.	Provided	Instead of submitting documents/required information from Drug Substance manufacturer, firm has submitted documents regarding Elucidation of Structure and relevant spectrum downloaded from online published sources (Pubchem etc)
4.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided	Provided	Results of analytical method verification study including specificity parameter has not been provided alongwith HPLC Chromatograms (sample, standard and blank) Moreover document need to be signed by authorized person.
5.	Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer.	Provided	Complied
6.	Potency adjustment (salt factor) of Drug substance to be justified in Batch formula i.e 10.4mg of Rosuvastatin calcium eq to 10mg Rosuvastatin, since reference product (MHRA approved) is provided as: 46.36 mg Rosuvastatin calcium eq to 10mg Rosuvastatin.	Firm has provided reference of RRA (Netherland) approved formulation wherein potency of rosuvastatin is mentioned as 10.40mg of Rosuvastatin calcium eq to 10mg Rosuvastatin	Complied Same has been verified from this link. https://www.geneesmiddeleninformatiebank.nl/ smpc/h126585_smpc_en.pdf

7.	Compatibility of the Drug Substance(s) with excipient (Calcium phosphate) is not provided.	Firm has provided reference of product monograph/SmPC of MHRA/EMA approved product i.e Crestor Tablet wherein Calcium phosphate was mentioned as excipient	Complied Compatibility study of the Drug Substance(s) with excipient is not required
8.	Batch no of innovator product and test product has not been mentioned under CDP.	Not provided	Not complied
9.	Documents for the procurement of API (approval from DRAP) to be submitted.	Firm has submitted Invoice No E1/3012100205 Dated 21.06.2021 confirming import of Rosuvastatin calcium 0.25gm Batch No 21RU000026.	Approval from DRAP is required
10.	Compliance Record of HPLC software 21CFR & audit trail reports is not submitted	Not provided	Not complied

Remarks of Assessor:
The reply submitted against above mentioned shortcomings was found unsatisfactory

Decision of 330th meeting: Registration Board deferred the case for following shortcomings:

a) Elucidation of Structure and other Characteristics of Drug Substance to be Provided from Drug substance manufacturer
b) Results of analytical method verification study including specificity parameter to be provided preferably HPLC Chromatograms (sample, standard and blank)
c) Provide details of Innovator Pack against which pharmaceutical equivalence study was performed (brand name, manufacturer, batch no. and expiry date).
d) Documents for the procurement of API (approval from DRAP) to be submitted.
e) Fee of Rs 7500/- is required as per SRO for correction of pharmacotherapeutic group.

Firm's response:

Observations	**Firm's response**
Elucidation of Structure and other Characteristics of Drug Substance to be Provided from Drug substance manufacturer	Submitted
Results of analytical method verification study including specificity parameter to be provided preferably HPLC Chromatograms (sample, standard and blank)	Submitted
Provide details of Innovator Pack against which pharmaceutical equivalence study was performed (brand name, manufacturer, batch no. and expiry date).	Submitted

Fee of Rs 7500/- is required as per SRO for correction of pharmacotherapeutic group	Not submitted

Decision: Approved. Firm shall submit fee Rs. 9000/- for pre-approval correction of pharmacotherapeutic group as per SRO 1324(I)/2024 dated 30-08-, before issuance of registration letter.

Miscellaneous case:

Following case was presented in 331st meeting of Registration Board and was approved but inadvertently in decision the product name was mentioned as "Caremont 10mg tablet" instead of "Caremont 4mg chewable tablet" be recorded in the final minutes. The case is re-produced here for correction please.

445.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat Industrial Estate, Rawat**
	Name, address of Manufacturing site.	M/s Carer pharmaceuticals Industries, Plot # 27, Main Road, Rawat 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.33969 dated 24/11/2022
	Details of fee submitted	PKR 30,000/- dated 21/11/2022
	The proposed proprietary name / brand name	**Caremont 4 mg chewable tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each chewable tablet contains: Montelukast as sodium……4 mg
	Pharmaceutical form of applied drug	Chewable tablet
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonist
	Reference to Finished product specifications	USP

	Proposed Pack size	2x7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Accord Healthcare Limited United Kingdom MHRA approved
	For generic drugs (me-too status)	M/s Sami Pharma Montika 4mg chewable Tablet Registration Number: 035560
	GMP status of the Finished product manufacturer	New license granted on 18/03/2021 Tablet (General) section was approved.
	Name and address of API manufacturer.	M/s Metrochem API Private Limited Unit-I Plot No 62/C/6, Pipeline Road, Phase-I, I.D.A. Jeedimetla, Quthbullapur (M), Medchal-malkajgiri (Dist), Telangana (State), India, Jeedimetla - Phase I&II (V), Quthbullapur(M), Medchal – Malkajgiri (Dist.)
	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 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 impurities & related substances (specified & unspecified), 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: MLS-F # 001/16 MLS-F # 002/16 MLS-F # 003/16
	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 and comparative dissolution profile was performed against Montika 4 mg Tablet by SAMI Pharma. Quality

		parameters were studied such as identification, uniformity of dosage, dissolution test and Assay. CDP was performed against same brand 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 linearity, range, accuracy, precision, specificity.

STABILITY STUDY DATA			
Manufacturer of API	M/s Metrochem API Private Limited Unit-I Plot No 62/C/6, Pipeline Road, Phase-I, I.D.A. Jeedimetla, Quthbullapur (M), Medchal-malkajgiri (Dist), Telangana (State), India, Jeedimetla - Phase I&II (V), Quthbullapur(M), Medchal – Malkajgiri (Dist.)		
API Lot No.	MKS/2107023		
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: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T-01	T-02	T-03
Batch Size	1000 tab	1000 tab	1000 tab
Manufacturing Date	09-2021	09-2021	09-2021
Date of Initiation	09-2021	09-2021	09-2021
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. L.DIS.No. 4084/A3/2019 dated 20.05.2020 issued by DCA(Drug control administration) Telangana, India valid till 20/05/2023.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted Invoice No AE/21-22/0172 Date 21.07.2021 confirming import of Montelukast sodium 5gm Batch No MKS/2107023. Approval from DRAP is required
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)	Submitted

Remarks of Assessor (DD PEC-XX):
2.3.S.3.1& 3.2.S.3 Elucidation of Structure and other Characteristics of Drug Substance has not been Provided.

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 no of innovator product and test product has not been mentioned under CDP.
3.2.P.8 Documents for the procurement of API (approval from DRAP) to be submitted.
3.2.P.8 Compliance Record of HPLC software 21CFR & audit trail reports is not submitted.

Decision 326th 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.

Remarks of Assessor:
Now the firm has submitted reply against above mentioned shortcomings as follows:

Sr.#	Observations	Reply	Remarks
1.	Elucidation of Structure and other Characteristics of Drug Substance has not been Provided.	Provided	Instead of submitting documents/required information from Drug Substance manufacturer, firm has submitted documents regarding Elucidation of Structure and relevant spectrum downloaded from online published sources (Pubchem etc)
2.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer to be provided	Provided	Results of analytical method verification study including specificity parameter has not been provided alongwith HPLC Chromatograms (sample, standard and blank) Moreover document need to be signed by authorized person.
3.	Detailed analytical procedures for the testing of drug substance to be provided by Drug product manufacturer.	Provided	Complied
4.	Batch no of comparator product and test product has not been mentioned under CDP.	Not provided	Not complied
5.	Documents for the procurement of API (approval from DRAP) to be submitted.	Provided Invoice No AE/21-22/0172 DATE 21.07.2021 confirming import of Montelukast sodium 5gm Batch No MKS/2107023. Acknowledgment/approval from I&E DRAP, Islamabad dated 31.08.2021	Complied
6.	Compliance Record of HPLC software 21CFR & audit trail reports is not submitted	Not provided	Not complied

Remarks of Assessor:
The reply submitted against above mentioned shortcomings was found unsatisfactory

Decision 330th meeting : Registration Board deferred the case for following shortcomings:

Elucidation of Structure and other Characteristics of Drug Substance to be Provided from Drug substance manufacturer.
Results of analytical method verification study including specificity parameter to be provided preferably HPLC Chromatograms (sample, standard and blank)
Provide details of Innovator Pack against which pharmaceutical equivalence study was performed (brand name, manufacturer, batch no. and expiry date)

Sr.#	Observations	Reply	Remarks
1.	Elucidation of Structure and other Characteristics of Drug Substance to be Provided from Drug substance manufacturer	Provided	Complied
2.	Results of analytical method verification study including specificity parameter to be provided preferably HPLC Chromatograms (sample, standard and blank)	Provided	Complied
3.	Provide details of Innovator Pack against which pharmaceutical equivalence study was performed (brand name, manufacturer, batch no. and expiry date)	Details of comparator products as under: Montika 4mg chewable Tablet by SAMI Pharma. Batch No: 001H	Complied

Decision of 331st meeting: Registration Board approved the application of Caremont 10mg Tablet.

- 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**.**

Decision: Registration Board noted the information and decided to correct the previous decision and approved the applied product of "Caremont 4mg chewable tablet"

Agenda of Ms. Najia Saleem

Case no. 01 Registration applications for local manufacturing of (veterinary) drugs
New Cases

446.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Tylogen-C Injection 10ml
	Composition	Each ml contains: Gentamycin Sulphate…50mg Tylosin Tartrate…100mg Colistin Sulphate…0.20 MIU
	Diary No. Date of R& I & fee	Dy.No 29900 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Cartel Injection (**50ml**) of M/s Mylab (Pvt) Ltd, Khankah Sharif, Bahawalpur. (Reg. No.116952)

	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, buffalo, sheep, goat, poultry **Shortcomings:** • Firm shall submit fee of Rs.37000/- for pre-approval correction in formulation/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024
	Decision: Approved with following label claim: **Each ml contains:** **Gentamycin as Sulphate…50mg** **Tylosin as Tartrate…100mg** **Colistin Sulphate…0.20 MIU** **The firm shall submit fee of Rs.37000/- for pre-approval correction in formulation/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024 before issuance of registration letter.**	
447.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Tylogen-C Injection 50ml
	Composition	Each ml contains: Gentamycin Sulphate…50mg Tylosin Tartrate…100mg Colistin Sulphate…0.20 MIU
	Diary No. Date of R& I & fee	Dy.No 29901 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Cartel Injection (**50ml**) of M/s Mylab (Pvt) Ltd, Khankah Sharif, Bahawalpur. (Reg. No.116952)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, buffalo, sheep, goat, poultry **Shortcomings:** • Firm shall submit fee of Rs.37000/- for pre-approval correction in formulation/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024
	Decision: Approved with following label claim: **Each ml contains:** **Gentamycin as Sulphate…50mg** **Tylosin as Tartrate…100mg** **Colistin Sulphate…0.20 MIU** **The firm shall submit fee of Rs.37000/- for pre-approval correction in formulation/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024 before issuance of registration letter.**	
448.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Tylogen-C Injection 100ml

	Composition	Each ml contains: Gentamycin Sulphate…50mg Tylosin Tartrate…100mg Colistin Sulphate…0.20 MIU
	Diary No. Date of R& I & fee	Dy.No 29902 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Cartel Injection (**50ml**) of M/s Mylab (Pvt) Ltd, Khankah Sharif, Bahawalpur. (Reg. No.116952)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, buffalo, sheep, goat, poultry **Shortcomings:** • Firm shall submit fee of Rs.37000/- for pre-approval correction in formulation/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024
	Decision: Approved with following label claim: **Each ml contains:** **Gentamycin as Sulphate…50mg** **Tylosin as Tartrate…100mg** **Colistin Sulphate…0.20 MIU** **The firm shall submit fee of Rs.37000/- for pre-approval correction in formulation/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024 before issuance of registration letter.**	
449.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Cyanofar-250 Injection 10ml
	Composition	Each ml contains: Cyanocobalamin…250mcg
	Diary No. Date of R& I & fee	Dy.No 28348 dated 08-12-2023 Rs 30,000/- dated 07-12-2023
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Apcyno-250 Injection (10ml) of M/s Aptly Pharmaceuticals, Faisalabad (Reg. No. 122081)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** sheep, foals, calves, cattle, horses
	Decision: Approved.	
450.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Cyanofar-250 Injection 100ml
	Composition	Each ml contains: Cyanocobalamin…250mcg

	Diary No. Date of R& I & fee	Dy.No 28350 dated 08-12-2023 Rs 30,000/- dated 07-12-2023
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Apcyno-250 Injection (100ml) of M/s Aptly Pharmaceuticals, Faisalabad (Reg. No. 122083)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** sheep, foals, calves, cattle, horses
	Decision: Approved.	
451.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Cyanofar-250 Injection 50ml
	Composition	Each ml contains: Cyanocobalamin…250mcg
	Diary No. Date of R& I & fee	Dy.No 28349 dated 08-12-2023 Rs 30,000/- dated 07-12-2023
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Apcyno-250 Injection (**10ml**) of M/s Aptly Pharmaceuticals, Faisalabad (Reg. No. 122081)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** sheep, foals, calves, cattle, horses
	Decision: Approved.	
452.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Cyanofar-1000 Injection 10ml
	Composition	Each ml contains: Cyanocobalamin…1000mcg
	Diary No. Date of R& I & fee	Dy.No 28351 dated 08-12-2023 Rs 30,000/- dated 07-12-2023
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Apcyno-100 Injection (100ml) of M/s Aptly Pharmaceuticals, Faisalabad (Reg. No. 122084)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** foals, calves, cattle, horses
	Decision: Approved.	

453.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Paractin DS Injection 50ml
	Composition	Each ml contains: Ivermectin…20mg Clorsulon…100mg
	Diary No. Date of R& I & fee	Dy.No 28358 dated 08-12-2023 Rs 30,000/- dated 07-12-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Actimec DS Injection (**100ml**) of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 101524)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle
	Decision: Approved.	
454.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Paractin DS Injection 100ml
	Composition	Each ml contains: Ivermectin…20mg Clorsulon…100mg
	Diary No. Date of R& I & fee	Dy.No 28359 dated 08-12-2023 Rs 30,000/- dated 07-12-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Actimec DS Injection (100ml) of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 101524)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle
	Decision: Approved.	
455.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Paractin DS Injection 10ml
	Composition	Each ml contains: Ivermectin…20mg Clorsulon…100mg
	Diary No. Date of R& I & fee	Dy.No 28357 dated 08-12-2023 Rs 30,000/- dated 07-12-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Actimec DS Injection (**100ml**) of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 101524)

	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle
	Decision: Approved.	
456.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Tylogen-50 Injection 50ml
	Composition	Each ml contains: Gentamycin Sulphate…50mg Tylosin Tartrate…100mg Colistin Sulphate…0.50 MIU
	Diary No. Date of R& I & fee	Dy.No 29502 dated 22-12-2023 Rs 30,000/- dated 21-12-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Gentafate Injection (**100ml**) of M/s Inshal Pharmaceutical Industries, Islamabad (Reg. No. 099348)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, buffalo, sheep, goat, poultry • Firm has submitted fee of Rs.37000/- vide challan No. 9180360439 for pre-approval correction in formulation/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024.
	Decision: Approvedwith following label claim: **Each ml contains:** **Gentamycin as Sulphate…50mg** **Tylosin as Tartrate…100mg** **Colistin Sulphate…0.50 MIU**	
457.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Tylogen-50 Injection 100ml
	Composition	Each ml contains: Gentamycin Sulphate…50mg Tylosin Tartrate…100mg Colistin Sulphate…0.50 MIU
	Diary No. Date of R& I & fee	Dy.No 29503 dated 22-12-2023 Rs 30,000/- dated 21-12-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Gentafate Injection (**100ml**) of M/s Inshal Pharmaceutical Industries, Islamabad (Reg. No. 099348)
	GMP status	GMP inspection n conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:**

		Cattle, buffalo, sheep, goat, poultry • Firm has submitted fee of Rs.37000/- vide challan No. 44870158 for pre-approval correction in formulation/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024.
	Decision: Approvedwith following label claim: **Each ml contains:** **Gentamycin as Sulphate…50mg** **Tylosin as Tartrate…100mg** **Colistin Sulphate…0.50 MIU**	
458.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Tylogen-50 Injection 10ml
	Composition	Each ml contains: Gentamycin Sulphate…50mg Tylosin Tartrate…100mg Colistin Sulphate…0.50 MIU
	Diary No. Date of R& I & fee	Dy.No 29501 dated 22-12-2023 Rs 30,000/- dated 21-12-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Gentafate Injection (**100ml**) of M/s Inshal Pharmaceutical Industries, Islamabad (Reg. No. 099348)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, buffalo, sheep, goat, poultry • Firm has submitted fee of Rs.37000/- vide challan No. 7591700111 for pre-approval correction in formulation/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024.
	Decision: Approved with following label claim: **Each ml contains:** **Gentamycin as Sulphate…50mg** **Tylosin as Tartrate…100mg** **Colistin Sulphate…0.50 MIU**	
459.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Aclofar Injection 50ml
	Composition	Each ml contains: Aceclofenac…25mg
	Diary No. Date of R& I & fee	Dy.No 28355 dated 08-12-2023 Rs 30,000/- dated 07-12-2023
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Inhouse specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Aklonac Injection (50ml) of M/s Manhattan Pharma, Karachi. (Reg. No. 106765)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014.

		Target species: Cattle, buffalo, sheep, goat, horses, camels, dogs, cats • Firm has submitted fee Rs. 9000/- vide challan No. 5537347262 for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024.
	Decision: Referred to sub-committee on veterinary drugs for review and recommendation.	
460.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Aclofar Injection 20ml
	Composition	Each ml contains: Aceclofenac…25mg
	Diary No. Date of R& I & fee	Dy.No 28354 dated 08-12-2023 Rs 30,000/- dated 07-12-2023
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Inhouse specifications
	Pack size & Demanded Price	20ml; Decontrolled
	Me-too status	Aceclovetz Injection (20ml) of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh (Reg. No. 088160)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, buffalo, sheep, goat, horses, camels, dogs, cats • Firm has submitted fee Rs. 9000/- vide challan No. 641609467238 for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024.
	Decision: Deferred for comments of Ministry of Food Security regarding therapeutic requirement keeping in view safety, efficacy and quality parameters. The Board further decided that the already registered formulation if any will be treated in line with comments/ recommendation of Ministry of Food Security.	
461.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Aclofar Injection 100ml
	Composition	Each ml contains: Aceclofenac…25mg
	Diary No. Date of R& I & fee	Dy.No 28356 dated 08-12-2023 Rs 30,000/- dated 07-12-2023
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Inhouse specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Aceclovetz Injection (**20ml**) of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh (Reg. No. 088160)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, buffalo, sheep, goat, horses, camels, dogs, cats • Firm has submitted fee Rs. 9000/- vide challan No. 566261074250 for pre-approval correction in FPP

		specifications as per SRO 1324(I)/2024 dated 30-08-2024.
	Decision: Deferred for comments of Ministry of Food Security regarding therapeutic requirement keeping in view safety, efficacy and quality parameters. The Board further decided that the already registered formulation if any will be treated in line with comments/ recommendation of Ministry of Food Security.	
462.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Florofar Injection 10ml
	Composition	Each ml contains: Florfenicol…300mg
	Diary No. Date of R& I & fee	Dy.No 29888 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Aplafen-30 Injection (10ml) of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 121964)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle
	Decision: Approved.	
463.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Melofar-10 Injection 10ml
	Composition	Each ml contains: Meloxicam…10mg
	Diary No. Date of R& I & fee	Dy.No 29903 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	BP Vet specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Aplacam-10 Injection (100ml) of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 122089)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, buffalo, sheep, goat, horses, camels, dogs, cats
	Decision: Approved.	
464.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Melofar-10 Injection 50ml
	Composition	Each ml contains: Meloxicam…10mg
	Diary No. Date of R& I & fee	Dy.No 29905 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	NSAID
	Type of Form	Form 5

	Finished product Specifications	BP Vet specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Aplacam-10 Injection (100ml) of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 122089)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, buffalo, sheep, goat, horses, camels, dogs, cats
	Decision: Approved.	
465.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Melofar-10 Injection 20ml
	Composition	Each ml contains: Meloxicam…10mg
	Diary No. Date of R& I & fee	Dy.No 29904 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	BP Vet specifications
	Pack size & Demanded Price	20ml; Decontrolled
	Me-too status	Aplacam-10 Injection (100ml) of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 122089)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, buffalo, sheep, goat, horses, camels, dogs, cats
	Decision: Approved.	
466.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Melofar-10 Injection 100ml
	Composition	Each ml contains: Meloxicam…10mg
	Diary No. Date of R& I & fee	Dy.No 29906 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	BP Vet specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Aplacam-10 Injection (100ml) of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 122089)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, buffalo, sheep, goat, horses, camels, dogs, cats
	Decision: Approved.	
467.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Danofar-25 Injection 100ml

	Composition	Each ml Contains: Danofloxacin as Mesilate…25mg
	Diary No. Date of R& I & fee	Dy.No 29458 dated 21-12-2023 Rs 30,000/- dated 15-12-2023
	Pharmacological Group	Fluoroquinolone antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Danovet Injection (50ml) of M/s Decent Pharma, Rawat (Reg. No. 120754)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No. F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle
	Decision: Approved.	
468.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Danofar-25 Injection 50ml
	Composition	Each ml Contains: Danofloxacin as Mesilate…25mg
	Diary No. Date of R& I & fee	Dy.No 29457 dated 21-12-2023 Rs 30,000/- dated 15-12-2023
	Pharmacological Group	Fluoroquinolone antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Danovet Injection (50ml) of M/s Decent Pharma, Rawat (Reg. No. 120754)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No. F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle
	Decision: Approved.	
469.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Cyanofar-1000 Injection 50ml
	Composition	Each ml contains: Cyanocobalamin…1000mcg
	Diary No. Date of R& I & fee	Dy.No 28352 dated 08-12-2023 Rs 30,000/- dated 07-12-2023
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Apcyno-100 Injection (100ml) of M/s Aptly Pharmaceuticals, Faisalabad (Reg. No. 122084)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** foals, calves, cattle, horses

	Decision: Approved.	
470.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Cyanofar-1000 Injection 100ml
	Composition	Each ml contains: Cyanocobalamin…1000mcg
	Diary No. Date of R& I & fee	Dy.No 28353 dated 08-12-2023 Rs 30,000/- dated 07-12-2023
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Apcyno-100 Injection (100ml) of M/s Aptly Pharmaceuticals, Faisalabad (Reg. No. 122084)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** foals, calves, cattle, horses
	Decision: Approved.	
471.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Enrofar 20% Injection 10ml
	Composition	Each ml contains: Enrofloxacin…200mg
	Diary No. Date of R& I & fee	Dy.No 29459 dated 21-12-2023 Rs 30,000/- dated 15-12-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Apro-EN-20 Injection (10ml) of M/s Aptly Pharmaceuticals, Faisalabad (Reg. No. 121959)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Calves, goats, sheep, poultry
	Decision: Approved.	
472.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Enrofar 20% Injection 50ml
	Composition	Each ml contains: Enrofloxacin…200mg
	Diary No. Date of R& I & fee	Dy.No 29460 dated 21-12-2023 Rs 30,000/- dated 15-12-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Apro-EN-20 Injection (10ml) of M/s Aptly Pharmaceuticals, Faisalabad (Reg. No. 121959)

	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Calves, goats, sheep, poultry
	Decision: Approved.	
473.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Butafar Injection 10ml
	Composition	Each ml contains: Phenylbutazone…200mg
	Diary No. Date of R& I & fee	Dy.No 29896 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Fenylbutazon-20 Injectable Solution of M/s Orient Traders International, Karachi. (Reg. No. 049540)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Horse, cattle, calf, foal, dogs, cats The sub-committee on veterinary drugs recommended use of **phenylbutazone** only in non-food producing animals limiting to equine.
	Decision: Approved in light of recommendations of Sub-committee on Veterinary Drugs regarding use of Phenylbutazone primarily in non-food-producing animals in Reference Regulatory Authorities (RRA) and its use should be restricted to equines only. Furthermore, a prominent warning on the label of drug products containing Phenylbutazone, restricting its use in these animals, should also be shown clearly.	
474.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Gentadon-20 Injection 50ml
	Composition	Each ml contains: Gentamycin as Sulphate…200mg
	Diary No. Date of R& I & fee	Dy.No 29455 dated 21-12-2023 Rs 30,000/- dated 15-12-2023
	Pharmacological Group	Aminoglycoside antibiotic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Gantasin-20% Injection (100ml) of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 112223)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Horse
	Decision: Approved.	
475.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.

	Brand Name +Dosage Form + Strength	Gentadon-20 Injection 100ml
	Composition	Each ml contains: Gentamycin as Sulphate…200mg
	Diary No. Date of R& I & fee	Dy.No 29456 dated 21-12-2023 Rs 30,000/- dated 15-12-2023
	Pharmacological Group	Aminoglycoside antibiotic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Gantasin-20% Injection (100ml) of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 112223)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Horse
	Decision: Approved.	
476.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Gentadon-20 Injection 10ml
	Composition	Each ml contains: Gentamycin as Sulphate…200mg
	Diary No. Date of R& I & fee	Dy.No 28857 dated 14-12-2023 Rs 30,000/- dated 11-12-2023
	Pharmacological Group	Aminoglycoside antibiotic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Gantasin-20% Injection (100ml) of M/s Univet Pharmaceuticals, Rawalpindi. (Reg. No. 112223)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Horse
	Decision: Approved.	
477.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Antizin Injection 10ml
	Composition	Each ml contains: **Antipyrine**…131mg Diminazine Aceturate…105mg
	Diary No. Date of R& I & fee	Dy.No 28858 dated 14-12-2023 Rs 30,000/- dated 11-12-2023
	Pharmacological Group	Antiprotozoal, analgesic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Pronifas Injection (50ml) of M/s Intervac (Pvt) Ltd., Sheikhupura. (Reg. No. 080724)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.

	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, sheep
	Decision: Deferred for review of Expert Working on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
478.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Antizin Injection 100ml
	Composition	Each ml contains: **Antipyrine**…131mg Diminazine Aceturate…105mg
	Diary No. Date of R& I & fee	Dy.No 28864 dated 14-12-2023 Rs 30,000/- dated 11-12-2023
	Pharmacological Group	Antiprotozoal, analgesic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Pronifas Injection (50ml) of M/s Intervac (Pvt) Ltd., Sheikhupura. (Reg. No. 080724)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, sheep
	Decision: Deferred for review of Expert Working on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
479.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Antizin Injection 50ml
	Composition	Each ml contains: **Antipyrine**…131mg Diminazine Aceturate…105mg
	Diary No. Date of R& I & fee	Dy.No 28851 dated 14-12-2023 Rs 30,000/- dated 11-12-2023
	Pharmacological Group	Antiprotozoal, analgesic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Pronifas Injection (50ml) of M/s Intervac (Pvt) Ltd., Sheikhupura. (Reg. No. 080724)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, sheep
	Decision: Deferred for review of Expert Working on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
480.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Marbofar Injection 50ml
	Composition	Each ml contains: Marbofloxacin…100mg

	Diary No. Date of R& I & fee	Dy.No 28856 dated 14-12-2023 Rs 30,000/- dated 11-12-2023
	Pharmacological Group	Fluoroquinolone antibiotic
	Type of Form	Form 5
	Finished product Specifications	In-house specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Marbocore Injection (50ml) of M/s Lucky Core Industries Limited, Lahore. (Reg. No. 120720)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle Firm has submitted fee Rs. 9000/- vide challan No. 21842110407 for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024.
	Decision: Approved with as per innovator's specifications.	
481.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Marbofar Injection 100ml
	Composition	Each ml contains: Marbofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 28860 dated 14-12-2023 Rs 30,000/- dated 11-12-2023
	Pharmacological Group	Fluoroquinolone antibiotic
	Type of Form	Form 5
	Finished product Specifications	In-house specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Marbocore Injection (50ml) of M/s Lucky Core Industries Limited, Lahore. (Reg. No. 120720)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle • Firm has submitted fee Rs. 9000/- vide challan No. 17314485 for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024.
	Decision: Approved with innovator's specifications.	
482.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Trisulfar Injection 10ml
	Composition	Each ml contains: Trimethoprim…40mg Sulphadiazine…60mg Sulphamerazine…100mg Sulphathiazole…40mg
	Diary No. Date of R& I & fee	Dy.No 29461 dated 21-12-2023 Rs 30,000/- dated 15-12-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	10ml; Decontrolled

	Me-too status	Vet-Sulpha Injection (100ml) of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 118426)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, sheep, goat, poultry
	Decision: Approved.	
483.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Trisulfar Injection 20ml
	Composition	Each ml contains: Trimethoprim…40mg Sulphadiazine…60mg Sulphamerazine…100mg Sulphathiazole…40mg
	Diary No. Date of R& I & fee	Dy.No 29889 dated 21-12-2023 Rs 30,000/- dated 15-12-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	20ml; Decontrolled
	Me-too status	Vet-Sulpha Injection (100ml) of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 118426)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, sheep, goat, poultry
	Decision: Approved.	
484.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Trisulfar Injection 50ml
	Composition	Each ml contains: Trimethoprim…40mg Sulphadiazine…60mg Sulphamerazine…100mg Sulphathiazole…40mg
	Diary No. Date of R& I & fee	Dy.No 29462 dated 21-12-2023 Rs 30,000/- dated 15-12-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Vet-Sulpha Injection (100ml) of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 118426)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, sheep, goat, poultry
	Decision: Approved.	
485.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.

	Brand Name +Dosage Form + Strength	Trisulfar Injection 100ml
	Composition	Each ml contains: Trimethoprim…40mg Sulphadiazine…60mg Sulphamerazine…100mg Sulphathiazole…40mg
	Diary No. Date of R& I & fee	Dy.No 29463 dated 21-12-2023 Rs 30,000/- dated 15-12-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Vet-Sulpha Injection (100ml) of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 118426)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, sheep, goat, poultry
	Decision: Approved.	
486.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Ketozar Injection 20ml
	Composition	Each ml contains: **Ketoprofen**…100mg
	Diary No. Date of R& I & fee	Dy.No 29890 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	20ml; Decontrolled
	Me-too status	Hansi Pro 10% Injection (100ml) of M/s D-Haans Pharmaceuticals, Bhimber, Azad Kashmir. (Reg. No. 114840)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, sheep, goat, poultry
	Decision: Deferred for review of Expert Working on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
487.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Oxyfar-PVP Injection 10ml
	Composition	Each ml contains: Oxytetracycline as HCl…100mg
	Diary No. Date of R& I & fee	Dy.No 28360 dated 08-12-2023 Rs 30,000/- dated 07-12-2023
	Pharmacological Group	Antibiotic and anti-inflammatory
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	10ml; Decontrolled

	Me-too status	Aplaox-10 Injection (100ml) of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 122106)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, calves **Shortcomings:** • Firm has submitted fee of Rs.37000/- vide challan No. 79033075 for pre-approval correction in formulation/ label claim in line with pharmacopeia, as per SRO 1324(I)/2014 dated 30-08-2024
	Decision: Approved with following label claim: **Each ml contains:** **Oxytetracycline HCl…100mg** **Firm shall submit fee Rs. 9000/- for pre-approval variation/correction of pharmacological group as per SRO 1324(I)/2024 dated 30-08-2024, before issuance of registration letter.**	
488.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Oxyfar-PVP Injection 50ml
	Composition	Each ml contains: Oxytetracycline as HCl…100mg
	Diary No. Date of R& I & fee	Dy.No 28361 dated 08-12-2023 Rs 30,000/- dated 07-12-2023
	Pharmacological Group	Antibiotic and anti-inflammatory
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Aplaox-10 Injection (100ml) of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 122106)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, calves **Shortcomings:** • Firm has submitted fee of Rs.37000/- vide challan No. 48513402921 for pre-approval correction in formulation/ label claim in line with pharmacopeia, as per SRO 1324(I)/2014 dated 30-08-2024
	Decision: Approved with following label claim: **Each ml contains:** **Oxytetracycline HCl…100mg** **Firm shall submit fee Rs. 9000/- for pre-approval variation/correction of pharmacological group as per SRO 1324(I)/2024 dated 30-08-2024, before issuance of registration letter.**	
489.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Oxyfar-PVP Injection 100ml
	Composition	Each ml contains: Oxytetracycline as HCl…100mg
	Diary No. Date of R& I & fee	Dy.No 28362 dated 08-12-2023 Rs 30,000/- dated 07-12-2023
	Pharmacological Group	Antibiotic and anti-inflammatory
	Type of Form	Form 5
	Finished product Specifications	USP specifications

	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Aplaox-10 Injection (100ml) of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 122106)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, calves **Shortcomings:** • Firm has submitted fee of Rs.37000/- vide challan No. 897011498 for pre-approval correction in formulation/ label claim in line with pharmacopeia, as per SRO 1324(I)/2014 dated 30-08-2024
	Decision: Approved with following label claim: **Each ml contains:** **Oxytetracycline HCl…100mg** **Firm shall submit fee Rs. 9000/- for pre-approval variation/correction of pharmacological group as per SRO 1324(I)/2024 dated 30-08-2024, before issuance of registration letter.**	
490.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Phenoxymin Injection 30ml
	Composition	Each ml contains: Oxytetracycline HCl as Base…50mg Phenylbutazone…25mg Mepyramine Maleate…25mg
	Diary No. Date of R& I & fee	Dy.No 29504 dated 22-12-2023 Rs 30,000/- dated 21-12-2023
	Pharmacological Group	Antibiotic, NSAID, antihistamine
	Type of Form	Form 5
	Finished product Specifications	Inhouse specifications
	Pack size & Demanded Price	30ml; Decontrolled
	Me-too status	Phenoxy-M Injection (30ml, 50ml, 1000ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd Lahore (Reg. No.057002)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, horse, sheep, goat • Firm has submitted fee Rs. 9000/- vide challan No. 374767484 for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024. The sub-committee on veterinary drugs recommended use of **phenylbutazone** only in non-food producing animals limiting to equine.
	Decision: Approved with innovator's specifications in light of recommendations of Sub-committee on Veterinary Drugs regarding use of Phenylbutazone primarily in non-food-producing animals in Reference Regulatory Authorities (RRA) and its use should be restricted to equines only. Furthermore, a prominent warning on the label of drug products containing Phenylbutazone, restricting its use in these animals, should also be shown clearly.	
491.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Phenoxymin Injection 50ml

	Composition	Each ml contains: Oxytetracycline HCl as Base…50mg Phenylbutazone…25mg Mepyramine Maleate…25mg
	Diary No. Date of R& I & fee	Dy.No 29505 dated 22-12-2023 Rs 30,000/- dated 21-12-2023
	Pharmacological Group	Antibiotic, NSAID, antihistamine
	Type of Form	Form 5
	Finished product Specifications	Inhouse specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Phenoxy-M Injection (30ml, 50ml, 1000ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd Lahore (Reg. No.057002)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, horse, sheep, goat • Firm has submitted fee Rs. 9000/- vide challan No. 3265829109 for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024. The sub-committee on veterinary drugs recommended use of **phenylbutazone** only in non-food producing animals limiting to equine.
	Decision: Approved with innovator's specifications in light of recommendations of Sub-committee on Veterinary Drugs regarding use of Phenylbutazone primarily in non-food-producing animals in Reference Regulatory Authorities (RRA) and its use should be restricted to equines only. Furthermore, a prominent warning on the label of drug products containing Phenylbutazone, restricting its use in these animals, should also be shown clearly.	
492.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Phenoxymin Injection 100ml
	Composition	Each ml contains: Oxytetracycline HCl as Base…50mg Phenylbutazone…25mg Mepyramine Maleate…25mg
	Diary No. Date of R& I & fee	Dy.No 29506 dated 22-12-2023 Rs 30,000/- dated 21-12-2023
	Pharmacological Group	Antibiotic, NSAID, antihistamine
	Type of Form	Form 5
	Finished product Specifications	Inhouse specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Phenoxy-M Injection (30ml, 50ml, 1000ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd Lahore (Reg. No.057002)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, horse, sheep, goat • Firm has submitted fee Rs. 9000/- vide challan No. 06348288444 for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024.

		The sub-committee on veterinary drugs recommended use of **phenylbutazone** only in non-food producing animals limiting to equine.
	Decision: Approved with innovator's specifications in light of recommendations of Sub-committee on Veterinary Drugs regarding use of Phenylbutazone primarily in non-food-producing animals in Reference Regulatory Authorities (RRA) and its use should be restricted to equines only. Furthermore, a prominent warning on the label of drug products containing Phenylbutazone, restricting its use in these animals, should also be shown clearly.	
493.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Trisulgenta Injection 50ml
	Composition	Each ml contains: Gentamycin…30mg Trimethoprim…25mg Sulfadimidine…125mg
	Diary No. Date of R& I & fee	Dy.No 28852 dated 14-12-2023 Rs 30,000/- dated 11-12-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Hail Injection (100ml) of M/s Decent Pharma, Rawat. (Reg. No. 118617)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle **Shortcomings:** • Firm shall submit fee of Rs.37000/- for pre-approval correction in formulation/ label claim (completion of salt form) in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024
	Decision: Approved. Firm shall submit fee of Rs.37000/- for pre-approval correction in formulation/ label claim (completion of salt form) in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024 before issuance of registration letter.	
494.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Trisulgenta Injection 10ml
	Composition	Each ml contains: Gentamycin…30mg Trimethoprim…25mg Sulfadimidine…125mg
	Diary No. Date of R& I & fee	Dy.No 28853 dated 14-12-2023 Rs 30,000/- dated 11-12-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	10ml; Decontrolled
	Me-too status	Hail Injection (100ml) of M/s Decent Pharma, Rawat. (Reg. No. 118617)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:**

		Cattle **Shortcomings:** • Firm shall submit fee of Rs.37000/- for pre-approval correction in formulation/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024
	Decision: Approved. Firm shall submit fee of Rs.37000/- for pre-approval correction in formulation/ label claim (completion of salt form) in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024 before issuance of registration letter.	
495.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Trisulgenta Injection 100ml
	Composition	Each ml contains: Gentamycin…30mg Trimethoprim…25mg Sulfadimidine…125mg
	Diary No. Date of R& I & fee	Dy.No 28859 dated 14-12-2023 Rs 30,000/- dated 11-12-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Hail Injection (100ml) of M/s Decent Pharma, Rawat. (Reg. No. 118617)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle **Shortcomings:** • Firm shall submit fee of Rs.37000/- for pre-approval correction in formulation/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024
	Decision: Approved. Firm shall submit fee of Rs.37000/- for pre-approval correction in formulation/ label claim (completion of salt form) in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024 before issuance of registration letter.	
496.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Multifar Injection 50ml
	Composition	Each 50ml contains: L-Carnitine…250mg Thioctic Acid...10mg Pyridoxine HCl…7.5mg Cyanocobalamin…1.5mg DL-Acetylmethionine…1000mg L-Arginine…120mg L-Ornithine...60mg L-Citruline…60mg L-Lysine...25mg Glycine…75mg Taurine...75mg Aspartic Acid…75mg Glutamic Acid ...75mg Fructose…2500mg Sorbitol...4000mg

	Diary No. Date of R& I & fee	Dy.No 28862 dated 14-12-2023 Rs 30,000/- dated 11-12-2023
	Pharmacological Group	Vitamins and minerals
	Type of Form	Form 5
	Finished product Specifications	Inhouse specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Multimino-V Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 058712)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, buffalo, horses, sheep, goats, calves, lambs & goat kids, dogs and cats, poultry • Firm has submitted fee Rs. 9000/- vide challan No. 72108260686 for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024.
	Decision: Approved with as per innovator's specifications.	
497.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Multifar Injection 100ml
	Composition	Each 50ml contains: L-Carnitine…250mg Thioctic Acid...10mg Pyridoxine HCl…7.5mg Cyanocobalamin…1.5mg DL-Acetylmethionine…1000mg L-Arginine…120mg L-Ornithine...60mg L-Citruline…60mg L-Lysine...25mg Glycine…75mg Taurine...75mg Aspartic Acid…75mg Glutamic Acid ...75mg Fructose…2500mg Sorbitol...4000mg
	Diary No. Date of R& I & fee	Dy.No 28863 dated 14-12-2023 Rs 30,000/- dated 11-12-2023
	Pharmacological Group	Vitamins and minerals
	Type of Form	Form 5
	Finished product Specifications	Inhouse specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Multimino-V Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 058712)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, buffalo, horses, sheep, goats, calves, lambs & goat kids, dogs and cats, poultry • Firm has submitted fee Rs. 9000/- vide challan No. 65475712967 for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024.

	Decision: Approved with as per innovator's specifications.	
498.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Novafort Injection 100ml
	Composition	Each ml contains: Novaminsulfone…40mg Etilefrin as HCl…0.2mg Caffeine…10mg Sodium Salicylate…7mg Nicotinamide…0.3mg Boric Acid…10mg Calcium Gluconate…100mg Magnesium Gluconate…10mg
	Diary No. Date of R& I & fee	Dy.No 28855 dated 14-12-2023 Rs 30,000/- dated 11-12-2023
	Pharmacological Group	Minerals and vitamins
	Type of Form	Form 5
	Finished product Specifications	Inhouse specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Pri-Sedaxvit Injection of M/s Prix Pharmaceutica (Pvt) Ltd, Lahore. (Reg. No. 079256)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Liquid Injection (General)** section confirmed vide letter No.F. 1-29/2007-Lic (M-236) dated 23-09-2014. **Target species:** Cattle, buffalo, sheep, goats, calves, horses, poultry • Firm has submitted fee Rs. 9000/- vide challan No. 01036864792 for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024.
	Decision: Deferred for review of sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
499.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Novafort Injection 250ml
	Composition	Each ml contains: **Novaminsulfone**…40mg Etilefrin as HCl…0.2mg Caffeine…10mg Sodium Salicylate…7mg Nicotinamide…0.3mg Boric Acid…10mg Calcium Gluconate…100mg Magnesium Gluconate…10mg
	Diary No. Date of R& I & fee	Dy.No 28854 dated 14-12-2023 Rs 30,000/- dated 11-12-2023
	Pharmacological Group	Minerals and vitamins
	Type of Form	Form 5
	Finished product Specifications	Inhouse specifications
	Pack size & Demanded Price	250ml; Decontrolled
	Me-too status	Pri-Sedaxvit Injection of M/s Prix Pharmaceutica (Pvt) Ltd, Lahore. (Reg. No. 079256)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Target species:** Cattle, buffalo, sheep, goats, calves, horses, poultry

		Shortcomings: • Confirmation of **relevant manufacturing facility** • Firm has submitted fee Rs. 9000/- vide challan No. 1030299729 for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024.
	Decision: Deferred for following: • **review of sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters** • **Confirmation of relevant manufacturing facility**	
500.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Novafort Injection 450ml
	Composition	Each ml contains: **Novaminsulfone**…40mg Etilefrin as HCl…0.2mg Caffeine…10mg Sodium Salicylate…7mg Nicotinamide…0.3mg Boric Acid…10mg Calcium Gluconate…100mg Magnesium Gluconate…10mg
	Diary No. Date of R& I & fee	Dy.No 28850 dated 14-12-2023 Rs 30,000/- dated 11-12-2023
	Pharmacological Group	Minerals and vitamins
	Type of Form	Form 5
	Finished product Specifications	Inhouse specifications
	Pack size & Demanded Price	450ml; Decontrolled
	Me-too status	Pri-Sedaxvit Injection of M/s Prix Pharmaceutica (Pvt) Ltd, Lahore. (Reg. No. 079256)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Target species:** Cattle, buffalo, sheep, goats, calves, horses, poultry **Shortcomings:** • Confirmation of **relevant manufacturing facility** • Firm has submitted fee Rs. 9000/- vide challan No. 544218644094 for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024.
	Decision: Deferred for following: • **review of sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.** • **Confirmation of relevant manufacturing facility**	
501.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Mil-D-Far Injection 450ml
	Composition	Each 100ml contains: Calcium Gluconate…20.83gm Calcium D-Saccharate…1gm Magnesium Hypophosphite…5.33gm Magnesium Chloride…2gm Boric Acid…4.33gm Dextrose…20gm Vitamin B1…100mg Vitamin B2…70mg Vitamin B12…3000mcg

		Nicotinamide…200mg
	Diary No. Date of R& I & fee	Dy.No 29897 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	Minerals and vitamins
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	450ml; Decontrolled
	Me-too status	**Could not be confirmed in the applied combination and strength**
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Target species:** Cattle, horse, sheep, goats **Shortcomings:** • Confirmation of **relevant manufacturing facility** • 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 submission of following: • **Confirmation of relevant manufacturing facility** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
502.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Neofar-72 Powder
	Composition	Each gram contains: Neomycin Sulphate 720mg Eq. to Neomycin…500mg
	Diary No. Date of R& I & fee	Dy.No 29892 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	50gm, 100gm, 500gm, 1Kg, 2Kg, 3Kg, 5Kg; Decontrolled
	Me-too status	AR Neomed-72 Oral Powder of M/s Medpharm Research Lab, Lahore. (Reg. No. 122023)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Powder (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Calves, sheep, goats, poultry
	Decision: Approved upto 1Kg pack size.	
503.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Resipidox Powder
	Composition	Each gram contains: Tylosin Tartrate…100mg Colistin sulphate…0.50 MIU Bromhexine HCl…5mg Doxycycline HCl…200mg
	Diary No. Date of R& I & fee	Dy.No 29893 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	Antibiotic

	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 500gm, 1Kg, 2Kg, 3Kg, 5Kg; Decontrolled
	Me-too status	Codot-50 Oral Powder of M/s Biorific Pharma, Islamabad. (Reg. No. 122034)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Powder (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** poultry **Shortcomings:** • Firm shall submit fee of Rs.37000/- for pre-approval correction in formulation/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024
	Decision: Approved upto 1Kg pack sizewith following label claim: **Each gram contains:** **Tylosin as Tartrate…100mg** **Colistin sulphate…0.50 MIU** **Bromhexine HCl…5mg** **Doxycycline HCl…200mg** **Firm shall submit fee of Rs.37000/- for pre-approval correction in formulation/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024.**	
504.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Hexafar Oral Solution
	Composition	Each ml contains: Bromhexine HCl…10mg
	Diary No. Date of R& I & fee	Dy.No 29895 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	Mucolytic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml,250ml, 500ml, 750ml, 1000ml, 2000ml, 3000ml, 4000ml, 5000ml, 10L; Decontrolled
	Me-too status	Arch Brom 1% Oral Liquid of M/s Archard Pharmaceuticals Pvt Ltd., Bhimber, AJK (Reg. No. 121914)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** poultry
	Decision: Approved upto 1000ml pack size.	
505.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Enrofar-20 Oral Solution
	Composition	Each ml contains: Enrofloxacin…200mg
	Diary No. Date of R& I & fee	Dy.No 29454 dated 21-12-2023 Rs 30,000/- dated 15-12-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications

	Pack size & Demanded Price	50ml, 100ml,250ml, 500ml, 750ml, 1000ml, 2000ml, 3000ml, 4000ml, 5000ml; Decontrolled
	Me-too status	Enroxal 20% Oral Solution of M/s Tarobina Corporation, Lahore. (Reg. No. 122133)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** poultry
	Decision: Approved upto 1000ml pack size.	
506.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Ricoben-15 Suspension
	Composition	Each ml contains: Ricobendazole…150mg
	Diary No. Date of R& I & fee	Dy.No 29494 dated 22-12-2023 Rs 30,000/- dated 21-12-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 750ml, 1000ml, 2000ml, 3000ml, 4000ml, 5000ml; Decontrolled
	Me-too status	Ricomin 15 % Suspension of M/s Star Laboratories (Pvt) Ltd., Lahore (Reg. No. 063597)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Cattle, sheep, goat
	Decision: Approved upto 1000ml pack size.	
507.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Ricoben-4 Suspension
	Composition	Each ml contains: Ricobendazole…40mg
	Diary No. Date of R& I & fee	Dy.No 29880 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 750ml, 1000ml, 2000ml, 3000ml, 4000ml, 5000ml; Decontrolled
	Me-too status	Ricomin 4% Suspension of M/s Star Laboratories (Pvt) Ltd., Lahore (Reg. No. 063596)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Cattle, sheep, goat
	Decision: Approved upto 1000ml pack size.	

508.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Colistofar Oral Solution
	Composition	Each ml contains: Colistin Sulphate…20 MIU
	Diary No. Date of R& I & fee	Dy.No 29887 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 500ml, 1000ml, 2000ml, 3000ml, 5000ml; Decontrolled
	Me-too status	**Could not be confirmed in the applied strength**
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Poultry **Shortcomings:** • 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 submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
509.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Floxafar Solution
	Composition	Each ml contains: Pefloxacin Methanesulfonate 139.6mg eq. to Pefloxacin …100mg
	Diary No. Date of R& I & fee	Dy.No 29883 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	Quinolone antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 750ml, 1000ml, 2000ml, 3000ml, 4000ml, 5000ml; Decontrolled
	Me-too status	PE Poul Oral Liquid of M/s Poulvet Pharmaceuticals (Pvt) Ltd., Multan (Reg. No. 120727)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Poultry
	Decision: Approved upto 1000ml pack size.	
510.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Flumeq 20 Solution
	Composition	Each ml contains: Flumequine…200mg

	Diary No. Date of R& I & fee	Dy.No 29891 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	Fluoroquinolone antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 750ml, 1000ml, 2000ml, 3000ml, 4000ml, 5000ml; Decontrolled
	Me-too status	Flume-Z 20% Liquid of M/s Zoic International, Lahore (Reg. No.090671)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Poultry
	Decision: Approved upto 1000ml pack size.	
511.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Flumeq-C Solution
	Composition	Each ml contains: Flumequine…200mg Colistin Sulphate…25,000 IU
	Diary No. Date of R& I & fee	Dy.No 29453 dated 21-12-2023 Rs 30,000/- dated 15-12-2023
	Pharmacological Group	Fluoroquinolone antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 500ml, 1000ml, 2000ml, 3000ml, 5000ml; Decontrolled
	Me-too status	C Fluquine Liquid of M/s Inshal Pharmaceutical Industries, Islamabad. (Reg. No. 103877)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Poultry
	Decision: Approved upto 1000ml pack size.	
512.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Bentel-25 Suspension
	Composition	Each ml contains: Febentel…25mg
	Diary No. Date of R& I & fee	Dy.No 29495 dated 22-12-2023 Rs 30,000/- dated 21-12-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 750ml, 1000ml, 2000ml, 3000ml, 4000ml, 5000ml; Decontrolled
	Me-too status	Forben Suspension of M/s Mylab (Pvt) Ltd, Bahawalpur. (Reg. No. 114955)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.

	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Cattle, sheep, goats
	Decision: Approved upto 1000ml pack size.	
513.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Toltrafar DS Solution
	Composition	Each ml contains: Toltrazuril…50mg Triethanolamine…300mg
	Diary No. Date of R& I & fee	Dy.No 29885 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 750ml, 1000ml, 2000ml, 3000ml, 4000ml, 5000ml; Decontrolled
	Me-too status	Toltra-D.S. Solution of M/s Bio Lab (Pvt). Ltd. Islamabad (Reg. No. 039987)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Cattle, sheep
	Decision: Approved upto 1000ml pack size.	
514.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Bactrafar 24% Solution
	Composition	Each ml contains: Trimethoprim…40mg Sulphadiazine…200mg
	Diary No. Date of R& I & fee	Dy.No 29881 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 750ml, 1000ml, 2000ml, 3000ml, 4000ml, 5000ml; Decontrolled
	Me-too status	Gelliprimoral Liquid of M/s Agro Marketing Karachi (Reg. No. 019919)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Horse, cattle, dogs, cats
	Decision: Approved upto 1000ml pack size.	
515.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Florocol Solution
	Composition	Each ml contains:

		Florfenicol…230mg Colistin Sulphate…0.5 MIU
	Diary No. Date of R& I & fee	Dy.No 29452 dated 21-12-2023 Rs 30,000/- dated 15-12-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 500ml, 1000ml, 2000ml, 3000ml, 5000ml; Decontrolled
	Me-too status	Hirra-Flore 23% Oral Liquid of M/s Hirra Pharmaceutical Laboratories (Private) Limited, Lahore (Reg. No. 120852)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Poultry
	Decision: Approved upto 1000ml pack size.	
516.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Colenrofar-20 Solution
	Composition	Each ml contains: Enrofloxacin…200mg Colistin Sulphate…500,000 IU
	Diary No. Date of R& I & fee	Dy.No 29452 dated 21-12-2023 Rs 30,000/- dated 15-12-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 750ml, 1000ml, 2000ml, 3000ml, 4000ml, 5000ml; Decontrolled
	Me-too status	Acmecoliflox 20/50 Oral Liquid of M/s Acme Pharmaceuticals, Islamabad. (Reg. No. 117021)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Poultry, calves
	Decision: Approved upto 1000ml pack size.	
517.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Encofar Solution
	Composition	Each ml contains: Enrofloxacin…100mg Colistin Sulphate…500,000 IU
	Diary No. Date of R& I & fee	Dy.No 29882 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 750ml, 1000ml, 2000ml, 3000ml, 4000ml, 5000ml; Decontrolled
	Me-too status	Enrokam C-10 Oral Solution of M/s M.A.Kamil Farma Pvt. Ltd., Karachi. (Reg. No. 119986)

	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Poultry, calves
	Decision: Approved upto 1000ml pack size.	
518.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Coxifar Plus Solution
	Composition	Each ml contains: Toltrazuril…25mg Vitamin A…2.5mg Vitamin K3…5mg
	Diary No. Date of R& I & fee	Dy.No 29899 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	Anticoccidial
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 750ml, 1000ml, 2000ml, 3000ml, 4000ml, 5000ml; Decontrolled
	Me-too status	Zurotil Oral Liquid of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 120773)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Poultry
	Decision: Approved upto 1000ml pack size.	
519.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Biocticfar + Solution
	Composition	Each ml contains: **Norfloxacin**…50mg Sulphamethoxypyridazine…50mg Trimethoprim…10mg **Phenylbutazone**…12mg Bromhexine as HCl…2mg
	Diary No. Date of R& I & fee	Dy.No 29492 dated 22-12-2023 Rs 30,000/- dated 21-12-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 750ml, 1000ml, 2000ml, 3000ml, 4000ml, 5000ml; Decontrolled
	Me-too status	Megabiotic Solution of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 057006)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Poultry

		The Registration Board, in its 335th meeting, deliberated the matter in the details, keeping in view absence of any recognized scientific data regarding the use of norfloxacin in any Reference Regulatory Authority (RRA) and based on the recommendation of Sub-committee on Veterinary Drugs decided to refer all such combinations to M/o NFS&R for their comments for their valuable inputs.
	Decision: Deferred for review of Expert Working on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters.	
520.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Spilinfar Solution
	Composition	Each ml contains: Lincomycin HCl…75mg Spiramycin Adipate…125mg
	Diary No. Date of R& I & fee	Dy.No 29898 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 750ml, 1000ml, 2000ml, 3000ml, 4000ml, 5000ml; Decontrolled
	Me-too status	Lincospira Solution of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 049628)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Poultry
	Decision: Approved upto 1000ml pack size.	
521.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Hepafar Solution
	Composition	Each ml contains: L-Carnitine…50mg Inositol…7mg Betain…20mg Choline Chloride…100mg Magnesium Sulphate…10mg
	Diary No. Date of R& I & fee	Dy.No 29884 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 750ml, 1000ml, 2000ml, 3000ml, 4000ml, 5000ml; Decontrolled
	Me-too status	**Could not be confirmed in the applied combination**
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Poultry, cow, cattle, horse, camel, goat **Shortcomings:**

		• 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 submission of following: • **evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Correct pharmacological group**	
522.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Selyte-Far Solution
	Composition	Each 1000ml contains: Vitamin B1…150mg Vitamin B2…1800 Vitamin B6…820mg Vitamin B12…1000ug Vitamin C…7000mg Sodium Chloride…50gm Magnesium Sulphate…5gm Dextrose…300gm Glycine…40gm Monopotassium Phosphate…25gm Citric Acid…5gm Potassium Citrate…70mg
	Diary No. Date of R& I & fee	Dy.No 29894 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	Vitamins/ minerals
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 750ml, 1000ml, 2000ml, 3000ml, 4000ml, 5000ml; Decontrolled
	Me-too status	Selyte-B Solution of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore. (Reg. No. 071078)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Poultry
	Decision: Approved upto 1000ml pack size.	
523.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Lycifar Solution
	Composition	Each ml contains: Vitamin C…50mg Lysine HCl…225mg
	Diary No. Date of R& I & fee	Dy.No 29886 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	Vitamin/ amino acid
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 750ml, 1000ml, 2000ml, 3000ml, 4000ml, 5000ml; Decontrolled
	Me-too status	Lyciliq Solution of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore. (Reg. No. 071076)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.

	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Poultry
	Decision: Approved upto 1000ml pack size.	
524.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Refox-CS Drench
	Composition	Each ml contains: Sodium Selenite…0.35mg Cobalt Sulphate…1.67mg Rafoxanide…45mg
	Diary No. Date of R& I & fee	Dy.No 29500 dated 22-12-2023 Rs 30,000/- dated 21-12-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 750ml, 1000ml, 2000ml, 3000ml, 4000ml, 5000ml; Decontrolled
	Me-too status	Rafoxa-CS Drench of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore. (Reg. No. 057015)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Cattle, sheep, goat
	Decision: Approved upto 1000ml pack size.	
525.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Oxynic Drench
	Composition	Each ml contains: Niclosamide…75mg Oxibendazole…10mg
	Diary No. Date of R& I & fee	Dy.No 29879 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 750ml, 1000ml, 2000ml, 3000ml, 4000ml, 5000ml; Decontrolled
	Me-too status	Nicox Drench of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 120771)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Cattle
	Decision: Approved upto 1000ml pack size.	
526.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Ricobalt-40 Drench

	Composition	Each ml contains: Ricobendazole…40mg Cobalt Sulphate…1.67mg
	Diary No. Date of R& I & fee	Dy.No 29879 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 750ml, 1000ml, 2000ml, 3000ml, 4000ml, 5000ml; Decontrolled
	Me-too status	Ricozole Plus Drench of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore. (Reg. No. 057011)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Ewes, gimmers, lambs
	Decision: Approved upto 1000ml pack size.	
527.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Lezan DS Drench
	Composition	Each ml contains: Levamisole…30mg Oxyclozanide…60mg Cobalt Sulphate…3.34mg Sodium Selenite…1mg
	Diary No. Date of R& I & fee	Dy.No 28861 dated 14-12-2023 Rs 30,000/- dated 11-12-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml; Decontrolled
	Me-too status	Flukacid Forte Drench of M/s Amazon Pharmaceuticals (Pvt.) Ltd. AJK. (Reg. No. 121929)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Cattle, sheep, goat **Shortcomings:** • Firm shall submit fee of Rs.37000/- for pre-approval correction in formulation/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024
	Decision: Approved upto 1000ml pack size. Firm shall submit fee of Rs.37000/- for pre-approval correction in formulation (salt form) / label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024 before issuance of registration letter.	
528.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Tilsin Solution
	Composition	Each ml contains: Tilmicosin as Phosphate…250mg

	Diary No. Date of R& I & fee	Dy.No 29493 dated 22-12-2023 Rs 30,000/- dated 21-12-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 750ml, 1000ml, 2000ml, 3000ml, 4000ml, 5000ml; Decontrolled
	Me-too status	Actimisin AK Oral Solution of M/s Tarobina Corporation, Lahore. (Reg. No. 122128)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Calves, chicken, turkeys
	Decision: Approved upto 1000ml pack size.	
529.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Levacloz Drench
	Composition	Each ml contains: Levamisole HCl…100mg Closantel…100mg
	Diary No. Date of R& I & fee	Dy.No 29499 dated 22-12-2023 Rs 30,000/- dated 21-12-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 750ml, 1000ml, 2000ml, 3000ml, 4000ml, 5000ml; Decontrolled
	Me-too status	Closole Suspension of M/s Attabak Pharmaceuticals, Islamabad. (Reg. No. 062140)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Sheep, goat, cattle
	Decision: Approved upto 1000ml pack size.	
530.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Zolox-DS Drench
	Composition	Each ml contains: Oxfendazole…34mg Oxyclozanide…94mg Cobalt Sulphate…3.82mg Sodium Selenite…0.5mg
	Diary No. Date of R& I & fee	Dy.No 29877 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 750ml, 1000ml, 2000ml, 3000ml, 4000ml, 5000ml; Decontrolled
	Me-too status	Soc-Nix Drench of M/s Pharmonix Pharmaceuticals, Rawat. (Reg. No. 122112)

	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Sheep, goat, cattle
	Decision: Approved upto 1000ml pack size.	
531.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Tricoben SC Drench
	Composition	Each ml contains: Selenium as Sodium Selenite…0.35mg Cobalt as Cobalt Sulphate…1.67mg Triclabendazole…50mg
	Diary No. Date of R& I & fee	Dy.No 29496 dated 22-12-2023 Rs 30,000/- dated 21-12-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 750ml, 1000ml, 2000ml, 3000ml, 4000ml, 5000ml; Decontrolled
	Me-too status	Endomall SC Oral Drench of M/s Mallard Pharmaceutical (Pvt) Ltd Multan (Reg. No. 058921)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Sheep, goat, buffalo, cattle
	Decision: Approved upto 1000ml pack size.	
532.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Refozol-CS Drench
	Composition	Each ml contains: Sodium Selenite…0.35mg Cobalt Sulphate…1.67mg Rafoxanide…45mg Levamisole HCl…22.5mg
	Diary No. Date of R& I & fee	Dy.No 29497 dated 22-12-2023 Rs 30,000/- dated 21-12-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 750ml, 1000ml, 2000ml, 3000ml, 4000ml, 5000ml; Decontrolled
	Me-too status	Rafoxazole Drench of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 057012)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Sheep, goat, cattle
	Decision: Approved upto 1000ml pack size.	

533.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt. Ltd., 542-A & B, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Triclosol SC Drench
	Composition	Each ml contains: Selenium as Sodium Selenite…0.35mg Cobalt as Cobalt Sulphate…1.67mg Triclabendazole…50mg Levamisole as HCl…37.5mg
	Diary No. Date of R& I & fee	Dy.No 29878 dated 29-12-2023 Rs 30,000/- dated 28-12-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 250ml, 500ml, 750ml, 1000ml, 2000ml, 3000ml, 4000ml, 5000ml; Decontrolled
	Me-too status	TL-Nix Forte Suspension of M/s Pharmonix Pharmaceuticals, Rawat (Reg. No. 122117)
	GMP status	GMP inspection conducted on 29-07-2022, report concludes GMP compliance on the day of inspection.
	Remarks of the Evaluator	**Veterinary Oral Liquid (General & General Antibiotics)** section confirmed vide letter No.F. 1-29/2007-Lic dated 04-09-2018. **Target species:** Sheep, goat, cattle, buffalo • Firm has submitted fee of Rs.37000/- vide challan No. 3798790132 for pre-approval correction in formulation/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024.
	Decision: Approved upto 1000ml pack size.	
534.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eter Carb 120 Injection 50ml
	Composition	Each ml contains: Imidocarb Dipropionate…120mg
	Diary No. Date of R& I & fee	Dy.No 29512 dated 22-12-2023 Rs 30,000/- dated 22-12-2023
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Imidoca Injection of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 122104)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Target species:** Cattle, horses, sheep, dogs, goat, donkey **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Firm shall submit fee of Rs.37000/- for pre-approval correction in formulation/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024

	Decision: Approved with following label claim: **Each ml contains:** **Imidocarb as Dipropionate…120mg** **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.37000/- for pre-approval correction in formulation/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024**	
535.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eter Carb 120 Injection 100ml
	Composition	Each ml contains: Imidocarb Dipropionate…120mg
	Diary No. Date of R& I & fee	Dy.No 29513 dated 22-12-2023 Rs 30,000/- dated 22-12-2023
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Imidoca Injection of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 122104)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Target species:** Cattle, horses, sheep, dogs, goat, donkey **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Firm shall submit fee of Rs.37000/- for pre-approval correction in formulation/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024
	Decision: Approved with following label claim: **Each ml contains:** **Imidocarb as Dipropionate…120mg** **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.37000/- for pre-approval correction in formulation/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024**	
536.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Enro Pro 10% Injection 10ml
	Composition	Each ml contains: Enrofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 29510 dated 22-12-2023 Rs 30,000/- dated 22-12-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	10ml,: Decontrolled
	Me-too status	Enisol-10 Injection of M/s Lucky Core Industries Limited, Lahore. (Reg. No. 122063)

	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Target species:** Poultry, cattle, buffalo, sheep, goat, dogs, cat **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
537.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Enro Pro 10% Injection 50ml
	Composition	Each ml contains: Enrofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 29511 dated 22-12-2023 Rs 30,000/- dated 22-12-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Enisol-10 Injection of M/s Lucky Core Industries Limited, Lahore. (Reg. No. 122064)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Target species:** Poultry, cattle, buffalo, sheep, goat, dogs, cat **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
538.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	ADE Injection 100ml
	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 29517 dated 22-12-2023 Rs 30,000/- dated 22-12-2023
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	APLA AD3E Injection of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 121985)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.

	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Target species:** Cattle, calves, yearlings, horses **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
539.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	ADE Injection 10ml
	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 29516 dated 22-12-2023 Rs 30,000/- dated 22-12-2023
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	10ml,: Decontrolled
	Me-too status	APLA AD3E Injection (100ml) of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 121985)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Target species:** Cattle, calves, yearlings, horses **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
540.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eter Diuretic Injection 10ml
	Composition	Each ml contains: Furosemide…50mg
	Diary No. Date of R& I & fee	Dy.No 29507 dated 22-12-2023 Rs 30,000/- dated 22-12-2023
	Pharmacological Group	Diuretic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	10ml,: Decontrolled
	Me-too status	Durectin Injection (10ml) of M/s Bio-Labs (Pvt) Ltd., Islamabad. (Reg. No. 122040)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021.

		Target species: Cattle, buffalo, horses, camel, sheep, goats, dogs, cats **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved with following label claim: **Each ml contains:** **Furosemide (As Monoethanolamine Salt)…50mg** **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.37000/- for pre-approval correction in formulation/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024**	
541.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Hepanol Injection 100ml
	Composition	Each ml contains: Phenoxy-2-methyl-2-Propionic Acid…100mg
	Diary No. Date of R& I & fee	Dy.No 29508 dated 22-12-2023 Rs 30,000/- dated 22-12-2023
	Pharmacological Group	Liver tonic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Ishepa Injection (100ml) of M/s ISIS Pharmaceuticals & Chemical Works, Karachi (Reg. No. 119968)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable General (Veterinary) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Target species:** Cattle, horses, sheep, goats **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
542.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Colistin Mox Injection 50ml
	Composition	Each ml contains: Amoxicillin as Trihydrate…100mg Colistin Sulphate…250,000 IU
	Diary No. Date of R& I & fee	Dy.No 29514 dated 22-12-2023 Rs 30,000/- dated 22-12-2023
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	50ml,: Decontrolled
	Me-too status	Aplostin Injection of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 121978)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable (Penicillin) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 11-11-2021.

		Target species: Poultry, calves, sheep, goats, cattle, horses, dogs, cats **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
543.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Colistin Mox Injection 100ml
	Composition	Each ml contains: Amoxicillin as Trihydrate…100mg Colistin Sulphate…250,000 IU
	Diary No. Date of R& I & fee	Dy.No 29515 dated 22-12-2023 Rs 30,000/- dated 22-12-2023
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml,: Decontrolled
	Me-too status	Aplostin Injection of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 121979)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable (Penicillin) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 11-11-2021. **Target species:** Poultry, calves, sheep, goats, cattle, horses, dogs, cats **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
544.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Pencin 5 Injection
	Composition	Each vial contains: Benzyl Penicillin…500,000 IU Streptomycin Sulphate…5gm
	Diary No. Date of R& I & fee	Dy.No 29506 dated 22-12-2023 Rs 30,000/- dated 22-12-2023
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	1s,: Decontrolled
	Me-too status	Benzon Dry Powder for Injection of M/s Amazon Pharmaceuticals (Pvt.) Ltd. Bhimber, AJK. (Reg. No. 120655)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Dry Powder Injectable (Penicillin) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 11-11-2021. **Target species:** Foal, calves, sheep, goats, cattle, horses, dogs, cats **Shortcomings:**

		• Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
545.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Amocillin 20% Injection 10ml
	Composition	Each ml contains: Amoxicillin as Trihydrate…200mg
	Diary No. Date of R& I & fee	Dy.No 29509 dated 22-12-2023 Rs 30,000/- dated 22-12-2023
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	10ml,: Decontrolled
	Me-too status	Aplamox-20 LA Injection (100ml) of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 121977)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Liquid Injectable (Penicillin) Section** confirmed vide letter No. F. 5-1/2016-Lic dated 11-11-2021. **Target species:** Poultry, calves, sheep, goats, cattle, horses, dogs, cats **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
546.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eter Choline Powder
	Composition	Each Kg contains: Choline Chloride…80gm L-Lysine…35gm DL Methionine…55gm Zinc Bacitracin…15gm Vitamin E…3000mg Nicotinic Acid…3000mg
	Diary No. Date of R& I & fee	Dy.No 29521 dated 22-12-2023 Rs 30,000/- dated 22-12-2023
	Pharmacological Group	Vitamin, amino acid and trace element preparation
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100gm, 200gm, 250gm, 500gm, 1000gm: Decontrolled
	Me-too status	DL-Chol Powder of M/s M.A. Kamil Farma (Pvt) Ltd., Karachi. (Reg. No. 119759)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Oral Powder Section (General) Veterinary** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Target species:** Poultry **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.

	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
547.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Enramin premix 8%
	Composition	Each gram contains: Enramycin…80mg
	Diary No. Date of R& I & fee	Dy.No 29518 dated 22-12-2023 Rs 30,000/- dated 22-12-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100gm, 200gm, 250gm, 500gm, 1000gm: Decontrolled
	Me-too status	Enracin-80 Premix of M/s Lucky Core Industries Limited, Lahore (Reg. No. 119844)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Oral Powder Section (General) Veterinary** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Target species:** Poultry **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
548.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Eter Phenoxy Water Soluble Powder
	Composition	Each gram contains: Phenoxymethyl Penicillin 293mg eq. to Potassium Phenoxymethyl Penicillin…325mg
	Diary No. Date of R& I & fee	Dy.No 29520 dated 22-12-2023 Rs 30,000/- dated 22-12-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100gm, 200gm, 250gm, 500gm, 1000gm: Decontrolled
	Me-too status	MAK Phenox Water Soluble Powder of M/s M.A.Kamil Farma Pvt. Ltd., Karachi (Reg. No. 119828)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Oral Dry Powder Section (Penicillin)** confirmed vide letter No. F. 5-1/2016-Lic dated 11-11-2021. **Target species:** Chicken **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
549.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.

	Brand Name +Dosage Form + Strength	Nilworm SC Drench
	Composition	Each ml contains: Oxyclozanide…94mg Oxfendazole…34mg Cobalt Sulphate…3.82mg Sodium Selenite…0.50mg
	Diary No. Date of R& I & fee	Dy.No 29519 dated 22-12-2023 Rs 30,000/- dated 22-12-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 200ml, 500ml, 1000ml: Decontrolled
	Me-too status	Soc-Nix Drench of M/s Pharmonix Pharmaceuticals, Rawat. (Reg. No. 122112)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Oral Liquid Section (General) Veterinary** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Target species:** Sheep, goat, cattle, buffalo, camel **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
550.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Oflobod Oral Liquid
	Composition	Each ml contains: Ofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 29522 dated 22-12-2023 Rs 30,000/- dated 22-12-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 200ml, 500ml, 1000ml: Decontrolled
	Me-too status	Ofloxkam-10 Oral Solution of M/s M.A.Kamil Farma Pvt. Ltd., Karachi (Reg. No. 120590)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Oral Liquid Section (General) Veterinary** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Target species:** Poultry **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
551.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Trimectin 122 Oral Suspension
	Composition	Each ml contains: Triclabendazole…120mg

		Ivermectin…2mg
	Diary No. Date of R& I & fee	Dy.No 29525 dated 22-12-2023 Rs 30,000/- dated 22-12-2023
	Pharmacological Group	Antiparasitic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 200ml, 500ml, 1000ml: Decontrolled
	Me-too status	Endozon Forte Oral Suspension of M/s Amazon Pharmaceuticals (Pvt.) Ltd. Bhimber, AJK. (Reg. No. 120681)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Oral Liquid Section (General) Veterinary** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Target species:** sheep **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
552.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Trimectin 51 Oral Suspension
	Composition	Each ml contains: Triclabendazole…50mg Ivermectin…1mg
	Diary No. Date of R& I & fee	Dy.No 29524 dated 22-12-2023 Rs 30,000/- dated 22-12-2023
	Pharmacological Group	Antiparasitic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 200ml, 500ml, 1000ml: Decontrolled
	Me-too status	I-Endecto Plus Suspension of M/s International Pharma Labs, Lahore. (Reg. No. 120696)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Oral Liquid Section (General) Veterinary** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Target species:** sheep **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
553.	Name and address of manufacturer / Applicant	M/s Eterna Pharma Pvt Ltd., Plot No. (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	Marboflox Oral Liquid
	Composition	Each ml contains: Marbofloxacin…100mg
	Diary No. Date of R& I & fee	Dy.No 29523 dated 22-12-2023 Rs 30,000/- dated 22-12-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5

	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 200ml, 500ml, 1000ml: Decontrolled
	Me-too status	Marbocore Injection of M/s Lucky Core Industries Limited, Lahore. (Reg. No. 120720)
	GMP status	GMP certificate dated 31-08-2022 based on inspection conducted on 14-10-2021.
	Remarks of the Evaluator	**Oral Liquid Section (General) Veterinary** confirmed vide letter No. F. 5-1/2016-Lic dated 07-06-2021. **Target species:** Poultry **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
554.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories (Pvt) Ltd., 136 sector 15 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Ascor-C Powder
	Composition	Each gram contains: Ascorbic Acid…1000mg
	Diary No. Date of R& I & fee	Dy.No 29221 dated 19-12-2023 Rs 30,000/- dated 13-12-2023
	Pharmacological Group	Vitamin supplement/ antioxidant
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 3Kg, 5Kg & 25Kg: Decontrolled
	Me-too status	C-Kam 100 Powder of M/s M.A.Kamil Farma (Pvt) Ltd., Karachi (Reg. No. 119760)
	GMP status	Firm has submitted routine GMP inspection report dated 25-01-2022 wherein it is concluded that keeping in view the attitude of the management towards continuous improvements and current observations their overall GMP compliance is rated as good.
	Remarks of the Evaluator	**Dry Powder Sachet (Veterinary) Section** confirmed vide letter No. F. 2-10/93-Lic(Vol-I) dated 07-06-2022. **Target species:** Poultry, cattle, calves, cold-water fish, warm-water fish, lambs, foals, sheep, goats, horses
	Decision: Approved up to 1Kg pack for poultry only. Moreover, Registration Board directed the applicant to clearly mention specific target species on label.	
555.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan.
	Brand Name +Dosage Form + Strength	Dairy Gold Powder
	Composition	Each 1000gm contains: Vitamin A...0.8gm Vitamin D3...0.16gm Vitamin E...0.38gm Vitamin B1...1gm Vitamin B2...1.25gm Vitamin B3...6.25gm Vitamin B6...4gm Vitamin B12...0.001gm Copper Sulphate...0.25gm Magnesium Sulphate...25gm Calcium Chloride...0.023gm Zinc Sulphate...2.17gm

		Manganese Sulphate...1.20gm Potassium Iodide...0.5gm Sodium Selenite...0.01gm Dicalcium Phosphate...150gm Sodium Chloride...120gm
	Diary No. Date of R& I & fee	Dy.No 29763 dated 27-12-2023 Rs 30,000/- dated 27-12-2023
	Pharmacological Group	Multivitamins & Minerals
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	0.5Kg, 1Kg, 5Kg, 25Kg & 50Kg: Decontrolled
	Me-too status	White Gold Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 058842) **Could not be confirmed in the applied strength**
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019
	Remarks of the Evaluator	**Oral powder (General) Veterinary** section confirmed vide letter No. F. 1-4/2007-Lic (vol-II) dated 07-03-2022 **Target species:** Poultry, cattle, sheep • Firm has submitted fee Rs. 9000/- vide challan No. 644737035 for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024. **Shortcomings:** • 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 submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
556.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Serilin Injection 20ml
	Composition	Each ml contains: Lecirelin (as Acetate)…25mcg
	Diary No. Date of R& I & fee	Dy.No 28345 dated 08-12-2023 Rs 30,000/- dated 29-11-2023
	Pharmacological Group	Gonadotropin releasing hormones
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	20ml: Decontrolled
	Me-too status	Recilin Injection (**10ml**) of M/s Ras Pharmaceuticals (Pvt) Ltd., Multan. (Reg. No. 116935)
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator	**Liquid Injection Hormone (Veterinary) Section** confirmed vide letter No. F.1-13/2000-Lic (Vol-II) dated 23-01-2019. **Target species:** cattle, mare
	Decision: Approved.	
557.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Selsync Injection 20ml
	Composition	Each ml contains: Gonadorelin as Acetate…100ug

	Diary No. Date of R& I & fee	Dy.No 28344 dated 08-12-2023 Rs 30,000/- dated 29-11-2023
	Pharmacological Group	Gonadotropin releasing hormones
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	20ml: Decontrolled
	Me-too status	Ovurelin Injection (20ml) of M/s Ghazi Brothers, Karachi. (Reg. No. 099428)
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator	**Liquid Injection Hormone (Veterinary) Section** confirmed vide letter No. F.1-13/2000-Lic (Vol-II) dated 23-01-2019. **Target species:** cattle
	Decision: Approved.	
558.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Loxin Injection 100ml
	Composition	Each ml contains: Flunixin as Meglumine…50mg
	Diary No. Date of R& I & fee	Dy.No 28342 dated 08-12-2023 Rs 30,000/- dated 29-11-2023
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Flu More 5% Injection (100ml) of M/s Moreno Iglisias Research Laboratories (Pvt) Ltd., Lahore (Reg. No. 120799)
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator	**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. **Target species:** Cattle, horses
	Decision: Approved.	
559.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Atrostar Injection 50ml
	Composition	Each ml contains: Atropine Sulphate…1mg
	Diary No. Date of R& I & fee	Dy.No 28848 dated 14-12-2023 Rs 30,000/- dated 05-12-2023
	Pharmacological Group	Anti-muscarinic
	Type of Form	Form 5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Ispine Injection of M/s ISIS Pharmaceuticals & Chemical Works, Karachi (Reg. No. 119970)
	GMP status	cGMP certificate dated 08-06-2023 based on inspection conducted on 30-05-2023.
	Remarks of the Evaluator	**Liquid injectable (veterinary) section** confirmed vide panel inspection dated 14-12-2015 report for renewal of DML.

		Target species: Cattle, buffalo, horses, sheep, goat, dog, cat
	Decision: Approved.	
560.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Oxytim Liquid Injection 100ml
	Composition	Each ml contains: Oxytetracycline as HCl…300mg Flunixin as Meglumine…20mg
	Diary No. Date of R& I & fee	Dy.No 28847 dated 14-12-2023 Rs 30,000/- dated 05-12-2023
	Pharmacological Group	Tetracycline antibiotic/ NSAID
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Oxymore-F Injection (100ml) of M/s Moreno Iglisias Research Laboratories (Pvt) Ltd., Lahore (Reg. No. 120803)
	GMP status	cGMP certificate dated 08-06-2023 based on inspection conducted on 30-05-2023.
	Remarks of the Evaluator	**Liquid injectable (veterinary) section** confirmed vide panel inspection dated 14-12-2015 report for renewal of DML. **Target species:** Cattle
	Decision: Approved.	
561.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Moxitril Injection 100ml
	Composition	Each ml contains: Amoxicillin as Trihydrate…100mg Colistin Sulphate…250,000 IU
	Diary No. Date of R& I & fee	Dy.No 28849 dated 14-12-2023 Rs 30,000/- dated 05-12-2023
	Pharmacological Group	Penicillin antibiotic/ polymixin antibiotic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Aplostin Injection (100ml) of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 121979)
	GMP status	cGMP certificate dated 08-06-2023 based on inspection conducted on 30-05-2023.
	Remarks of the Evaluator	**Shortcomings:** Confirmation of **relevant manufacturing facility**.
	Decision: Deferred for confirmation of relevant manufacturing facility.	
562.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Oxytocin-20 Injection 100ml
	Composition	Each ml contains: Oxytocin…20 IU
	Diary No. Date of R& I & fee	Dy.No 29782 dated 28-12-2023 Rs 30,000/- dated 20-12-2023
	Pharmacological Group	Hormone
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	**100ml**: Decontrolled

	Me-too status	Oxytocin Injection (20 IU/ml) (100ml) of M/s ISIS Pharmaceuticals & Chemical Works, Karachi. (Reg. No. 119965)
	GMP status	cGMP certificate dated 08-06-2023 based on inspection conducted on 30-05-2023.
	Remarks of the Evaluator	**Target species:** Mares and cows, sows, ewes and goats **Shortcomings:** Confirmation of **relevant manufacturing facility.** Registration Board in its 313th meeting wherein Board endorsed the following recommendations of Expert Working group on Veterinary Drugs: "*The Expert Working Group on Veterinary Drugs deliberate the case and decided to allow for granting multidose vials for Oxytocin as per following details:* • *Oxytocin .... 10 UI upto 500ml as per Spanish authority approval or any pack size available in any other RRA.* • *Oxytocin .... 20 UI upto 50ml as per Australian Pesticides and Veterinary Medicine Authority approval or any pack size available in any other RRA."*
	Decision: Deferred for submission of following: • **confirmation of relevant manufacturing facility** • **fill volume/pack size as per recommendations of the Expert Working Group on Veterinary Drugs, presented in 313th meeting of Registration Board.**	
563.	Name and address of manufacturer / Applicant	M/S Star Laboratories Pvt Ltd., 23-Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Nilpro Spray 100ml
	Composition	Each ml contains: Fipronil…0.25% w/v
	Diary No. Date of R& I & fee	Dy. No 29781 dated 28-12-2023 Rs 30,000/- dated 20-12-2023
	Pharmacological Group	Insecticide
	Type of Form	Form 5
	Finished product Specifications	As per innovator's Specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Prosel Spray of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore (Reg. No. 114800)
	GMP status	cGMP Certificate Dated 08-06-2023 Based On Inspection Conducted On 30-05-2023.
	Remarks of the Evaluator	**Target Species:** Dogs and cats **Shortcomings:** Confirmation of **relevant manufacturing facility**.
	Decision: Deferred for confirmation of relevant manufacturing facility.	
564.	Name and address of manufacturer / Applicant	M/s Mili Vet Pharmaceuticals Pvt Ltd, Had Bast, Mouza Kamas, Tehsil Raiwind, District Lahore.
	Brand Name +Dosage Form + Strength	Mili Neo-70% Water Soluble Powder
	Composition	Each gram contains: Neomycin Sulphate…700mg
	Diary No. Date of R& I & fee	Dy.No 1883 dated 29-01-2024 Rs 30,000/- dated 10-01-2024
	Pharmacological Group	Aminoglycoside antibiotic
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled

	Me-too status	Eleneo 70 Powder of M/s Elegance Pharmaceuticals, Distt. Rawalpindi. (Reg. No.118628)
	GMP status	Panel inspection report recommended for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021.
	Remarks of the Evaluator	**Oral Powder section (Veterinary)** confirmed from panel inspection report for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021. **Target species:** Cattle, poultry **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved upto 1000gm pack size. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
565.	Name and address of manufacturer / Applicant	M/s Mili Vet Pharmaceuticals Pvt Ltd, Had Bast, Mouza Kamas, Tehsil Raiwind, District Lahore.
	Brand Name +Dosage Form + Strength	Trimil Powder
	Composition	Each gram contains: Trichlorfon…980mg
	Diary No. Date of R& I & fee	Dy.No 1880 dated 29-01-2024 Rs 30,000/- dated 10-01-2024
	Pharmacological Group	Insecticide
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	Stone Fon 98 Powder of M/s Archard Pharmaceuticals Pvt Ltd., Bhimber, AJK (Reg. No. 121904)
	GMP status	Panel inspection report recommended for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021.
	Remarks of the Evaluator	**Oral Powder section (Veterinary)** confirmed from panel inspection report for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved upto 1000gm pack size. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
566.	Name and address of manufacturer / Applicant	M/s Mili Vet Pharmaceuticals Pvt Ltd, Had Bast, Mouza Kamas, Tehsil Raiwind, District Lahore.
	Brand Name +Dosage Form + Strength	Mili Tyldox-BC Water Soluble Powder
	Composition	Each gram contains: Tylosin Tartrate…100mg Doxycycline HCl…200mg Colistin Sulphate…0.500 MIU Bromhexine HCl…5mg
	Diary No. Date of R& I & fee	Dy.No 1882 dated 29-01-2024 Rs 30,000/- dated 21-12-2023
	Pharmacological Group	Antibiotic/ antibacterial/ expectorant
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	Codot-50 Oral Powder of M/s Biorific Pharma, Islamabad. (Reg. No. 122034)

	GMP status	Panel inspection report recommended for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021.
	Remarks of the Evaluator	**Oral Powder section (Veterinary)** confirmed from panel inspection report for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021. **Target species:** Cows, goats, sheep, dogs, horses **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Firm shall submit fee of Rs.37000/- for pre-approval correction in formulation/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024
	Decision: Approved upto 1000gm pack size. 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.37000/- for pre-approval correction in formulation/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024.**	
567.	Name and address of manufacturer / Applicant	M/s Mili Vet Pharmaceuticals Pvt Ltd, Had Bast, Mouza Kamas, Tehsil Raiwind, District Lahore.
	Brand Name +Dosage Form + Strength	Tylomil-10 Premix
	Composition	Each gram contains: Tylosin Phosphate…100mg
	Diary No. Date of R& I & fee	Dy.No 1879 dated 29-01-2024 Rs 30,000/- dated 10-01-2024
	Pharmacological Group	Antibiotic/ antibacterial
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	Avilosin 10 Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 118657)
	GMP status	Panel inspection report recommended for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021.
	Remarks of the Evaluator	**Oral Powder section (Veterinary)** confirmed from panel inspection report for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021. **Target species:** Cattle, poultry **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Firm shall submit fee of Rs.37000/- for pre-approval correction in formulation/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024
	Decision: Approved upto 1000gm pack size. 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.37000/- for pre-approval correction in formulation/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024.**	
568.	Name and address of manufacturer / Applicant	M/s Mili Vet Pharmaceuticals Pvt Ltd, Had Bast, Mouza Kamas, Tehsil Raiwind, District Lahore.
	Brand Name +Dosage Form + Strength	Milipara-CE Oral Powder

	Composition	Each 100gm contains: **Paracetamol**…20gm **Vitamin C**…5gm Potassium Carbonate…12.5gm Sodium Bicarbonate…12.5gm Vitamin E…12.5gm
	Diary No. Date of R& I & fee	Dy.No 1881 dated 29-01-2024 Rs 30,000/- dated 10-01-2024
	Pharmacological Group	Analgesic/ antipyretic with vitamin C, E and electrolytes
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	10gm, 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm: Decontrolled
	Me-too status	C-Rox Para Powder of M/s Vetrox Pharmaceutical Pvt Ltd, Toba Tek Singh. (Reg. No. 112366)
	GMP status	Panel inspection report recommended for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021.
	Remarks of the Evaluator	**Oral Powder section (Veterinary)** confirmed from panel inspection report for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for review of Expert Working on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and submission of latest GMP inspection report conducted within the period of last three years.	
569.	Name and address of manufacturer / Applicant	M/s Mili Vet Pharmaceuticals Pvt Ltd, Had Bast, Mouza Kamas, Tehsil Raiwind, District Lahore.
	Brand Name +Dosage Form + Strength	Mili Oxazole Oral Drench
	Composition	Each ml contains: Oxfendazole…22.65mg
	Diary No. Date of R& I & fee	Dy.No 1888 dated 29-01-2024 Rs 30,000/- dated 10-01-2024
	Pharmacological Group	Anthelmintic/ dewormer
	Type of Form	Form 5
	Finished product Specifications	BP vet specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Hirra-Faxazol Oral Drench of M/s Hirra Pharmaceutical Laboratories (Private) Limited, Lahore (Reg. No. 27445)
	GMP status	Panel inspection report recommended for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021.
	Remarks of the Evaluator	**Oral Liquid section (Veterinary)** confirmed from panel inspection report for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021. **Target species:** Cattle, sheep **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved upto 1000ml pack size. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
570.	Name and address of manufacturer / Applicant	M/s Mili Vet Pharmaceuticals Pvt Ltd, Had Bast, Mouza Kamas, Tehsil Raiwind, District Lahore.
	Brand Name +Dosage Form + Strength	Mili Clobend Oral Drench

	Composition	Each 100ml contains: Albendazole…10gm Closantel…2gm
	Diary No. Date of R& I & fee	Dy.No 1887 dated 29-01-2024 Rs 30,000/- dated 10-01-2024
	Pharmacological Group	Anthelmintic/ dewormer
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Arch Clozol 10 Suspension of M/s Archard Pharmaceuticals Pvt Ltd., Bhimber, AJK (Reg. No.121924)
	GMP status	Panel inspection report recommended for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021.
	Remarks of the Evaluator	**Oral Liquid section (Veterinary)** confirmed from panel inspection report for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021. **Target species:** Cattle, sheep **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved upto 1000ml pack size. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
571.	Name and address of manufacturer / Applicant	M/s Mili Vet Pharmaceuticals Pvt Ltd, Had Bast, Mouza Kamas, Tehsil Raiwind, District Lahore.
	Brand Name +Dosage Form + Strength	Mili Alben-10% Oral Drench
	Composition	Each 100ml contains: Albendazole…10gm
	Diary No. Date of R& I & fee	Dy.No 1886 dated 29-01-2024 Rs 30,000/- dated 10-01-2024
	Pharmacological Group	Anthelmintic/ dewormer
	Type of Form	Form 5
	Finished product Specifications	BP vet specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Henzole-10% Suspension of M/s Huzaifa International, District Sargodha. (Reg. No.120743)
	GMP status	Panel inspection report recommended for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021.
	Remarks of the Evaluator	**Oral Liquid section (Veterinary)** confirmed from panel inspection report for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021. **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved upto 1000ml pack size. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
572.	Name and address of manufacturer / Applicant	M/s Mili Vet Pharmaceuticals Pvt Ltd, Had Bast, Mouza Kamas, Tehsil Raiwind, District Lahore.
	Brand Name +Dosage Form + Strength	Enrme-25 Oral Liquid
	Composition	Each 100ml contains: Enrofloxacin…25gm Colistin Sulphate…50 MIU

	Diary No. Date of R& I & fee	Dy.No 1884 dated 29-01-2024 Rs 30,000/- dated 10-01-2024
	Pharmacological Group	Antibiotic, antimicrobial
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 500ml, 1L, 2.5L, 5L, 10L, 25L: Decontrolled
	Me-too status	Quino Poul-75-Oral Liquid of M/s Poulvet Pharmaceuticals (Pvt) Ltd., Multan (Reg. No. 118541)
	GMP status	Panel inspection report recommended for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021.
	Remarks of the Evaluator	**Oral Liquid section (Veterinary)** confirmed from panel inspection report for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021. **Target species:** Dogs, cats, camel, pets, cattle, calves, sheep **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved upto 1L pack size. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
573.	Name and address of manufacturer / Applicant	M/s Mili Vet Pharmaceuticals Pvt Ltd, Had Bast, Mouza Kamas, Tehsil Raiwind, District Lahore.
	Brand Name +Dosage Form + Strength	Mili OCS Oral Drench
	Composition	Each ml contains: Oxfendazole…22.65mg Cobalt…1.67mg Selenium…0.5mg
	Diary No. Date of R& I & fee	Dy.No 1894 dated 29-01-2024 Rs 30,000/- dated 21-12-2023
	Pharmacological Group	Anthelmintic/ dewormer / minerals
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Ocs-Nix Suspension of M/s Pharmonix Pharmaceuticals, Rawat (Reg. No. 122118)
	GMP status	Panel inspection report recommended for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021.
	Remarks of the Evaluator	**Oral Liquid section (Veterinary)** confirmed from panel inspection report for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021. **Target species:** cattle, sheep **Shortcomings:** • Confirmation of **relevant testing facility** • Latest GMP inspection report conducted within the period of last three years. • Firm shall submit fee of Rs.37000/- for pre-approval correction in formulation/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024
	Decision: Deferred for submission of following: • **Confirmation of relevant testing facility** • **Latest GMP inspection report conducted within the period of last three years.** • **fee of Rs.37000/- for pre-approval correction in formulation (salt form completion)/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024**	

574.	Name and address of manufacturer / Applicant	M/s Mili Vet Pharmaceuticals Pvt Ltd, Had Bast, Mouza Kamas, Tehsil Raiwind, District Lahore.
	Brand Name +Dosage Form + Strength	Mili Levacot-S Oral Drench
	Composition	Each ml contains: Levamisole HCl…37.5mg Triclabendazole…50mg Sodium Selenite…0.035mg Cobalt Sulphate…1.67mg
	Diary No. Date of R& I & fee	Dy.No 1889 dated 29-01-2024 Rs 30,000/- dated 21-12-2023
	Pharmacological Group	Anthelmintic/ dewormer
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Tribex Drench of M/s Evergreen Pharmaceuticals, Lahore. (Reg. No. 073989)
	GMP status	Panel inspection report recommended for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021.
	Remarks of the Evaluator	**Oral Liquid section (Veterinary)** confirmed from panel inspection report for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021. **Target species:** Cow, goats, sheep, dogs, horses **Shortcomings:** • Confirmation of **relevant testing facility** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for submission of following: • **Confirmation of relevant testing facility** • **Latest GMP inspection report conducted within the period of last three years.**	
575.	Name and address of manufacturer / Applicant	M/s Mili Vet Pharmaceuticals Pvt Ltd, Had Bast, Mouza Kamas, Tehsil Raiwind, District Lahore.
	Brand Name +Dosage Form + Strength	Mili Tribectin Oral Drench
	Composition	Each ml contains: Triclabendazole…12gm Albendazole…10gm Ivermectin…0.20gm
	Diary No. Date of R& I & fee	Dy.No 1895 dated 29-01-2024 Rs 30,000/- dated 21-12-2023
	Pharmacological Group	Anthelmintic/ dewormer
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Mecben Drench of M/s Archard Pharmaceuticals Pvt Ltd., Bhimber, AJK (Reg. No. 121897)
	GMP status	Panel inspection report recommended for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021.
	Remarks of the Evaluator	**Oral Liquid section (Veterinary)** confirmed from panel inspection report for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021. **Target species:** goats, sheep, cat, dogs, horses **Shortcomings:**

		• Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for review of Expert Working on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and submission of latest GMP inspection report conducted within the period of last three years.	
576.	Name and address of manufacturer / Applicant	M/s Mili Vet Pharmaceuticals Pvt Ltd, Had Bast, Mouza Kamas, Tehsil Raiwind, District Lahore.
	Brand Name +Dosage Form + Strength	Mili Lecox Oral Drench
	Composition	Each 100ml contains: Levamisole HCl…1.5gm Oxyclozanide…3gm Cobalt Sulphate…0.382gm
	Diary No. Date of R& I & fee	Dy.No 1891 dated 29-01-2024 Rs 30,000/- dated 21-12-2023
	Pharmacological Group	Anthelmintic/ dewormer
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Oxzmisole Oral Liquid of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh (Reg. No. 117206)
	GMP status	Panel inspection report recommended for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021.
	Remarks of the Evaluator	**Oral Liquid section (Veterinary)** confirmed from panel inspection report for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021. **Target species:** Cattle, goats, sheep **Shortcomings:** • Confirmation of **relevant testing facility** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for submission of following: • **Confirmation of relevant testing facility** • **Latest GMP inspection report conducted within the period of last three years.**	
577.	Name and address of manufacturer / Applicant	M/s Mili Vet Pharmaceuticals Pvt Ltd, Had Bast, Mouza Kamas, Tehsil Raiwind, District Lahore.
	Brand Name +Dosage Form + Strength	Mili FTI Oral Drench
	Composition	Each 100ml contains: Febendazole…5gm Triclabendazole…5gm Ivermectin…0.1gm
	Diary No. Date of R& I & fee	Dy.No 1890 dated 29-01-2024 Rs 30,000/- dated 21-12-2023
	Pharmacological Group	Anthelmintic/ dewormer
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Endo-Try Oral Drench of M/s Biorise Pharmaceuticals, Multan. (Reg. No. 120770)
	GMP status	Panel inspection report recommended for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021.

	Remarks of the Evaluator	**Oral Liquid section (Veterinary)** confirmed from panel inspection report for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021. **Target species:** Cattle, sheep **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for review of Expert Working on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and submission of latest GMP inspection report conducted within the period of last three years.	
578.	Name and address of manufacturer / Applicant	M/s Mili Vet Pharmaceuticals Pvt Ltd, Had Bast, Mouza Kamas, Tehsil Raiwind, District Lahore.
	Brand Name +Dosage Form + Strength	Mili Deworm Oral Drench
	Composition	Each 100ml contains: Levamisole HCl…3gm Oxyclozanide…6gm Cobalt Sulphate…0.764gm Sodium Selenite…0.076gm
	Diary No. Date of R& I & fee	Dy.No 1892 dated 29-01-2024 Rs 30,000/- dated 21-12-2023
	Pharmacological Group	Anthelmintic/ dewormer
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Flukacid SC Drench of M/s Amazon Pharmaceuticals (Pvt.) Ltd. Bhimber, AJK (Reg. No. 120684)
	GMP status	Panel inspection report recommended for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021.
	Remarks of the Evaluator	**Oral Liquid section (Veterinary)** confirmed from panel inspection report for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021. **Shortcomings:** • Confirmation of **relevant testing facility** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for submission of following: • **Confirmation of relevant testing facility** • **Latest GMP inspection report conducted within the period of last three years.**	
579.	Name and address of manufacturer / Applicant	M/s Mili Vet Pharmaceuticals Pvt Ltd, Had Bast, Mouza Kamas, Tehsil Raiwind, District Lahore.
	Brand Name +Dosage Form + Strength	Mili Oxazole Plus Oral Drench
	Composition	Each ml contains: Oxfendazole…22.5mg Oxyclozanide…62.5mg Cobalt Sulphate…3.82mg Sodium Selenite…0. 35mg
	Diary No. Date of R& I & fee	Dy.No 1893 dated 29-01-2024 Rs 30,000/- dated 21-12-2023
	Pharmacological Group	Anthelmintic/ dewormer
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Sodox D Oral Drench of M/s Athan Pharmaceuticals,

		Hattar (Reg. No. 115032)
	GMP status	Panel inspection report recommended for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021.
	Remarks of the Evaluator	**Oral Liquid section (Veterinary)** confirmed from panel inspection report for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021. **Target species:** Cows, goats, sheep, dogs, horses **Shortcomings:** • Confirmation of **relevant testing facility** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for submission of following: • **Confirmation of relevant testing facility** • **Latest GMP inspection report conducted within the period of last three years.**	
580.	Name and address of manufacturer / Applicant	M/s Mili Vet Pharmaceuticals Pvt Ltd, Had Bast, Mouza Kamas, Tehsil Raiwind, District Lahore.
	Brand Name +Dosage Form + Strength	Mili Scor Oral Suspension
	Composition	Each ml contains: Sulphadiazine…35.50mg Sulphadimidine…28.40mg Neomycin Sulphate…1.80mg Hyoscine Methylbromide…0.04mg Pectin…7.10mg Kaolin…103.30mg Vitamin B1…0.15mg Vitamin B2…0.22mg
	Diary No. Date of R& I & fee	Dy.No 1885 dated 29-01-2024 Rs 30,000/- dated 10-01-2024
	Pharmacological Group	Antidiarrheal
	Type of Form	Form 5
	Finished product Specifications	As per innovator's specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1000ml, 2500ml, 5000ml: Decontrolled
	Me-too status	Sulphavet Oral Suspension of M/s Bio-Labs (Pvt) Ltd., Islamabad. (Reg. No. 122044)
	GMP status	Panel inspection report recommended for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021.
	Remarks of the Evaluator	**Oral Liquid section (Veterinary)** confirmed from panel inspection report for grant of new DML based on inspection conducted on 09-10-2020 and 23-04-2021. **Target species:** Cows, goats, sheep, dogs, horses **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved upto 1000ml pack size. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
581.	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	Calceo-44 Injection 100ml
	Composition	Each ml contains: Calcium Gluconate…440mg Boric Acid…60mg
	Diary No. Date of R& I & fee	Dy.No 497 dated 08-01-2024 Rs 30,000/- dated 03-01-2024

	Pharmacological Group	Calcium supplement
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Glucal 44 Solution for Injection of M/s Ghazi Brothers, Karachi (Reg. No. 087820)
	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	**Liquid Injectable (Veterinary) Section** confirmed vide letter No. F.2-44/84-Lic(Vol-IV) dated 20-09-2021 **Target species:** • Cattle, horses, sheep, dogs, cats **Shortcomings:** • Firm shall submit fee Rs. 9000/-for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024.
	Decision: Approved with as per innovator's specifications. Firm shall submit fee Rs. 9000/-for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024 before issuance of registration letter.	
582.	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	Vital-D Oral Liquid
	Composition	Each 100ml Contains: Vitamin A…39mg Vitamin D3…0.1mg Vitamin E…1gm Vitamin B1…1.3gm Sodium Chloride…0.1gm Tricalcium Phosphate…24.66gm
	Diary No. Date of R& I & fee	Dy.No 498 dated 08-01-2024 Rs 30,000/- dated 03-01-2024
	Pharmacological Group	Vitamin and mineral supplement
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Vetcal-D Oral Liquid of M/s Pivotal Nutraceutical China. Marketed by Diversified Marketing Group **Could not be confirmed**
	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	**Oral Liquid (Veterinary) Section** confirmed vide letter No. F.2-44/84-Lic(Vol-IV) dated 20-09-2021 **Shortcomings:** • 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 Rs. 9000/-for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024.
	Decision: Deferred for submission of following: • **evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **fee Rs. 9000/-for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024.**	
583.	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	Phocal Oral Liquid
	Composition	Each 500ml contains: Calcium…59mg Phosphorous…45gm
	Diary No. Date of R& I & fee	Dy.No 496 dated 08-01-2024 Rs 30,000/- dated 03-01-2024
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	500ml; Decontrolled
	Me-too status	Uni Calzo Pro Liquid of M/s Henan Yeehua Animal Pharmaceutical China. Marketed by Unique Pharma, Multan **Could not be confirmed**
	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	**Oral Liquid (Veterinary) Section** confirmed vide letter No. F.2-44/84-Lic(Vol-IV) dated 20-09-2021 **Target species:** • Cows, buffaloes **Shortcomings:** • 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 Rs. 9000/-for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024.
	Decision: Deferred for submission of following: • **evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **fee Rs. 9000/-for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024.**	
584.	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	Levox drench 100ml
	Composition	Each ml contains: Levamisole HCl…1.5gm
	Diary No. Date of R& I & fee	Dy.No 495 dated 08-01-2024 Rs 30,000/- dated 03-01-2024
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Arch Leva 1.5% Drench of M/s Archard Pharmaceuticals Pvt Ltd., AJK. (Reg. No. 121894)
	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	**Oral Liquid (Veterinary) Section** confirmed vide letter No. F.2-44/84-Lic(Vol-IV) dated 20-09-2021 **Shortcomings:** • Firm shall submit fee Rs. 9000/-for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024.
	Decision: Approved with as per innovator's specifications. Firm shall submit fee Rs. 9000/-for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024 before issuance of registration letter.	

585.	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	Founder Oral Solution
	Composition	Each 100ml contains: Triclabendazole…12gm Ivermectin…0.2gm Albendazole…10gm
	Diary No. Date of R& I & fee	Dy.No 494 dated 08-01-2024 Rs 30,000/- dated 03-01-2024
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 1000ml; Decontrolled
	Me-too status	Kix Drench of M/s International Pharma Labs. Lahore. (Reg. No. 120758)
	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	**Oral Liquid (Veterinary) Section** confirmed vide letter No. F.2-44/84-Lic(Vol-IV) dated 20-09-2021 **Shortcomings:** • Firm shall submit fee Rs. 9000/-for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024.
	Decision: Deferred for review of Expert Working on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and submission of latest GMP inspection report conducted within the period of last three years.	
586.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Floricam 100ml Injection
	Composition	Each ml contains: Florfenicol…400mg Meloxicam…5mg
	Diary No. Date of R& I & fee	Dy.No 1878 dated 29-01-2024 **Rs 75,000/-** dated 24-01-2024
	Pharmacological Group	Antibiotic, NSAID
	Type of Form	**Form 5D**
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Not already registered with DRAP
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator	**Injectable vial General (Veterinary) Section** confirmed vide panel inspection report based on evaluation conducted on 24-01-2023 & 25-01-2023. The firm has submitted the reference of **EU authorization** in (Austria, Belgium, France, Germany, Ireland, Italy, Netherlands, Spain, Sweden, United Kingdom (Northern Ireland)) accessed on 19-11-2024 through following URL: www.ema.europa.eu/en/documents/product-information/zeleris-epar-product-information_en.pdf
	Decision: Approved.	
587.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd., 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Floricam 50ml Injection
	Composition	Each ml contains: Florfenicol…400mg

		Meloxicam…5mg
	Diary No. Date of R& I & fee	Dy.No 1877 dated 29-01-2024 **Rs 75,000/-** dated 24-01-2024
	Pharmacological Group	Antibiotic, NSAID
	Type of Form	**Form 5D**
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Not already registered with DRAP
	GMP status	cGMP certificate dated 27-02-2023 based on inspection dated 24-01-2023 & 25-01-2023
	Remarks of the Evaluator	**Injectable vial General (Veterinary) Section** confirmed vide panel inspection report based on evaluation conducted on 24-01-2023 & 25-01-2023. The firm has submitted the reference of **EU authorization** in (Austria, Belgium, France, Germany, Ireland, Italy, Netherlands, Spain, Sweden, United Kingdom (Northern Ireland)) accessed on 19-11-2024 through following URL: www.ema.europa.eu/en/documents/product-information/zeleris-epar-product-information_en.pdf
	Decision: Deferred for submission of stability studies data of drug product at both accelerated and long term stability conditions as per checklist approved in 293rd meeting of Registration Board.	
588.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Cyno-XL Injection 100ml
	Composition	Each ml contains: Cyanocobalamin…1000mcg
	Diary No. Date of R& I & fee	Dy.No 1195 dated 19-01-2024 Rs 30,000/- dated 05-01-2024
	Pharmacological Group	Vitamins B12
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Apcyno-100 Injection (100ml) of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 122084)
	GMP status	cGMP certificate dated 08-06-2023 based on inspection conducted on 30-05-2023.
	Remarks of the Evaluator	**Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML. **Target species:** Cattle, horse, sheep, dogs, cats
	Decision: Approved.	
589.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Vigo Injection 50ml
	Composition	Each ml contains: Gentamycin Sulphate…50mg Tylosin as Tartrate…100mg Colistin Sulphate…0.2 MIU
	Diary No. Date of R& I & fee	Dy.No 1194 dated 19-01-2024 Rs 30,000/- dated 05-01-2024
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled

	Me-too status	Combigent Injection (**100ml**) of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 088086)
	GMP status	cGMP certificate dated 08-06-2023 based on inspection conducted on 30-05-2023.
	Remarks of the Evaluator	**Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML. **Target species:** Cattle, buffalo, sheep, goat, poultry
	Decision: Approved with change of brand name.	
590.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Tystar Injection 100ml
	Composition	Each ml contains: Tylosin as Tartrate…100mg Gentamycin as Sulphate…50mg
	Diary No. Date of R& I & fee	Dy.No 1196 dated 19-01-2024 Rs 30,000/- dated 05-01-2024
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Aplagent Injection (100ml) of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 121968)
	GMP status	cGMP certificate dated 08-06-2023 based on inspection conducted on 30-05-2023.
	Remarks of the Evaluator	**Liquid injectable (veterinary)** section confirmed vide panel inspection dated 14-12-2015 report for renewal of DML. **Target species:** sheep, goat, poultry
	Decision: Approved.	
591.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Biogent Injection 100ml
	Composition	Each ml contains: Amoxicillin Trihydrate eq. to Amoxicillin…150mg Gentamycin Sulphate eq. to Gentamycin…40mg
	Diary No. Date of R& I & fee	Dy.No 1198 dated 19-01-2024 Rs 30,000/- dated 05-01-2024
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Aplacin Injection (100ml) of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 122075)
	GMP status	cGMP certificate dated 08-06-2023 based on inspection conducted on 30-05-2023.
	Remarks of the Evaluator	**Liquid injectable vial (vet- Penicillin)** section confirmed vide panel inspection dated 30-05-2023 report for renewal of DML & regularization. **Target species:** Cattle, buffalo, sheep, goat, poultry
	Decision: Approved.	
592.	Name and address of manufacturer / Applicant	M/s Star Laboratories Pvt Ltd., 23-km, Multan Road, Lahore.

	Brand Name +Dosage Form + Strength	Biogent Injection 50ml
	Composition	Each ml contains: Amoxicillin Trihydrate eq. to Amoxicillin…150mg Gentamycin Sulphate eq. to Gentamycin…40mg
	Diary No. Date of R& I & fee	Dy.No 1197 dated 19-01-2024 Rs 30,000/- dated 05-01-2024
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Aplacin Injection (50ml) of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 122074)
	GMP status	cGMP certificate dated 08-06-2023 based on inspection conducted on 30-05-2023.
	Remarks of the Evaluator	**Liquid injectable vial (vet- Penicillin)** section confirmed vide panel inspection dated 30-05-2023 report for renewal of DML & regularization. **Target species:** Cattle, buffalo, sheep, goat, poultry
	Decision: Approved.	
593.	Name and address of manufacturer / Applicant	M/s Zakfas Pharmaceuticals Pvt. Ltd., 12-Km, Bosan Road, Multan.
	Brand Name +Dosage Form + Strength	Ketofos Injection 50ml
	Composition	Each ml contains: **Ketoprofen**…100mg
	Diary No. Date of R& I & fee	Dy.No 1303 dated 22-01-2024 Rs 30,000/- dated 18-01-2024
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Hansi Pro 10% Injection of M/s D-Haans Pharmaceuticals, Bhimber, Azad Kashmir. (Reg. No.114839)
	GMP status	Panel inspection report for renewal of DML dated 15-06-2021 recommends renewal of DML
	Remarks of the Evaluator	**Veterinary Liquid injection (General) section** confirmed vide panel inspection report for renewal of DML dated 15-06-2021 **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for review of sub-committee on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and submission of latest GMP inspection report conducted within the period of last three years.	
594.	Name and address of manufacturer / Applicant	M/s Zakfas Pharmaceuticals Pvt. Ltd., 12-Km, Bosan Road, Multan.
	Brand Name +Dosage Form + Strength	Fluzak Forte Injection 50ml
	Composition	Each ml contains: Flunixin Meglumine…83mg
	Diary No. Date of R& I & fee	Dy.No 1304 dated 22-01-2024 Rs 30,000/- dated 18-01-2024
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	50ml: Decontrolled

	Me-too status	Menixin-83 Injection of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 122099)
	GMP status	Panel inspection report for renewal of DML dated 15-06-2021 recommends renewal of DML
	Remarks of the Evaluator	**Veterinary Liquid injection (General) section** confirmed vide panel inspection report for renewal of DML dated 15-06-2021 **Target species:** Horses, cattle, sheep, goat, dogs **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Firm shall submit fee of Rs.37000/- for pre-approval correction in formulation/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024
	Decision: Approved with following label claim: **Each ml contains:** **Flunixin as Meglumine…83mg** **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.37000/- for pre-approval correction in formulation/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024.**	
595.	Name and address of manufacturer / Applicant	M/s Zakfas Pharmaceuticals Pvt. Ltd., 12-Km, Bosan Road, Multan.
	Brand Name +Dosage Form + Strength	Methicob Injection 100ml
	Composition	Each ml contains: Cyanocobalamin…250mcg
	Diary No. Date of R& I & fee	Dy.No 1309 dated 22-01-2024 Rs 30,000/- dated 18-01-2024
	Pharmacological Group	Vitamin B-12
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Apcyno-100 Injection (100ml) of M/s Aptly Pharmaceuticals, Faisalabad. (Reg. No. 122084)
	GMP status	Panel inspection report for renewal of DML dated 15-06-2021 recommends renewal of DML
	Remarks of the Evaluator	**Veterinary Liquid injection (General) section** confirmed vide panel inspection report for renewal of DML dated 15-06-2021 **Shortcomings:** Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
596.	Name and address of manufacturer / Applicant	M/s Zakfas Pharmaceuticals Pvt. Ltd., 12-Km, Bosan Road, Multan.
	Brand Name +Dosage Form + Strength	Salix Injection 50ml
	Composition	Each ml contains: Furosemide…50mg
	Diary No. Date of R& I & fee	Dy.No 1307 dated 22-01-2024 Rs 30,000/- dated 18-01-2024
	Pharmacological Group	Diuretic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled

	Me-too status	Durectin Injection (50ml) of M/s Bio-Labs (Pvt) Ltd., Islamabad. (Reg. No. 122041)
	GMP status	Panel inspection report for renewal of DML dated 15-06-2021 recommends renewal of DML
	Remarks of the Evaluator	**Veterinary Liquid injection (General) section** confirmed vide panel inspection report for renewal of DML dated 15-06-2021 **Target species:** Horses, cattle **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Firm shall submit fee of Rs.37000/- for pre-approval correction in formulation/ label claim (salt form) in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024
	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.37000/- for pre-approval correction in formulation (salt form completion)/ label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024.**	
597.	Name and address of manufacturer / Applicant	M/s Zakfas Pharmaceuticals Pvt. Ltd., 12-Km, Bosan Road, Multan.
	Brand Name +Dosage Form + Strength	Clofen Injection 100ml
	Composition	Each ml contains: Oxytetracycline…200mg **Ketoprofen**…30mg
	Diary No. Date of R& I & fee	Dy.No 1310 dated 22-01-2024 Rs 30,000/- dated 18-01-2024
	Pharmacological Group	Antibiotic & NSAID
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Pro Cycline Injection (100ml) of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 111329)
	GMP status	Panel inspection report for renewal of DML dated 15-06-2021 recommends renewal of DML
	Remarks of the Evaluator	**Veterinary Liquid injection (General) section** confirmed vide panel inspection report for renewal of DML dated 15-06-2021 **Target species:** Cattle, buffalo, sheep, goat **Shortcomings:** Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for review of Expert Working on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and submission of latest GMP inspection report conducted within the period of last three years.	
598.	Name and address of manufacturer / Applicant	M/s Zakfas Pharmaceuticals Pvt. Ltd., 12-Km, Bosan Road, Multan.
	Brand Name +Dosage Form + Strength	Butafas Injection 50ml
	Composition	Each ml contains: Butaphosphan…100mg Cyanocobalamin…0.05mg Taurine…37.3mg Nicotinamide…23mg DL-Methionine…18.7mg

	Diary No. Date of R& I & fee	Dy.No 1305 dated 22-01-2024 Rs 30,000/- dated 18-01-2024
	Pharmacological Group	Vitamin & amino acids
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	Hilfos Injection (50ml) of M/s Hilton Pharma Pvt Ltd., Karachi. (Reg. No. 116939)
	GMP status	Panel inspection report for renewal of DML dated 15-06-2021 recommends renewal of DML
	Remarks of the Evaluator	**Veterinary Liquid injection (General) section** confirmed vide panel inspection report for renewal of DML dated 15-06-2021 **Target species:** Cattle, horse, calf, foal, dog, cat **Shortcomings:** Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
599.	Name and address of manufacturer / Applicant	M/s Zakfas Pharmaceuticals Pvt. Ltd., 12-Km, Bosan Road, Multan.
	Brand Name +Dosage Form + Strength	Carafas Injection 100ml
	Composition	Each ml contains: DL-Acetylmethionine…200mg Cyanocobalamin…0.2mg L-Carnitine HCl eq. to L-Carnitine…50mg Alpha-Tocopherol Acetate eq. to Alpha Tocopherol…30mg
	Diary No. Date of R& I & fee	Dy.No 1306 dated 22-01-2024 Rs 30,000/- dated 18-01-2024
	Pharmacological Group	Vitamin & amino acids
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Hylase Forte Injection (100ml) of M/s Mylab (Pvt) Ltd, Bahawalpur. (Reg. No. 116863)
	GMP status	Panel inspection report for renewal of DML dated 15-06-2021 recommends renewal of DML
	Remarks of the Evaluator	**Veterinary Liquid injection (General) section** confirmed vide panel inspection report for renewal of DML dated 15-06-2021 **Target species:** Cattle, horse, sheep, cow, ewes, sows, mares **Shortcomings:** Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
600.	Name and address of manufacturer / Applicant	M/s Zakfas Pharmaceuticals Pvt. Ltd., 12-Km, Bosan Road, Multan.
	Brand Name +Dosage Form + Strength	Energizer Injection 250ml
	Composition	Each 100ml contains: L-Carnitine HCl…500mg Thioctic Acid…20mg Pyridoxine HCl…15mg DL-Acetylmethionine…2000mg

		L-Arginine…240mg L-Ornithine…120mg L-Citrulline…120mg L-Lysine…50mg Glycine...150mg Taurine...150mg Aspartic Acid...150mg Glutamic Acid...150mg Fructose...5000mg Sorbitol...8000mg
	Diary No. Date of R& I & fee	Dy.No 1308 dated 22-01-2024 Rs 30,000/- dated 18-01-2024
	Pharmacological Group	Multivitamin, minerals, amino acids & electrolytes
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	250ml: Decontrolled
	Me-too status	Vetzpower Injection (250ml) of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No.088074)
	GMP status	Panel inspection report for renewal of DML dated 15-06-2021 recommends renewal of DML
	Remarks of the Evaluator	**Veterinary Liquid injection (General) section** confirmed vide panel inspection report for renewal of DML dated 15-06-2021 **Target species:** Cattle, calves, buffalo, foals, sheep, goats, lambs, goat kids, rabbits, cats, dogs **Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Confirmation of **relevant manufacturing facility i.e. LVP**
	Decision: Deferred for submission of following: • **Confirmation of relevant manufacturing facility i.e. LVP** • **Latest GMP inspection report conducted within the period of last three years.**	
601.	Name and address of manufacturer / Applicant	M/s Zakfas Pharmaceuticals Pvt. Ltd., 12-Km, Bosan Road, Multan.
	Brand Name +Dosage Form + Strength	Aspera-C Water Soluble Powder
	Composition	Each 1000gm contains: **Acetylsalicylic Acid**…67gm **Vitamin C**…200gm
	Diary No. Date of R& I & fee	Dy.No 1298 dated 22-01-2024 Rs 30,000/- dated 18-01-2024
	Pharmacological Group	Antipyretic/ analgesic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg, 2Kg, 5Kg: Decontrolled
	Me-too status	Hyper-C Oral Powder of M/s Evergreen Pharmaceuticals, Lahore. (Reg. No. 081732)
	GMP status	Panel inspection report for renewal of DML dated 15-06-2021 recommends renewal of DML
	Remarks of the Evaluator	**Dry Powder Section (General)** (**Veterinary)** confirmed vide panel inspection report for renewal of DML dated 15-06-2021 **Target species:** Broilers **Shortcomings:** Latest GMP inspection report conducted within the period of last three years.

	Decision: Deferred for review of Expert Working on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and submission of latest GMP inspection report conducted within the period of last three years.	
602.	Name and address of manufacturer / Applicant	M/s Zakfas Pharmaceuticals Pvt. Ltd., 12-Km, Bosan Road, Multan.
	Brand Name +Dosage Form + Strength	Rumble Drench
	Composition	Each 100ml contains: Triclabendazole…12gm Albendazole…10gm Ivermectin…0.2gm
	Diary No. Date of R& I & fee	Dy.No 1299 dated 22-01-2024 Rs 30,000/- dated 18-01-2024
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 200ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Mecben Drench of M/s Archard Pharmaceuticals Pvt Ltd., Bhimber, AJK (Reg. No. 121897)
	GMP status	Panel inspection report for renewal of DML dated 15-06-2021 recommends renewal of DML
	Remarks of the Evaluator	**Oral Liquid Section (Veterinary)** confirmed vide panel inspection report for renewal of DML dated 15-06-2021 **Target species:** Cattle, sheep, goats **Shortcomings:** Latest GMP inspection report conducted within the period of last three years.
	Decision: Deferred for review of Expert Working on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and submission of latest GMP inspection report conducted within the period of last three years.	
603.	Name and address of manufacturer / Applicant	M/s Zakfas Pharmaceuticals Pvt. Ltd., 12-Km, Bosan Road, Multan.
	Brand Name +Dosage Form + Strength	OTC Blue Spray
	Composition	Each ml contains: Oxytetracycline HCl…40mg Gentian Violet…4mg
	Diary No. Date of R& I & fee	Dy.No 1302 dated 22-01-2024 Rs 30,000/- dated 18-01-2024
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	200gm aerosol spray container: Decontrolled
	Me-too status	Gentox Spray of M/s Leads Pharma Pvt Ltd., Islamabad. (Reg. No. 120805)
	GMP status	Panel inspection report for renewal of DML dated 15-06-2021 recommends renewal of DML
	Remarks of the Evaluator	**Spray Section (Veterinary)** confirmed vide panel inspection report for renewal of DML dated 15-06-2021 **Shortcomings:** Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
604.	Name and address of manufacturer / Applicant	M/s Zakfas Pharmaceuticals Pvt. Ltd., 12-Km, Bosan Road, Multan.
	Brand Name +Dosage Form + Strength	C-Metherin Spray

	Composition	Each 100ml contains: Cypermethrin…10gm
	Diary No. Date of R& I & fee	Dy.No 1300 dated 22-01-2024 Rs 30,000/- dated 18-01-2024
	Pharmacological Group	Insecticide
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml: Decontrolled
	Me-too status	Rafal Spray of M/s Kayans Pharmaceuticals, Rawalpindi. (Reg. No. 111388)
	GMP status	Panel inspection report for renewal of DML dated 15-06-2021 recommends renewal of DML
	Remarks of the Evaluator	**Spray Section (Veterinary)** confirmed vide panel inspection report for renewal of DML dated 15-06-2021 **Target species:** sheep, lambs **Shortcomings:** Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	
605.	Name and address of manufacturer / Applicant	M/s Zakfas Pharmaceuticals Pvt. Ltd., 12-Km, Bosan Road, Multan.
	Brand Name +Dosage Form + Strength	P.N.K Fly Spray
	Composition	Each ml contains: Oxytetracycline HCl…40mg Gentian-Violet…4mg Citronella Oil…20mg Permethrin…10mg
	Diary No. Date of R& I & fee	Dy.No 1301 dated 22-01-2024 Rs 30,000/- dated 18-01-2024
	Pharmacological Group	Antibacterial & fly repellant
	Type of Form	Form 5
	Finished product Specifications	Innovator's specifications
	Pack size & Demanded Price	125ml, 250ml: Decontrolled
	Me-too status	Ledogen Spray of M/s Leads Pharma Pvt Ltd., Islamabad. (Reg. No. 120806)
	GMP status	Panel inspection report for renewal of DML dated 15-06-2021 recommends renewal of DML
	Remarks of the Evaluator	**Spray Section (Veterinary)** confirmed vide panel inspection report for renewal of DML dated 15-06-2021 **Shortcomings:** Latest GMP inspection report conducted within the period of last three years.
	Decision: Approved. Firm shall submit latest GMP inspection report conducted within the period of last three years before issuance of registration letter.	

b. Deferred Cases

606.	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	Acmetet-N 2.5 Water Soluble Powder
	Composition	Each gram contains: Oxytetracycline HCl…250mg Neomycin Sulphate…150mg
	Diary No. Date of R& I & fee	Dy.No 6841 dated 10-03-2023 Rs.30,000/- dated 08-03-2023

	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Could not be confirmed in the applied strength
	GMP status	New DML
	Remarks of the Evaluator	**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 327th 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 the following: • **Me-too/generic status:** Neo-Oxy Powder of M/s Vital Mark Laboratories Toba Tek Singh. (Reg. No. 006867) And requested to correct the composition according to me-too reference. Revised formulation: **Each 450gm Contains:** **Oxytetracycline HCl = 25gm** **Neomycin Sulphate = 15gm** **Remarks of the evaluator:** The firm shall submit fee Rs. 37000/- for pre-approval change in label claim before issuance of registration letter.	
	Decision: Approved with following label claim: **Each 450gm Contains:** **Oxytetracycline HCl = 25gm** **Neomycin Sulphate = 15gm** **Firm shall submit fee of Rs.37000/- for pre-approval correction in formulation / label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024 before issuance of registration letter.**	
607.	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	Acmetet-N 10 Water Soluble Powder
	Composition	Each gram contains: Oxytetracycline HCl…100mg Neomycin Sulphate…100mg
	Diary No. Date of R& I & fee	Dy.No 6842 dated 10-03-2023 Rs.30,000/- dated 09-03-2023
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg: Decontrolled
	Me-too status	Could not be confirmed in the applied strength
	GMP status	New DML
	Remarks of the Evaluator	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 327th 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 the following: • **Me-too/generic status:** Oxyride-N Powder of M/s Vital Mark Laboratories Toba Tek Singh. (Reg. No. 013696)	

	And requested to correct the composition according to me-too reference. Revised formulation: **Each 5gms contains:** **Oxytetracycline HCl 100mg** **Neomycine Sulphate…100mg** **Remarks of the evaluator:** The firm shall submit fee Rs. 37000/- for pre-approval change in label claim before issuance of registration letter.	
	Decision: Approved with following label claim: **Each 5gms contains:** **Oxytetracycline HCl 100mg** **Neomycine Sulphate…100mg** **Firm shall submit fee of Rs.37000/- for pre-approval correction in formulation / label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024 before issuance of registration letter.**	
608.	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	Acmelev DS Oral Suspension
	Composition	Each ml contains: Oxyclozanide…0.3mg Levamisole HCl…0.15mg Sodium Selenite…0.038mg Cobalt Chloride…0.035mg
	Diary No. Date of R& I & fee	Dy.No 6861 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Could not be confirmed in the applied strength
	GMP status	New DML
	Remarks of the Evaluator	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 327th 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 the following: • **Me-too/generic status:** Roldzen Oral Suspension of M/s Haarolds Pharmaceuticals (Pvt) Ltd., Bhimber. (Reg. No.109063**)** And requested to correct the composition according to me-too reference. Revised formulation: **Each 100ml contains:** **Oxyclozanide…….…....3.0%** **Levamisole HCl……..…1.5%** **Cobalt Chloride)……..0.075%** **Sodium Selenite ……...0.035%** **Remarks of the evaluator:** The firm shall submit fee Rs. 37000/- for pre-approval change in label claim before issuance of registration letter.	
	Decision: Approved with following label claim: **Each 100ml contains:** **Oxyclozanide…….…....3.0%** **Levamisole HCl……..…1.5%** **Cobalt Chloride)……..0.075%**	

	Sodium Selenite ……...0.035% **Firm shall submit fee of Rs.37000/- for pre-approval correction in formulation / label claim in line with reference product, as per SRO 1324(I)/2014 dated 30-08-2024 before issuance of registration letter.**	
609.	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	Acmecoliflox 10/48 Oral Liquid
	Composition	Each ml contains: Enrofloxacin…100mg Colistin Sulphate…0.48 MIU
	Diary No. Date of R& I & fee	Dy.No 6894 dated 10-03-2023 Rs.30,000/- dated 08-03-2023
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	30ml, 50ml, 100ml, 120ml, 250ml, 500ml, 1000ml, 2.5L, 5L: Decontrolled
	Me-too status	Could not be confirmed in the applied strength
	GMP status	New DML
	Remarks of the Evaluator	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 327th 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 the following: • **Me-too/generic status:** Eflin-VL 10% Oral Liquid of M/s Vetec Laboratories, Rawat, Rawalpindi. (Reg. No. 099309)	
	Decision: Approved.	
610.	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	Pri Calphos Injection 300ml
	Composition	Each 100ml contains: Calcium Gluconate…20.83gm Calcium D-Saccharate…1gm Magnesium Hypophosphite…5.33gm Magnesium Chloride…2gm Boric Acid…4.33gm Dextrose…20gm
	Diary No. Date of R& I & fee	Dy.No 1968 dated 20-01-2023 Rs.30,000/- dated 09-01-2023 (slip No. 05589039180)
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	300ml: Decontrolled
	Me-too status	Dicalfon-C Injection (300ml, 450ml) of M/s Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur (Reg. No. 073912)
	GMP status	
	Remarks of the Evaluator	**Veterinary Liquid Injectable (General) section** confirmed vide Letter No. F. 1-9/2000-Lic dated 29-06-2012. **Shortcomings:** • Confirmation of **relevant manufacturing facility, i.e LVP**

		• Latest GMP inspection report conducted within the period of last three years.
	Decision of 336th meeting: Deferred for following: • Confirmation of relevant manufacturing facility, i.e LVP • Latest GMP inspection report conducted within the period of last three years.	
	Updated status: The firm has submitted the following: • GMP certificate dated 24-09-2024 based upon evaluation conducted on 08-05-2024 • The firm has stated that "We confirm that we have the facility of manufacturing, LVP is demand not only of Veterinary doctors but also of market due to establish of corporate farming with day to day increase of cattle heads. At the same time LVP is economical for farmers"	
	Decision: Deferred for confirmation of relevant manufacturing facility, i.e. LVP	
611.	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	Pri Calphos Injection 450ml
	Composition	Each 100ml contains: Calcium Gluconate…20.83gm Calcium D-Saccharate…1gm Magnesium Hypophosphite…5.33gm Magnesium Chloride…2gm Boric Acid…4.33gm Dextrose…20gm
	Diary No. Date of R& I & fee	Dy.No 1962 dated 20-01-2023 Rs.30,000/- dated 09-01-2023 (slip No. 84129257537)
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	450ml: Decontrolled
	Me-too status	Dicalfon-C Injection (300ml, 450ml) of M/s Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur (Reg. No. 073912)
	GMP status	
	Remarks of the Evaluator	**Veterinary Liquid Injectable (General) section** confirmed vide Letter No. F. 1-9/2000-Lic dated 29-06-2012. **Shortcomings:** • Confirmation of **relevant manufacturing facility, i.e LVP** • Latest GMP inspection report conducted within the period of last three years.
	Decision of 336th meeting: Deferred for following: • Confirmation of relevant manufacturing facility, i.e LVP • Latest GMP inspection report conducted within the period of last three years.	
	Updated status: The firm has submitted the following: • GMP certificate dated 24-09-2024 based upon evaluation conducted on 08-05-2024 • The firm has stated that "We confirm that we have the facility of manufacturing, LVP is demand not only of Veterinary doctors but also of market due to establish of corporate farming with day to day increase of cattle heads. At the same time LVP is economical for farmers"	
	Decision: Deferred for confirmation of relevant manufacturing facility, i.e. LVP	
612.	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	Pri-Calcio 250ml Injection
	Composition	Each 250ml contains: Calcium Gluconate ….....50gm Sodium Dimethyl Aminomethyl Phenyl phosphinite… .....1gm Magnesium Camphosulphonate….....2gm

		Boric Acid….....6gm Sorbitol….....12.50gm
	Diary No. Date of R& I & fee	Dy.No 36727 dated 16-12-2022 Rs.30,000/- dated 29-11-2022 (slip No. 169414165388)
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	250ml: Decontrolled
	Me-too status	Calcimax Injection of M/s Mylab (Pvt) Ltd, Bahawalpur. (Reg. No. 088126)
	GMP status	
	Remarks of the Evaluator	**Veterinary Liquid Injectable (General)** section confirmed vide Letter No. F. 1-9/2000-Lic(vol-) dated 29-06-2012. **Shortcomings:** • latest GMP inspection report conducted within the period of last three years • Confirmation of **relevant manufacturing facility i.e LVP**
	Decision of 336th meeting: Deferred for following: • Confirmation of relevant manufacturing facility, i.e LVP • Latest GMP inspection report conducted within the period of last three years.	
	Updated status: The firm has submitted the following: • GMP certificate dated 24-09-2024 based upon evaluation conducted on 08-05-2024 • The firm has stated that "We confirm that we have the facility of manufacturing, LVP is demand not only of Veterinary doctors but also of market due to establish of corporate farming with day to day increase of cattle heads. At the same time LVP is economical for farmers"	
	Decision: Deferred for confirmation of relevant manufacturing facility, i.e. LVP	
613.	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	Pri-Calcio 500ml Injection
	Composition	Each 250ml contains: Calcium Gluconate ….....50gm Sodium Dimethyl Aminomethyl Phenyl phosphinite… .....1gm Magnesium Camphosulphonate….....2gm Boric Acid….....6gm Sorbitol….....12.50gm
	Diary No. Date of R& I & fee	Dy.No 36726 dated 16-12-2022 Rs.30,000/- dated 29-11-2022 (slip No. 9093421636)
	Pharmacological Group	Restorative
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	500ml: Decontrolled
	Me-too status	Calcio PH Injectable Solution of M/s Prix Pharmaceutical Lahore (Reg. No. 018843)
	GMP status	
	Remarks of the Evaluator	**Veterinary Liquid Injectable (General)** section confirmed vide Letter No. F. 1-9/2000-Lic(vol-) dated 29-06-2012. **Shortcomings:** • latest GMP inspection report conducted within the period of last three years • Confirmation of **relevant manufacturing facility i.e LVP**
	Decision of 336th meeting: Deferred for following:	

	• Confirmation of relevant manufacturing facility, i.e LVP • Latest GMP inspection report conducted within the period of last three years.	
	Updated status: The firm has submitted the following: • GMP certificate dated 24-09-2024 based upon evaluation conducted on 08-05-2024 • The firm has stated that "We confirm that we have the facility of manufacturing, LVP is demand not only of Veterinary doctors but also of market due to establish of corporate farming with day to day increase of cattle heads. At the same time LVP is economical for farmers"	
	Decision: Deferred for confirmation of relevant manufacturing facility, i.e. LVP	
614.	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	Pridox 75 Water Soluble Powder
	Composition	Each gram contains: Doxycycline as Hyclate…750mg
	Diary No. Date of R& I & fee	Dy.No 29858 dated 21-10-2022 Rs.30,000/- dated 26-09-2022 (slip No. 44275863609)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm and 1Kg; Decontrolled
	Me-too status	Not available in the applied strength
	GMP status	
	Remarks of the Evaluator	**Target species:** Poultry, calves **Shortcomings:** • The instant formulation in the applied strength is not already registered in Pakistan. The firm has submitted reference of DOXYCYCLINE 75% Kela, 750 mg/g, powder for oral use in drinking water or feed **for pigs** approved in **Belgium**. • latest GMP inspection report conducted within the period of last three years • confirmation of **relevant manufacturing facility** • The firm shall submit fee Rs. 7500/- for pre-approval change in FPP specifications prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023 before issuance of registration letter.
	Decision of 336th meeting: Deferred for following: • availability of the said formulation approved for poultry and calves in any reference country or PICs member country or ML-4 country. • Confirmation of relevant manufacturing facility. • latest GMP inspection report conducted within the period of last three years • fee Rs. 7500/- for pre-approval change in FPP specifications	
	Updated status: The firm has submitted the following: • The firm has submitted copy of brochure of product Doxycycline 75 water soluble powder approved in Belgium, showing product is used also for poultry and calves (to be confirmed from official website) • GMP certificate dated 24-09-2024 based upon evaluation conducted on 08-05-2024 • The firm has stated that "We confirm that we have the facility of manufacturing" • The firm has submitted fee Rs. 9000/- vide fee challan No. 6110680905 dated 18-10-2024	
	Decision: Deferred for submission of following: • **Evidence of approval of applied formulation in any reference regulatory authorities/agencies since in Belgium it is approved only for pigs and not for poultry and calves.** • **Confirmation of relevant manufacturing facility.**	
615.	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	Farmox LA Suspension for Injection 250ml
	Composition	Each ml contains: Amoxicillin Trihydrate Eq. To Amoxicillin Base…200mg
	Diary No. Date of R& I & fee	Dy.No 9046 dated 08-04-2022 Rs.30,000/- dated 01-04-2022 (slip No. 327880350866)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	250ml: Decontrolled
	Me-too status	
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Approval of **Liquid Injectable (Penicillin) LVP** section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Clarification regarding the applied formulation is required since Amoxicillin Trihydrate Eq. To Amoxicillin Base…**150mg** is mentioned in cover letter and throughout the dossier while Amoxicillin Trihydrate Eq. To Amoxicillin Base…**200mg** is mentioned in label claim in Form-5. • Accordingly provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 331st meeting: Deferred for following: • Latest GMP inspection report conducted within the period of last three years. • Confirmation of relevant manufacturing facility • Clarification regarding the applied formulation since Amoxicillin Trihydrate Eq. To Amoxicillin Base…150mg is mentioned in cover letter and throughout the dossier while Amoxicillin Trihydrate Eq. To Amoxicillin Base…200mg is mentioned in label claim in Form-5. • 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 the following: • GMP certificate dated 24-09-2024 based upon evaluation conducted on 08-05-2024 • **Liquid Injectable vial (penicillin) (veterinary) section** confirmed vide letter No. F. 1-9/2000-Lic (vol-II) dated 22-09-2019 • The firm has stated that "We confirm that we have the facility of manufacturing, LVP is demand not only of Veterinary doctors but also of market due to establish of corporate farming with day to day increase of cattle heads. At the same time LVP is economical for farmers" • **Applied formulation** **Each ml contains:** **Amoxicillin Trihydrate Eq. To Amoxicillin Base…150mg** • Me-too status: Aplamox-15 LA Injection (50ml) of M/s Aptly Pharmaceuticals, Faisalabad. (121974)	
	Decision: Deferred for submission of following: • **confirmation of relevant manufacturing facility, i.e. LVP** • **Revised form-5 with correct label claim along with fee of Rs.37000/- for pre-approval correction in label claim, since Amoxicillin Trihydrate Eq. To Amoxicillin Base…200mg/ml was mentioned instead of 150mg/ml.**	
616.	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	Farmox LA Suspension for Injection 50ml
	Composition	Each ml contains: Amoxicillin Trihydrate Eq. To Amoxicillin Base…200mg
	Diary No. Date of R& I & fee	Dy.No 9044 dated 08-04-2022 Rs.30,000/- dated 01-04-2022 (6654135137)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Approval of **Liquid Injectable (Penicillin)** section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Clarification regarding the applied formulation is required since Amoxicillin Trihydrate Eq. To Amoxicillin Base…**150mg** is mentioned in cover letter and throughout the dossier while Amoxicillin Trihydrate Eq. To Amoxicillin Base…**200mg** is mentioned in label claim in Form-5. • Accordingly provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 331st meeting: Deferred for following: • latest GMP inspection report conducted within the period of last three years. • confirmation of relevant manufacturing facility • clarification regarding the applied formulation since Amoxicillin Trihydrate Eq. To Amoxicillin Base…150mg is mentioned in cover letter and throughout the dossier while Amoxicillin Trihydrate Eq. To Amoxicillin Base…200mg is mentioned in label claim in Form-5. • 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 the following: • GMP certificate dated 24-09-2024 based upon evaluation conducted on 08-05-2024 • **Liquid Injectable vial (penicillin) (veterinary) section** confirmed vide letter No. F. 1-9/2000-Lic (vol-II) dated 22-09-2019 • **Applied formulation:** **Each ml contains:** **Amoxicillin Trihydrate Eq. To Amoxicillin Base…150mg** • Me-too status: Aplamox-15 LA Injection of M/s Aptly Pharmaceuticals, Faisalabad. (121974)	
	Decision: Approved. Firm shall submit revised form-5 with correct label claim along with fee of Rs. 37000/- for pre-approval correction in label claim, since Amoxicillin Trihydrate Eq. To Amoxicillin Base…200mg/ml was mentioned instead of 150mg/ml.	
617.	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	Farmox LA Suspension for Injection 100ml
	Composition	Each ml contains: Amoxicillin Trihydrate Eq. To Amoxicillin Base…150mg
	Diary No. Date of R& I & fee	Dy.No 9045 dated 08-04-2022 Rs.30,000/- dated 01-04-2022 (slip No. 937303380)

	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	BP Vet specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	Amocillin 15% Injection (100ml) of M/s Eterna Pharma (Pvt) Ltd. AJK (Reg. No. 113596)
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** • Latest GMP inspection report (conducted within the period of last three years). • Approval of **Liquid Injectable (Penicillin)** 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 331st meeting: Deferred for following: • latest GMP inspection report conducted within the period of last three years. • confirmation of relevant manufacturing facility	
	Updated status: The firm has submitted the following: • GMP certificate dated 24-09-2024 based upon evaluation conducted on 08-05-2024 • **Liquid Injectable vial (penicillin) (veterinary) section** confirmed vide letter No. F. 1-9/2000-Lic (vol-II) dated 22-09-2019	
	Decision: Approved.	
618.	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	Allevia 20% Injection 50ml
	Composition	Each ml contains: Sodium Iodide…200mg
	Diary No. Date of R& I & fee	Dy.No 21420 dated 05-08-2021 Rs.30,000/- dated 29-07-2021 (slip No. 7327494652)
	Pharmacological Group	Ionic compound
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	50ml: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	
	Remarks of the Evaluator	**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. • Evidence of approval of applied formulation, with same pack size as applied, in reference regulatory authorities/agencies • Confirmation of **relevant manufacturing facility**
	Decision of 331st meeting: 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) alongwith registration number, brand name and name of firm. • Evidence of approval of applied formulation, with same pack size as applied, in reference regulatory authorities/agencies • Confirmation of relevant 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.	
	Updated status: The firm has submitted the following:	

	• GMP certificate dated 24-09-2024 based upon evaluation conducted on 08-05-2024 • RRA status: iodopen 20% injection and Sodium Iodide 20% injection of M/s Aspen and M/s VetOne approved in USA (**could not be confirmed from official website**) • **Liquid Injectable vial (General) (veterinary) section** confirmed vide letter No. F. 1-9/2000-Lic dated 29-06-2012	
	Decision: Deferred for submission of evidence of approval of applied formulation in reference regulatory authorities/agencies.	
619.	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	Allevia 20% Injection 100ml
	Composition	Each ml contains: Sodium Iodide…200mg
	Diary No. Date of R& I & fee	Dy.No 21421 dated 05-08-2021 Rs.30,000/- dated 29-07-2021 (slip No. 50847449403)
	Pharmacological Group	Ionic compound
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	100ml: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	
	Remarks of the Evaluator	**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. • Evidence of approval of applied formulation, with same pack size as applied, in reference regulatory authorities/agencies • Confirmation of **relevant manufacturing facility**
	Decision of 331st meeting: 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) alongwith registration number, brand name and name of firm. • Evidence of approval of applied formulation, with same pack size as applied, in reference regulatory authorities/agencies • Confirmation of relevant 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.	
	Updated status: The firm has submitted the following: • GMP certificate dated 24-09-2024 based upon evaluation conducted on 08-05-2024 • RRA status: iodopen 20% injection and Sodium Iodide 20% injection of M/s Aspen and M/s VetOne approved in USA (**could not be confirmed from official website**) • **Liquid Injectable vial (General) (veterinary) section** confirmed vide letter No. F. 1-9/2000-Lic dated 29-06-2012	
	Decision: Deferred for submission of evidence of approval of applied formulation in reference regulatory authorities/agencies.	
620.	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 5 Injection 250ml
	Composition	Each ml contains: Oxytetracycline HCl 53.91mg eq. to Oxytetracycline ……50mg
	Diary No. Date of R& I & fee	Dy.No 18627 dated 02-07-2021 Rs.30,000/- dated 24-06-2021 (slip No. 75961978247)

	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	250ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied pack size**
	GMP status	
	Remarks of the Evaluator	**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. • Confirmation of **relevant manufacturing facility**
	Decision of 331st meeting: 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) alongwith registration number, brand name and name of firm. • Confirmation of relevant 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.	
	Updated status: The firm has submitted the following: • GMP certificate dated 24-09-2024 based upon evaluation conducted on 08-05-2024 • **Me-too/generic status:** Oxytetracycline Injection (**50ml**) of M/s Lawrance Pharma (Pvt) Ltd Lahore (Reg. No. 026597) • **Liquid Injectable vial (General) (veterinary) section** confirmed vide letter No. F. 1-9/2000-Lic dated 29-06-2012 • The firm has stated that "We confirm that we have the facility of manufacturing, LVP is demand not only of Veterinary doctors but also of market due to establish of corporate farming with day to day increase of cattle heads. At the same time LVP is economical for farmers" • Registration letter No. F. 3-3/2012-Reg-I (M-234) dated 06-09-2012 of Primec 10 injection (reg. No. 072696) in pack sizes 250ml and 500ml	
	Decision: Deferred for confirmation of relevant manufacturing facility, i.e. LVP.	
621.	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	Ectomec 10 Injection 250ml
	Composition	Each ml contains: Doramectin…10mg
	Diary No. Date of R& I & fee	Dy.No 18628 dated 02-07-2021 Rs.30,000/- dated 24-06-2021 (slip No. 57149996568)
	Pharmacological Group	Anti-parasitic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	250ml: Decontrolled
	Me-too status	Doramec-DMG Injection (250ml) of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 043544)
	GMP status	
	Remarks of the Evaluator	**Shortcomings:** • Latest GMP inspection report conducted within the period of last three years. • Confirmation of **relevant manufacturing facility**
	Decision of 331st meeting: Deferred for following: • Latest GMP inspection report conducted within the period of last three years. • Confirmation of relevant 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.	
	Updated status: The firm has submitted the following: • GMP certificate dated 24-09-2024 based upon evaluation conducted on 08-05-2024 • **Liquid Injectable vial (General) (veterinary) section** confirmed vide letter No. F. 1-9/2000-Lic dated 29-06-2012 • The firm has stated that "We confirm that we have the facility of manufacturing, LVP is demand not only of Veterinary doctors but also of market due to establish of corporate farming with day to day increase of cattle heads. At the same time LVP is economical for farmers" • Registration letter No. F. 3-3/2012-Reg-I (M-234) dated 06-09-2012 of Primec 10 injection (reg. No. 072696) in pack sizes 250ml and 500ml	
	Decision: Deferred for confirmation of relevant manufacturing facility, i.e. LVP.	
622.	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	Primec Super Injection 250ml
	Composition	Each ml Contains: Ivermectin…20mg
	Diary No. Date of R& I & fee	Dy.No 20424 dated 27-07-2021 Rs.30,000/- dated 07-07-2021 (slip No. 03648779839)
	Pharmacological Group	Anti-parasitic
	Type of Form	Form 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	250ml: Decontrolled
	Me-too status	**Could not be confirmed in the applied pack size**
	GMP status	
	Remarks of the Evaluator	**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. • Confirmation of **relevant manufacturing facility**
	Decision of 331st meeting: 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) alongwith registration number, brand name and name of firm. • Confirmation of relevant 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.	
	Updated status: The firm has submitted the following: • GMP certificate dated 24-09-2024 based upon evaluation conducted on 08-05-2024 • **Me-too/generic status:** Selmec Injection (**10ml, 50ml, 100ml**) of M/s Selmore Pharmaceutical (Pvt) Ltd., Lahore. (Reg. No. 071087) • **Liquid Injectable vial (General) (veterinary) section** confirmed vide letter No. F. 1-9/2000-Lic dated 29-06-2012 • The firm has stated that "We confirm that we have the facility of manufacturing, LVP is demand not only of Veterinary doctors but also of market due to establish of corporate farming with day to day increase of cattle heads. At the same time LVP is economical for farmers"	
	Decision: Deferred for confirmation of relevant manufacturing facility, i.e. LVP.	
623.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories (Pvt) Ltd., 136 sector 15 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	SE-BE 12 Injection

	Composition	Each ml contains: Sodium Selenite…0.5mg Vitamin E Acetate…70mg Vitamin B12…0.1mg Vitamin B1…20mg Adenosine 5-Monophosphate…5mg
	Diary No. Date of R& I & fee	Dy.No 2033 dated 21-01-2022 Rs.30,000/- dated 14-01-2022 (slip No. 561064476)
	Pharmacological Group	Combination of vitamins and minerals
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml: Decontrolled
	Me-too status	Vitamin-SA Injection (50ml, 100ml) of M/s Alina Combine Pharmaceutical (Pvt) Ltd. Karachi (Reg. No. 052349)
	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	**Liquid Injection Vet Section** confirmed from panel inspection report conducted on 31-03-2022 for renewal of DML. **Shortcomings:** • Separate registration is granted to separate pack size/fill volume of injectable dosage form. However, multiple pack sizes (**50ml and 100ml)** 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. • Confirmation of **relevant testing facility.**
	Decision of 331st meeting: Deferred for following: • Choice of only one pack size. • Confirmation of relevant testing facility.	
	Updated status: The firm has submitted the following: Demanded pack size: **100ml vial** Firm has also submitted a list of equipment in their quality control laboratory mentioning 2 HPLCs, UV spectrophotometer, FTIR, 02 Atomic absorptions spectrophotometer	
	Decision: Approved.	
624.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories (Pvt) Ltd., 136 sector 15 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Cephicure 500mg Intrauterine Suspension
	Composition	Each 19.5gm Syringe Contains: Cephapirin as Benzathine…500mg
	Diary No. Date of R& I & fee	Dy.No 33290 dated 15-12-2020 Rs.20,000/- dated 15-12-2020
	Pharmacological Group	Antibacterial/ Anti-infective/ Antiseptic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10 x 19.5gm Syringes: Decontrolled
	Me-too status	Metricure white oily homogenous Intra-Uterine suspension of M/s ICI Pakistan Ltd Karachi (Reg. No. 078355) **Could not be confirmed in the applied strength**
	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	**Shortcomings:** • Approval of **Relevant section** • evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.

	Decision of 326th meeting: Deferred for following: • approval of **relevant manufacturing facility** • evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
	Updated status: The firm has submitted the following: "that in our Routine GMP Inspection Report which was conducted on 11-01-2021 in which clearly mentioned ***"the firm has well dedicated facility for sterile Cephalosporin liquid vials for veterinary use and the same is intended to be used for IMM Tubes based on same GMP requirement"***. We use Sterile Liquid Injection Section veterinary for preparation of "Cephicure 500mg Intrauterine Suspension" based on same GMP requirement. There's no any difference in manufacturing preparation as manufacturing intramammary only the way of administration is difference like as "The contents of syringe should be introduced into the lumen of the uterus using the disposable catheter through the cervix into the lumen of the uterus and gentle oscillating movements of the cervix and then inject the suspension." **Me-too/ generic status:** Metricure white oily homogenous Intra-Uterine suspension of M/s ICI Pakistan Ltd Karachi (Reg. No. 078355) **Remarks of the evaluator:** The strength of applied formulation is different than that of reference product approved in the Netherland and already registered in DRAP (the applied formulation contains same quantity of API as in reference product per 19.5gm instead of 19gm)	
	Decision: Deferred for submission of evidence of approval of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or any RRA.	
625.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan.
	Brand Name +Dosage Form + Strength	Trisulf Granules
	Composition	Each 100gram contains: Trimethoprim…4.62gm Sulphaquinoxaline…15.02gm
	Diary No. Date of R& I & fee	Dy.No 5675 dated 28-02-2023 Rs.30,000/- dated 28-02-2023 (slip No. 444031460913)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1Kg: Decontrolled
	Me-too status	**Could not be confirmed**
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator	**Shortcomings:** • Confirmation of **relevant manufacturing facility.** • Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 336th meeting: Deferred for following: • Confirmation of relevant manufacturing facility. • Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
	Updated status: The firm has submitted the following: • **Oral powder (General) Veterinary section** confirmed vide letter No. F. 1-4/2007-Lic (vol-II) dated 07-03-2022 • **Me-too/generic status:** Triquin granules of M/s Alton Pharmaceuticals (Pakistan) **Remarks:** The submitted reference to generic product could not be confirmed **Shortcomings:** Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or approval status in any RRA.	

	Decision of 339th meeting: Deferred for submission of evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or approval status in any RRA.	
	Updated status: The firm has submitted the following metoo status: Sulquin Granules of M/s Epla Laboratories (Pvt) Ltd Karachi (Reg. No. 023465)	
	Decision: Approved with as per innovator's specidfications. Firm shall submit fee Rs. 9000/- for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024 before issuance of registration letter.	
626.	Name and address of manufacturer / Applicant	M/s Biogen Pharma, 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan.
	Brand Name +Dosage Form + Strength	DMG Booster Oral Powder
	Composition	Each Kg contains: Vitamin A…2,000,000 IU Vitamin D3…400,000 IU Vitamin E…160 IU Vitamin K…900mg Vitamin B1…125mg Vitamin B2…2000mg Vitamin B6…600mg Vitamin B12…3000mg Vitamin C…1000mg Folic Acid…200mg Nicotinic Acid…10,000mg Calcium Pantothenate…3000mg L-Lysine...50,000mg DL-Methionine...30,000mg
	Diary No. Date of R& I & fee	Dy.No 5674 dated 28-02-2023 Rs.30,000/- dated 28-02-2023 (slip No. 941626168)
	Pharmacological Group	Multivitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	500gm, 1Kg: Decontrolled
	Me-too status	Kerry Vit Amino Powder of M/s Bio-Labs (Pvt) Ltd., Islamabad. (Reg. No. 031480) **Could not be confirmed in the applied strength**
	GMP status	cGMP certificate dated 30-07-2020 based on inspection conducted on 12-12-2019.
	Remarks of the Evaluator	The submitted reference to generic product is of different strength than applied. **Shortcomings:** • Confirmation of **relevant manufacturing facility.** • Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision of 336th meeting: Deferred for following: • Confirmation of relevant manufacturing facility. • Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
	Updated status: The firm has submitted the following: • **Oral powder (General) Veterinary section** confirmed vide letter No. F. 1-4/2007-Lic (vol-II) dated 07-03-2022 • **Me-too/generic status:** Kerry Vit Amino Powder of M/s Bio-Labs (Pvt) Ltd., Islamabad (Reg. No. 031480) **Remarks:** The submitted generic product contains same quantities of APIs, as in applied formulation, per 100gm instead of per Kg **Shortcomings:**	

	Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or approval status in any RRA.	
	Decision of 339th meeting: Deferred for submission of evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or approval status in any RRA.	
	Updated status: The firm has submitted the following me-too/generic status: White Gold Powder of M/s Leads Pharma (Pvt) Ltd Islamabad (Reg. No. 058842) **Remarks of the evaluator:** The submitted generic product has different strength than the applied formulation. **Shortcomings:** Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or approval status in any RRA.	
	Decision: Deferred for submission of evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or approval status in any RRA.	
627.	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	**Shortcomings:** • Approval of Penicillin Injection (Veterinary) Section. • Provide conversion of Penicillin G Procaine and Penicillin G Sodium from IU to grams
	Decision of 329th meeting: 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.	
	Updated status: The firm has submitted the following: • Letter No. F.2-8/2011-Lic(Vol-I) dated 15-06-2021 for renewal of DML of the firm for following sections. ▪ Oral powder (Veterinary) Section ▪ Oral Liquid (Veterinary) Section ▪ Aerosol ▪ Sterile Liquid Vial Injection (Veterinary) Section ▪ Sterile Powder Vial Injection (Veterinary) Section ▪ Sterile Liquid Vial Injection Penicillin (Veterinary) Section ▪ Oral powder (Penicillin) (Veterinary) Section The firm has also submitted conversion of Penicillin G Procaine and Penicillin G Sodium from IU to grams	

	Remarks of the Evaluator: Evidence of approval of Dry Powder Penicillin Injection (Veterinary) Section is required. **Shortcomings:** Evidence of approval of Sterile Powder Vial Injection (Penicillin) (Veterinary) Section from CLB/ latest panel inspection report for renewal of DML	
	Decision of 340th meeting: Deferred for submission of evidence of approval of Sterile Powder Vial Injection (Penicillin) (Veterinary) Section from CLB/ latest panel inspection report for renewal of DML.	
	Updated status: The firm has submitted following as an evidence of section approval. • Grant of additional section approval letter No. F. 2-8/2011-Lic dated 11-04-2017 • GMP certificate dated 20-02-2023 (Oman) • GMP certificate dated 26-03-2024 (Myanmar) • Area FID last GMP inspection report dated 08-08-2024	
	Decision: Deferred for submission of evidence of approval of Sterile Powder Vial Injection (Penicillin) (Veterinary) Section from CLB/ latest panel inspection report for renewal of DML.	
628.	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	M Vit injection 250ml
	Composition	Each 100ml contains: L-Carnitine…500mg Pyridoxine HCl…15mg L-Arginine…240mg L-Citruline …120mg Glycine…150mg Aspartic Acid …150mg Fructose...5000mg Thiotic Acid...20mg DL-Acetylmethionine ...2000mg L-Ornithine...120mg L-Lysine ...50mg Taurine...150mg Glutamic Acid ...150mg Sorbitol...8000mg
	Diary No. Date of R& I & fee	Dy.No 22369 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Multivitamins and Amino acids
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	250ml; Decontrolled
	Me-too status	Multimino-V Injection (250ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 058712)
	GMP status	**New Section**
	Remarks of the Evaluator	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022
	Decision of 326th meeting: Deferred for confirmation of relevant manufacturing facility(LVP) and testing facility.	
	Updated status: The firm has submitted the copy of panel inspection report dated 15-04-2022 for renewal of DML stating filling capacity of 10ml to 500ml and availability of HPLC.	
	Decision: Approved.	
629.	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	M Vit injection 500ml
	Composition	Each 100ml contains: L-Carnitine…500mg Pyridoxine HCl…15mg L-Arginine…240mg L-Citruline …120mg

		Glycine…150mg Aspartic Acid …150mg Fructose...5000mg Thiotic Acid...20mg DL-Acetylmethionine ...2000mg L-Ornithine...120mg L-Lysine ...50mg Taurine...150mg Glutamic Acid ...150mg Sorbitol...8000mg
	Diary No. Date of R& I & fee	Dy.No 22367 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Multivitamins and Amino acids
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	500ml; Decontrolled
	Me-too status	Multimino-V Injection (500ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 058712)
	GMP status	**New Section**
	Remarks of the Evaluator	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022
	Decision of 326th meeting: Deferred for confirmation of relevant manufacturing facility(LVP) and testing facility.	
	Updated status: The firm has submitted the copy of panel inspection report dated 15-04-2022 for renewal of DML stating filling capacity of 10ml to 500ml and availability of HPLC.	
	Decision: Approved.	
630.	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	M Vit injection 100ml
	Composition	Each 100ml contains: L-Carnitine…500mg Pyridoxine HCl…15mg L-Arginine…240mg L-Citruline …120mg Glycine…150mg Aspartic Acid …150mg Fructose...5000mg Thiotic Acid...20mg DL-Acetylmethionine ...2000mg L-Ornithine...120mg L-Lysine ...50mg Taurine...150mg Glutamic Acid ...150mg Sorbitol...8000mg
	Diary No. Date of R& I & fee	Dy.No 22367 dated 05-08-2022 Rs.30,000/- dated 05-08-2022
	Pharmacological Group	Multivitamins and Amino acids
	Type of Form	Form 5
	Finished product Specification	As per innovator's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	Multimino-V Injection (100ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. No. 058712)
	GMP status	**New Section**
	Remarks of the Evaluator	**Liquid Injection Section (General-Veterinary)** granted vide letter No. F.3-9/91-Lic. (Vol-II) dated 01-06-2022
	Decision of 326th meeting: Deferred for confirmation of relevant testing facility.	
	Updated status: The firm has submitted the copy of panel inspection report dated 15-04-2022 for renewal of DML stating availability of HPLC.	

	Decision: Approved.	
631.	Name and address of manufacturer / Applicant	M/s Grand Pharma, Plot No. 5-A, St. No N-5, National Industrial Zone, RCCI Estate, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	GP-Pred 2.5% Injection 10ml
	Composition	Each ml contains: Prednisolone Acetate…25mg
	Diary No. Date of R& I & fee	Dy.No 19114 dated 01-08-2023 Rs.30,000/- dated 26-07-2023 (slip No. 6201450514)
	Pharmacological Group	Steroid
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml: Decontrolled
	Me-too status	Premsone 25 Injection of M/s Kayans Pharmaceuticals, Rawat, Rawalpindi. (Reg. No. 111331)
	GMP status	GMP inspection report dated 18-01-2023 concluded good level of GMP compliance.
	Remarks of the Evaluator	**Shortcomings:** • Confirmation of **relevant manufacturing facility**
	Decision of 339th meeting: Deferred for confirmation of relevant manufacturing facility.	
	Updated status: The firm has submitted the registration letter of **GP-Pred 2.5% Injection 50ml** granted vide letter No. F.7-1/2021-I&V-I (M-297) (Vet) dated 04-05-2021 approved by DRAP under the section Liquid Injection vial (Steroid) Veterinary. However, Liquid Injection vial (Steroid) Veterinary section is not mentioned in letter No. F. 1-36/2006-Lic (Vol-III) dated 29-09-2021 for renewal of DML.	
	Decision: Deferred for review of Expert Working on Veterinary Drugs regarding therapeutic requirement keeping in view safety, efficacy and quality parameters and for submission of evidence of approval of Liquid Injection vial (Steroid) Veterinary Section from CLB/ latest panel inspection report for renewal of DML.	
632.	Name and address of manufacturer / Applicant	M/s Eterna Pharma (Pvt.) Ltd. Plot # (99,100,101,198)C,Sector D1,Old Industrial Estate, Mirpur,Azad Jammu & Kashmir.
	Brand Name +Dosage Form + Strength	ETER FEN 23 ET ORAL LIQUID
	Composition	Each 100ml contains: Florfenicol……23%
	Diary No. Date of R& I & fee	Dy.No.133 dated 01-01-2021 Rs.20,000/- Dated 01-01-2021
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's Specs
	Pack size & Demanded Price	50ml,100ml,150ml,250ml,500ml,1L.2.5L & 5 L / Decontrolled
	Me-too status	Floral Plus Oral Liquid by M/s Nawal Pharmaceuticals (Reg#074090)
	GMP status	Keeping in view the above facts, detailed visit of the facility and supporting documents provided by the firm, the panel unanimously recommended M/s Eterna Pharma Plot No. 99,100,101 &198-C, Sector D1,Old Industrial Estate, Mirpur,AJ & K for the grant of drug manufacturing License for the following sections namely: 1. Oral Powder Section (Veterinary) General 2. Oral Liquid Section (Veterinary) General 3. Liquid Injection section (Veterinary) General
	Remarks of the Evaluator [XI]	-
	Previous Decision (**297-DRB**)	Deferred for scientific rationale of related strength of the same formulation
	Evaluation by PEC	The firm replied that based on the scientific rational of related strength of the formulation, it is USFDA approved

		product having brand name of Florvio 23mg/ml by Novartis Animal Health, Netherland. Moreover, the given formulation is stable formulation and we have applied for market demand.
	Decision of 307th meeting: Registration Board deferred the application since applied formulation differs from the submitted reference product approved by US FDA in terms of w/v percentage.	
	Updated status: The firm has submitted that **"*in recent meetings of Registration Board we have noticed that same products are approved and there is no objection on dossiers on scientific* basis of other manufacturers."** Makflor-23 Oral Liquid (119748) of M/s M.A. Kamil Farma (Pvt) Ltd., Karachi approved in 331st meeting of Registration Board	
	Decision: Approved.	
633.	Name and address of manufacturer / Applicant	M/s Eterna Pharma (Pvt.) Ltd., Plot # (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir (Liquid Injection section (Veterinary) General).
	Brand Name +Dosage Form + Strength	Prime Mectin INJECTION
	Composition	Each ml Contains: Ivermectin ……..…10mg
	Diary No. Date of R& I & fee	Dy. No. 109 dated: 01-01-2021 Rs.20,000/- Dated 01-01-2021.
	Pharmacological Group	Anthelmintic.
	Type of Form	Form 5.
	Finished product Specification	BP Specification
	Pack size & Demanded Price	50ml / Decontrolled
	Me-too status	Ectin Injection, M/s. A & K Pharmaceytical, Reg. No. 075795.
	GMP status	Keeping in view the above facts, detailed visit of the facility and supporting documents provided by the firm, the panel unanimously recommended M/s Eterna Pharma Plot No. 99,100,101 &198-C, Sector D1,Old Industrial Estate, Mirpur,AJ & K for the grant of drug manufacturing License for the following sections namely: 1. Oral Powder Section (Veterinary) General 2. Oral Liquid Section (Veterinary) General 3. Liquid Injection section (Veterinary) General
	Remarks of the Evaluator XIII	
	Decision of 307th meeting: Deferred for scientific rationale of related strength of the same formulation.	
	Updated status: The firm has submitted that **"*in recent meetings of Registration Board we have noticed that same products are approved and there is no objection on dossiers on scientific* basis of other manufacturers."** Ivozon 1% Injection (119701) of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK. approved in 331st meeting of Registration Board	
	Decision: Approved.	
634.	Name and address of manufacturer / Applicant	M/s Eterna Pharma (Pvt.) Ltd., Plot # (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir (Liquid Injection section (Veterinary) General).
	Brand Name +Dosage Form + Strength	Veta-Meloxy Injection.
	Composition	Each ml contains: Meloxicam ……. 7.5mg
	Diary No. Date of R& I & fee	Dy. No. 118 dated: 01-01-2021 Rs.20,000/- Dated 01-01-2021.
	Pharmacological Group	NSAID's.
	Type of Form	Form 5.
	Finished product Specification	BP Specification
	Pack size & Demanded Price	50ml / Decontrolled

	Me-too status	Pri-Dolocam 7.5 Injection, M/s. Prix Pharmaceutica, Reg. No. 075781.
	GMP status	Keeping in view the above facts, detailed visit of the facility and supporting documents provided by the firm, the panel unanimously recommended M/s Eterna Pharma Plot No. 99,100,101 &198-C, Sector D1,Old Industrial Estate, Mirpur,AJ & K for the grant of drug manufacturing License for the following sections namely: 1. Oral Powder Section (Veterinary) General 2. Oral Liquid Section (Veterinary) General 3. Liquid Injection section (Veterinary) General
	Remarks of the Evaluator [XIII]	
	Decision of 307th meeting: Deferred for scientific rationale of related strength of the same formulation.	
	Updated status: The firm has submitted that **"*in recent meetings of Registration Board we have noticed that same products are approved and there is no objection on dossiers on scientific* basis of other manufacturers."** Diclozon 7.5 Injection (119695) of M/s Amazon Pharmaceutical (Pvt.) Ltd, Bhimber, AJK approved in 331st meeting of Registration Board	
	Decision: Approved.	
635.	Name and address of manufacturer / Applicant	M/s Eterna Pharma (Pvt.) Ltd., Plot # (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir (Oral Powder section (Veterinary) General.
	Brand Name +Dosage Form + Strength	Eter-A Dox Powder.
	Composition	Each 100gm contains: Doxycycline Hyclate ……25% w/w
	Diary No. Date of R& I & fee	Dy. No. 93 dated: 01-01-2021 Rs.20,000/- Dated 01-01-2021.
	Pharmacological Group	Antibacterial.
	Type of Form	Form 5.
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	100gm, 500gm, 1kg, 5kg & 25kg powder filled in plastic jar with aluminium seal / Decontrolled
	Me-too status	Unidox Powder, Univet Pharma, Reg. No. 029642.
	GMP status	Keeping in view the above facts, detailed visit of the facility and supporting documents provided by the firm, the panel unanimously recommended M/s Eterna Pharma Plot No. 99,100,101 &198-C, Sector D1,Old Industrial Estate, Mirpur,AJ & K for the grant of drug manufacturing License for the following sections namely: 1. Oral Powder Section (Veterinary) General 2. Oral Liquid Section (Veterinary) General 3. Liquid Injection section (Veterinary) General
	Remarks of the Evaluator [XIII]	• Firm has revised their label claim in line with reference product. **Revised label claim is as under:** **Each 100gm contains:** **Doxycycline Hyclate eq. to Doxycycline ……25% w/w**
	Decision of 307th meeting: Deferred for scientific rationale of related strength of the same formulation.	
	Updated status: The firm has submitted that **"*in recent meetings of Registration Board we have noticed that same products are approved and there is no objection on dossiers on scientific* basis of other manufacturers."** Doxyskill-25% Powder (111408) of M/s Bioskils Pharmaceuticals, Gujranwala approved in 312th meeting of Registration Board	
	Decision: Approved.	

636.	Name and address of manufacturer / Applicant	M/s Eterna Pharma (Pvt.) Ltd., Plot # (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir (Oral Powder section (Veterinary) General.
	Brand Name +Dosage Form + Strength	Diamp 98 Oral Powder.
	Composition	Each 100gm contains: Amprolium Hydrochloride ……98% w/w.
	Diary No. Date of R& I & fee	Dy. No. 88 dated: 01-01-2021 Rs.20,000/- Dated 01-01-2021.
	Pharmacological Group	Anticoccidial.
	Type of Form	Form 5.
	Finished product Specification	Innovator's Specification.
	Pack size & Demanded Price	100gm, 500gm, 1kg, 5kg & 25kg powder filled in plastic jar with aluminium seal / Decontrolled.
	Me-too status	Ampro-Forte Oral Powder, M/S. Breeze Pharma, Reg. No. 088630.
	GMP status	Keeping in view the above facts, detailed visit of the facility and supporting documents provided by the firm, the panel unanimously recommended M/s Eterna Pharma Plot No. 99,100,101 &198-C, Sector D1,Old Industrial Estate, Mirpur,AJ & K for the grant of drug manufacturing License for the following sections namely: 1. Oral Powder Section (Veterinary) General 2. Oral Liquid Section (Veterinary) General 3. Liquid Injection section (Veterinary) General
	Remarks of the Evaluator [XIII]	Official monograph of applied formulation is available in USP.
	Decision of 307th meeting: Deferred for scientific rationale of related strength of the same formulation.	
	Updated status: The firm has submitted that **"*in recent meetings of Registration Board we have noticed that same products are approved and there is no objection on dossiers on scientific* basis of other manufacturers."** AR Empro-Med Oral Powder (122027) of M/s Medpharm Research Lab, Lahore approved in 335th meeting of Registration Board	
	Decision: Approved.	
637.	Name and address of manufacturer / Applicant	M/s Eterna Pharma (Pvt.) Ltd., Plot # (99,100,101,198) C, Sector D1, Old Industrial Estate, Mirpur, Azad Jammu & Kashmir (Oral Powder section (Veterinary) General.
	Brand Name +Dosage Form + Strength	Eter-Brocin 72%.
	Composition	Each 100gm contains: Neomycin Sulphate …….72% w/w
	Diary No. Date of R& I & fee	Dy. No. 78 dated: 01-01-2021 Rs.20,000/- Dated 01-01-2021.
	Pharmacological Group	Antibacterial.
	Type of Form	Form 5.
	Finished product Specification	Innovator's Specification.
	Pack size & Demanded Price	100gm, 500gm, 1kg, 5kg & 25kg powder filled in plastic jar with aluminium seal / Decontrolled.
	Me-too status	Breno-Cin Oral Powder, M/S. Breeze Pharma, Reg. No. 097897.
	GMP status	Keeping in view the above facts, detailed visit of the facility and supporting documents provided by the firm, the panel unanimously recommended M/s Eterna Pharma Plot No. 99,100,101 &198-C, Sector D1,Old Industrial Estate, Mirpur,AJ & K for the grant of drug manufacturing License for the following sections namely: 1. Oral Powder Section (Veterinary) General 2. Oral Liquid Section (Veterinary) General

		3. Liquid Injection section (Veterinary) General
	Remarks of the Evaluator [XIII]	
	Decision of 307th meeting: Deferred for scientific rationale of related strength of the same formulation.	
	Updated status: The firm has submitted that **"*in recent meetings of Registration Board we have noticed that same products are approved and there is no objection on dossiers on scientific* basis of other manufacturers."** AR Neomed-72 Oral Powder (122023) of M/s Medpharm Research Lab, Lahore approved in 335th meeting of Registration Board	
	Decision: Approved.	

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

a. New Cases

638.	Name and address of Applicant	M/s Orient Animal Health Pvt Ltd., Commercial # 6, Block-A, 1st Floor, Kazimabad, 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, Model Colony, Karachi Validity: 22-10-2024. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Univet Ltd., Tullyvin, Cootehil, County Cavan, H16 T 183, Ireland
	Name and address of marketing authorization holder	M/s Univet Ltd., Tullyvin, Cootehil, County Cavan, H16 T 183, Ireland
	Name of exporting country	Ireland
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 29282 Dated 19-12-2023
	Fee including differential fee	Rs: 150,000 Dated 08-12-2023
	Brand Name +Dosage Form + Strength	Aquaprim 40/200 Solution for Injection
	Composition	Each ml contains: Sulfadiazine…200mg Trimethoprim…40mg
	Finished Product Specification	Eur. Ph. specifications
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	Aquaprim solution for injection (HPRA, Ireland approved)
	Me-too status	Coliprim Injection of M/s U.M. Enterprises, Karachi. (Reg. No. 120706)
	Detail of certificates attached	➢ Scanned copy of Apostille COPP dated 26-07-2023 certified by HPRA Ireland confirms GMP status of the manufacturer and free sale status of the applied product in country of origin. ➢ Scanned copy of legalized Eudra GMP certificate No. 32065/V10864 dated 07.09.2022 certified by HPRA Ireland. ➢ Letter of authorization/ distribution agreement **Not Provided**
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated and 36-month real time stability studies data of three batches at zone IV-A conditions. **Target species:** Cattle **Shortcomings:**

		• Copy of valid DSL • valid original legalized/ apostille certified COPP, since the already submitted is scanned copy. • valid notarized original letter of authorization (LOA)/ distribution agreement. • 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.
	Decision: Deferred for submission of following: • **Copy of valid DSL** • **valid original legalized/ apostille certified COPP, since the already submitted is scanned copy.** • **valid notarized original letter of authorization (LOA)/ distribution agreement.** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.**	
639.	Name and address of Applicant	M/s Orient Animal Health Pvt Ltd., Commercial # 6, Block-A, 1st Floor, Kazimabad, 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, Model Colony, Karachi Validity: 22-10-2024. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Univet Ltd., Tullyvin, Cootehil, County Cavan, Ireland
	Name and address of marketing authorization holder	M/s Univet Ltd., Tullyvin, Cootehil, County Cavan, Ireland
	Name of exporting country	Ireland
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 29283 Dated 19-12-2023
	Fee including differential fee	Rs: 150,000 Dated 08-12-2023
	Brand Name +Dosage Form + Strength	Ubroseal Blue Dry Cow 2.6gm Intramammary Suspension for Cattle
	Composition	Each gram contains: Bismuth Subnitrate…650mg
	Finished Product Specification	Eur. Ph. specifications
	Pharmacological Group	Intramammary suspension
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	4 gram syringe
	International availability	HPRA, Ireland approved
	Me-too status	Not registered with DRAP
	Detail of certificates attached	➢ Scanned copy of Apostille COPP dated 26-07-2023 certified by HPRA Ireland confirms GMP status of the manufacturer and free sale status of the applied product in country of origin. ➢ Scanned copy of legalized Eudra GMP certificate No. 32065/V10864 dated 07.09.2022 certified by HPRA Ireland. ➢ Letter of authorization/ distribution agreement **Not Provided**
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated and 36-month real time stability studies data of three batches at zone IV-A conditions. **Target species:** Cattle (dairy cows at drying off) **Shortcomings:** • Copy of valid DSL • valid original legalized/ apostille certified COPP, since the

		already submitted is scanned copy. • valid notarized original letter of authorization (LOA)/ distribution agreement. • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision: Deferred for submission of following: • **Copy of valid DSL** • **valid original legalized/ apostille certified COPP, since the already submitted is scanned copy.** • **valid notarized original letter of authorization (LOA)/ distribution agreement.** • **label in accordance with The Drugs (Labeling and Packing) Rules, 1986.**	
640.	Name and address of Applicant	M/s Chappal Enterprises, Office No. G8, Muhammadi Trade Tower, Opposite Adam Chamber, Altaf Hussain Road, New Challi, Karachi
	Detail of Drug Sale License	**Not provided**
	Name and address of manufacturer	M/s Roam Technology NV I.Z. Poort Genk, 6835-Geleen Lean 24, 3600 Genk, Belgium
	Name and address of marketing authorization holder	M/s Roam Technology NV I.Z. Poort Genk, 6835-Geleen Lean 24, 3600 Genk, Belgium
	Name of exporting country	Belgium
	Type of Form	Form-5A Form-5A Dy.No 19719 dated 12-08-2020 Rs.100,000/- dated 12-08-2020
	Diary No. & Date of R& I	**Duplicate dossier** (R&I 11937 dated 06-09-2024) Dy.No 19719 Dated 12-08-2020 (**R&I confirmed from R&I DRAP and PEC record**)
	Fee including differential fee	Rs: 100,000 Dated 12-08-2020
	Brand Name +Dosage Form + Strength	HUWA-SAN TR 50 disinfectant
	Composition	Active ingredient: Hydrogen peroxide.....49.0-49.9 (% w/w) Other ingredients: Colloidal Silver 0.026%-0.033% w/w Demineralized water.....q.s 100% w/w
	Finished Product Specification	
	Pharmacological Group	Disinfectant
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	5Kg
	International availability	Could not be confirmed
	Me-too status	Aqua Clean Liquid of M/s Ghazi Bros Karachi. (Reg. No. 021449) Each litre contains: - Hydrogen Peroxide 50%, Silver…100mg Kanters Special Products, The Netherlands
	Detail of certificates attached	➢ Scanned copy of legalized ISO 13485 certificate valid from 27-07-2016 to 01-03-2019 It is pertinent to mention that Roam Technology NV is **not GMP certified.** However, Roam Technology does have a QMS according to ISO 9001 and ISO 13485 (for the production of medical devises) ➢ Scanned copy of legalized power of attorney dated 06-12-2016 between M/s Chappal Enterprises and M/s Roam Technology N M/s Roam Technology NV ➢ Copy of certificate by Federal Public Service Health, Food chain safety and Environment General Direction Environment for Huwa-San VET (comntaining Hydrogen peroxide 25%)

	Remarks of the Evaluator [XXV]	Firm **has not** provided 06-month accelerated and 36-month real time stability studies data of three batches at zone IV-A conditions. **Shortcomings:** • Copy of valid DSL • valid notarized original letter of authorization (LOA)/ distribution agreement. • valid notarized original CoPP • 06-month accelerated and 36-month real time stability studies data of three batches at zone IV-A conditions. • 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 submission of following: • **Copy of valid DSL** • **valid original notarized letter of authorization (LOA)/ distribution agreement.** • **valid original legalized CoPP** • **valid original legalized GMP and Free sale certificates.** • **06-month accelerated and 36-month real time stability studies data of three batches at zone IV-A conditions.** • **evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	

b. Deferred cases

641.	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: 29-06-2028. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Univet Ltd., Tullyvin Cootehill Co, Cavan Ireland
	Name and address of marketing authorization holder	M/s Bimeda Animal Health Limited 2, 3,& 4 Airton close, Airton Road Tallaght Dublin 24 Ireland.
	Name of exporting country	Ireland
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 37 Dated 02-01-2023
	Fee including differential fee	Rs : 75,000/- Dated 27-12-2022 (slip No. 511559016)
	Brand Name +Dosage Form + Strength	Multishield DC Intramammary Suspension for Cows
	Composition	Each 4.5gm Intramammary syringe contains: Neomycin 70,000 IU (corresponding to Neomycin Sulphate…100mg) Penethamate 77.2mg (corresponding to Penethamate Hydriodide…100mg) Benzyl Penicillin 227.2mg (corresponding to Procaine Benzyl Penicillin…400mg)
	Finished Product Specification	Inhouse
	Pharmacological Group	Combination of Beta lactam and aminoglycoside antibacterial
	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	4.5gm
	International availability	Ireland approved
	Me-too status	N/A

	Detail of certificates attached	➢ Original Legalized FSC No. FSC-22-0006 dated 28-02-2022 issued by HPRA Ireland confirms Free Sale status of the product in the exporting country. ➢ Copy of EUDRA GMP certificate No. 29062/V10864 issued on the basis of inspection conducted on 25-09-2020 with scope **small volume liquids (beta lactam antibiotics)** ➢ Copy of **Un-notarized** Power of attorney dated 15-11-2022 provided.
	Remarks of the Evaluator [XXV]	**Shortcomings:** • original notarized Power of attorney/sole agency certificate**.** • Original legalized valid GMP certificate • 06 months accelerated and 24 months long term stability studies data of three batches as per zone-IV-A conditions
	Decision of 336th meeting: Deferred for submission of following: • original notarized Power of attorney/sole agency certificate. • Original legalized valid relevant GMP certificate • 06 months accelerated and 24 months long term stability studies data of three batches as per zone-IV-A conditions • clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise	
	Updated status: The firm has submitted the following: • Original notarized power of attorney was already submitted in another product application (Embotape) of same manufacturer dated 02-01-2023 • EUDR GMP based on inspection conducted on 13-05-2022 having scope of beta lactam antibiotics • Regarding the stability study conducted under accelerated conditions (40C/ 75%RH), it is important to note that ***there was a significant drop in potency, along with some out of specification results, observed after 6 months. Based on these findings, it was concluded that the product is sensitive to temperature. However, despite not being stable after 6 months under accelerated conditions, the long-term trend at 25C/ 60% RH indicates that the product should remain well within specifications for at least 24 months. Therefore, the appropriate storage condition is "Store below 25C" as stability testing was performed at this temperature*** • In the liquid sterile (aseptic) formulation area, **both beta lactam and non-beta-lactam antibiotics (general preparations) are manufactured on a campaign basis**. However, no cephalosporin manufacturing occurs in areas where penicillin is produced in liquid sterile preparation. **Remarks of the evaluator:** • Original **un-notarized** power of attorney submitted (confirmed from minutes of 336th meeting of the Registration Board)	
	Decision: Deferred for submission of original notarized Power of attorney/sole agency certificate.	
642.	Name and address of Applicant	M/s Brand Station, 69 Wocland villas Lahore, near Raiwind road, Lahore.
	Detail of Drug Sale License	Name: M/s Brand Station, Address: 69 Wocland villas Lahore, near Raiwind road, Lahore. Validity: **10-08-2027** Status: License to sell Drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Thien Quan Joint Stock Company, Lot 17F2-17F8, Road 5, Tra Noc 1 Industrial Zone, Binh Thuy District, Can Tho City, Vietnam
	Name and address of marketing authorization holder	M/s Thien Quan Joint Stock Company. 39 Nguyen Huu Cau Road, Con Khuong, Cai Khe Ward, Ninh Kieu District, Cantho City, Vietnam North Star Import Export Joint Stock Company, 69 Hung Vuong Road, Thoi Binh Ward, Ninh Kieu District, Cantho City, Vietnam. (supplier)
	Name of exporting country	Vietnam
	Type of Form	Form-5A

	Diary No. & Date of R& I	Dy.No 21719 Dated 04-09-2023
	Fee including differential fee	Rs: 150,000 Dated 01-09-2023 (slip N0. 725194199)
	Brand Name +Dosage Form + Strength	Amox 500 Water Soluble Powder
	Composition	Each 1000gm contains: Amoxicillin Trihydrate…500gm
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	aluminum coated PE bags: 5gm, 10gm, 20gm, 30gm, 50gm, 100gm, 200gm, 250gm, 400gm, 500gm, 1000gm, 1500gm, 2000gm, 5000gm, 10000gm with corresponding active substances. aluminum coated plastic can: 5gm, 10gm, 20gm, 30gm, 50gm, 200gm, 250gm, 400gm, 500gm, 1000gm, 1500gm, 2000gm, 5000gm, 10000gm with corresponding active substances.
	International availability	N/A
	Me-too status	Amoxinal 50% Water Soluble Powder of M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi.(Reg. No. 069626)
	Detail of certificates attached	Originally legalized Certificate of free sale No. 256/2023/QLT-CFS dated 21-02-2023 certified by Department of animal Health, Ministry of Agriculture and Rural Development, Vietnam **DOES NOT CONFIRM** free sale status of the product in the exporting country. **Validity: 2 years** ➢ Copy of legalized GMP certificate No. 17/16/GCN-GMP dated 20-12-2016 certified by Department of animal Health, Ministry of Agriculture and Rural Development, Vietnam Validity: 5 years ➢ Original legalized letter of distribution agreement dated 06-01-2024 between the supplier and PLH.
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated (40±2ºC/ 75±5%) and 36-month real time (30±2ºC/ 65±5%) stability studies data of three batches at zone IV-A conditions. **Target species:** Cattle, poultry Initially, the firm has submitted originally legalized Certificate of free sale No. 256/2023/QLT-CFS dated 21-02-2023 certified by Department of animal Health, Ministry of Agriculture and Rural Development, Vietnam DOES NOT CONFIRM free sale status of the product in the exporting country. In response to the query, the firm has submitted **copy of FSC (not legalized) of even number and date** declaring that the product is registered in Vietnam ***for export and distribution in local market*** ➢ Confirmation letter dated 06-08-2024 from M/s Thien Quan Joint Stock Company that "we have two certificate of GMP-WHO of Department of Animal Health-Ministry of Agriculture and Rural Development. The first certificate is for production lines of Beta lactam in the forms of powder, granule for oral use and the second for production line of Non-Beta Lactam in the forms of powder, granule for oral; liquid for oral; solution for injection" **Shortcomings:** • Original legalized valid free sale certificate confirming Free sale status of applied product in exporting country of origin

		• clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise.
	Decision of 340th meeting: Deferred for submission of following: • Original legalized valid free sale certificate confirming Free sale status of applied product in exporting country of origin • Decision of DRAP Authority regarding manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise.	
	Updated status: The firm has submitted the following: • Originally legalized Certificate of free sale No. 989/2024/QLT-CFS dated 27-08-2024 certified by Department of animal Health, Ministry of Agriculture and Rural Development, Vietnam stating that the applied product is ***registered in Vietnam and can be freely sold in Vietnam and oversea markets*** (valid for **2 years**) • Originally legalized GMP certificate No. 22/23/GCN-GMP dated 17-10-2023 certified by Department of animal Health, Ministry of Agriculture and Rural Development, Vietnam (having scope of production lines of Beta-lactam in the forms of ***powder for injection and suspension for injection***) Validity: 5 years **Remarks of the evaluator/ shortcomings:** Originally legalized **relevant GMP certificate** having scope of production lines of penicillin in the forms of **oral powder**	
	Decision: Deferred for following: • **Originally legalized relevant GMP certificate having scope of production lines of penicillin in the forms of oral powder** • **Decision of DRAP Authority regarding manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise.**	
643.	Name and address of Applicant	M/s A&S Animal Health, 61-A Westwood Colony, Thokar Niaz Baig, Lahore, Pakistan.
	Detail of Drug Sale License	Name: M/s A&S Animal Health Address: 61-A Westwood Colony, Thokar Niaz Baig, Lahore Validity: 20/10/2027 Status: License to sell drugs as a Distributor (Form No. 11)
	Name and address of manufacturer	M/s The Modern Company for Veterinary Medicines and Agricultural Pesticides (Movetco), Al-Mwuaqar Industrial Area, District No. 1, Area No. 47, Jordan
	Name and address of marketing authorization holder	M/s The Modern Company for Veterinary Medicines and Agricultural Pesticides (Movetco), Al-Mwuaqar Industrial Area, District No. 1, Area No. 47, Jordan
	Name of exporting country	Jordan
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 22594 Dated 14-09-2023
	Fee including differential fee	Rs : 150,000 Dated 12-09-2023 (Slip No. 63590401677)
	Brand Name +Dosage Form + Strength	Amoxicillin-Move 50% Powder
	Composition	Each gram contains: Amoxicillin Trihydrate…500mg
	Finished Product Specification	As per innovator's specifications
	Pharmacological Group	antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	500gm
	International availability	Yemen
	Me-too status	Bio-Amoxyllin 50 Powder of M/s Bio-Labs (Pvt) Ltd., Islamabad. (Reg. No. 079234)
	Detail of certificates attached	➢ Original Legalized COPP NO. 003617 dated 23-03-2023 issued by the Ministry of Agriculture, Veterinary and Animal Health Directorate, The Hashemite Kingdom of

		Jordan confirms the free sale status in exporting country as well as GMP status of the manufacturer ➢ Copy of legalized letter of authorization dated 25-04-2023 from PLH for the applied product.**(original in Movedox 50% Powder dossier)**
	Remarks of the Evaluator [XXV]	Firm has provided 24-month accelerated and 36-month real time stability studies data of three batches at zone IV-A conditions. **Target species:** Poultry, calves, lambs **Shortcomings:** • clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise. • Valid legalized original GMP certificate covering scope of penicillin containing products. • 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. • Firm shall submit full fee of registration for pre-approval revision of label claim in line with reference product as prescribed vide S.R.O. 496(I)/2023 dated 17-04-2023.
	Decision of 340th meeting: Deferred for submission of following: • Clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise. • Valid legalized original GMP certificate covering scope of penicillin containing products. • Label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • fee Rs.300,000/- for pre-approval revision of label claim in line with reference product as prescribed vide S.R.O. 1324(I)/2024 dated 30-08-2024.	
	Updated status: The firm has submitted the following: • Clarification from The Modern Company for Veterinary Medicines & agricultural Pesticides Industries that all penicillin formulations are manufacturing in a separate section. The firm has also submitted copy of factory layout plan depicting a separate building for penicillin containing products. • Label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • The firm has stated that they **have not applied for any revision of label claim.** **Shortcomings:** • Valid legalized original GMP certificate **covering scope of penicillin containing products**. • Metoo/ generic status or approval status in any RRA	
	Decision: Deferred for following: • **Decision of DRAP Authority regarding manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise.** • **Valid legalized original GMP certificate covering scope of penicillin containing products** • **Metoo/ generic status or approval status in any RRA**	
644.	Name and address of Applicant	M/s A&S Animal Health, 61-A Westwood Colony, Thokar Niaz Baig, Lahore, Pakistan.
	Detail of Drug Sale License	Name: M/s A&S Animal Health Address: 61-A Westwood Colony, Thokar Niaz Baig, Lahore Validity: 20/10/2027 Status: License to sell drugs as a Distributor (Form No. 11)
	Name and address of manufacturer	M/s The Modern Company for Veterinary Medicines and Agricultural Pesticides (Movetco), Al-Mwuaqar Industrial Area, District No. 1, Area No. 47, Jordan
	Name and address of marketing authorization holder	M/s The Modern Company for Veterinary Medicines and Agricultural Pesticides (Movetco), Al-Mwuaqar Industrial Area, District No. 1, Area No. 47, Jordan
	Name of exporting country	Jordan

	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 22593 Dated 14-09-2023
	Fee including differential fee	Rs : 150,000 Dated 12-09-2023 (Slip No. 8609051804)
	Brand Name +Dosage Form + Strength	Tylofosfodern Plus Powder
	Composition	Each gram contains: Fosfomycin **Sodium**…200mg Tylosin Tartrate…50mg Fructose 1,6 Diphosphate…180mg
	Finished Product Specification	As per innovator's specifications
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	500gm
	International availability	Yemen, Jordan
	Me-too status	**Could not be confirmed in the applied combination**
	Detail of certificates attached	➢ Original Legalized COPP NO. 003618 dated 23-03-2023 issued by the Ministry of Agriculture, Veterinary and Animal Health Directorate, The Hashemite Kingdom of Jordan confirms the free sale status in exporting country as well as GMP status of the manufacturer ➢ Copy of legalized letter of authorization dated 25-04-2023 from PLH for the applied product.**(original in Movedox 50% Powder dossier)**
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated and 36-month real time stability studies data of three batches at zone IV-A conditions. **Target species:** Poultry **Shortcomings:** • 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 approval status in any RRA or evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision of 340th meeting: Deferred for the confirmation of metoo or RRA.	
	Updated status: The firm has submitted the following: • label in accordance with The Drugs (Labeling and Packing) Rules, 1986 • **me-too generic status:** Fosvet Plus-T Powder of M/s Epla Labs Karachi (Reg. No. 025721) • **Demanded pack size:** 1000gm • **Remarks of the evaluator/ shortcomings:** The submitted reference product contains different composition than the applied product. (different salt form of Fosfomycin and also does not contain Fructose 1,6 Diphosphate)	
	Decision: Deferred for submission of evidence of approval status in any RRA or evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
645.	Name and address of Applicant	M/s Chakwal Pharma International, OTI Plaza, Basement Ground, 1st ,2nd & 3rd floor, 210 Lalazar Commercial Market, Thokar Niaz Baig, Raiwind Road, Lahore
	Detail of Drug Sale License	Name: M/s Chakwal Pharma International Address: OTI Plaza, Basement Ground, 1st ,2nd & 3rd floor, 210 Lalazar Commercial Market, Thokar Niaz Baig, Raiwind Road, Lahore Validity: 13/11/2028

		Status: License to sell drugs as a Distributor (Form No. 11)
	Name and address of manufacturer	M/S. Alfasan International B.V., Kuipersweg 9, 3449 JA Woerden The Netherland
	Name and address of marketing authorization holder	M/S. Alfasan Netherland B.V. Kuipersweg 9, 3449 JA Woerden The Netherland
	Name of exporting country	The Netherland
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 22591 Dated 14-09-2023
	Fee including differential fee	Rs : 150,000 Dated 01-09-2023 (Slip No. 849948788520)
	Brand Name +Dosage Form + Strength	Ceftiosan 50mg/ml Suspension for Injection
	Composition	Each ml contains: Ceftiofur as HCl…50mg
	Finished Product Specification	As per innovator's specifications
	Pharmacological Group	Cephalosporin antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100ml vial
	International availability	Ceftiosan, 50 mg/ml, suspension for injection (**Approved in Netherlands**)
	Me-too status	Eficur Injectable Suspension 50mg/ml of M/s Hipra Pakistan (Private) Limited, Lahore. (Reg. No. 094466)
	Detail of certificates attached	➢ Original legalized COPP BD/2022/No. of Certificate 257952 dated 04-08-2022 certified by Medicines Evaluation Board Agency- Veterinary Medicinal Products Unit, Ministry of Agriculture, Nature and Food Quality, The Netherlands confirms the free sale status in exporting country as well as GMP status of the manufacturer ➢ Scanned copy of legalized letter of exclusive sole distributor/ authorization dated: 11-07-2022
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated and 36-month real time stability studies data of three batches at zone IV-A conditions. **Target species:** Cattle **Shortcomings:** • clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise. • Valid notarized original Letter of distribution/ sole distribution agreement since already submitted is copy.
	Decision of 340th meeting: Deferred for submission of following: • Clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise. • Valid notarized original Letter of distribution/ sole distribution agreement since already submitted is copy.	
	Updated status: The firm has submitted the following: • Declaration letter that Alfasan would like to clarify that we follow international GMP guidelines, using dedicated facilities and equipment for manufacturing products containing penicillins (e.g. ampicillin, amoxicillin, etc.). The facilities and manufacturing protocols undergo regular inspections to ensure compliance with GMP guidelines. These inspections confirm that our measures to prevent cross-contamination are effective and in-line with the regulatory standards. In conclusion, Alfasan ensures compliance with GMP guidelines, minimizing cross-contamination risks across all veterinary medicinal products manufacturing processes. • Originally legalized letter of exclusive sole distributor/ authorization from Alfasan International BV in the name of Ms Chakwal pharma International.	

	Decision: Deferred till decision of DRAP Authority regarding manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise.	
646.	Name and address of Applicant	M/s Bio-Vet Pvt Ltd., Permanent Address: 97-A Jail Road, Lahore. Correspondence Address: Suite 4, Block G2, Near Doctors Hospital Underpass, Canal Road, Johar Town, Lahore, Pakistan.
	Detail of Drug Sale License	Name: M/s Bio-Vet, Address: Bhatti street Dhana Singh Wala House No 332 Mohallah New Campus Road, Johar Town Lahore. Validity: **11 August, 2023.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Jovet Jordan Vet & Agr. Med. Ind. Co. P.O.Box 2760 Amman 11953 Jordan.
	Name and address of marketing authorization holder	M/s Jovet Jordan Vet & Agr. Med. Ind. Co. P.O.Box 2760 Amman 11953 Jordan.
	Name of exporting country	Jordan
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 6359 Dated 06-03-2023
	Fee including differential fee	Rs : 150,000 Dated 28-02-2023(slip No. 8973214821)
	Brand Name +Dosage Form + Strength	Doxycycline-50 Water Soluble Powder
	Composition	Each gram contains: Doxycycline HCl…500mg
	Finished Product Specification	
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	1Kg
	International availability	Lebanon
	Me-too status	Vetroxin Oral Water Soluble Powder of M/s Athan Pharmaceuticals, Hattar (Reg. No. 115052)
	Detail of certificates attached	➢ Original Legalized Free Sale Certificate No. 5/5/10/003616 dated 26-04-2018 issued by Ministry of Agriculture Veterinary Department Pharmacy and drug control division, Jordan confirms free sale status of the applied product in country of origin ➢ Copy of GMP certificate No. 5/5/10/003095 dated 11-04-2018 issued by Ministry of Agriculture Veterinary Department Pharmacy and drug control division, Jordan confirms GMP status of the manufacturer. (**Original in Colistin 6M Oral Powder**) ➢ Scanned copy of legalized letter of authorization (LOA) dated 01-04-2018, issued in the name of applicant by PLH (**Original in Colistin 6M Oral Powder**)
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated and 36-month real time stability studies data of three batches as per zone IV-A conditions. **Target species:** Poultry **Shortcomings:** • Form 5A is not attached in the dossier. • Copy of valid DSL • Clarification regarding address of the applicant since the address mentioned on form 5A is not the same as mentioned on copy of DSL. • Original legalized valid FSC and GMP certificate, since

		already submitted certificates are 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) instructions for use; Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision of 339th meeting: Deferred for submission of following: • Original signed Form 5A • Copy of valid DSL • Clarification regarding address of the applicant since the address mentioned on form 5A is • not the same as mentioned on copy of DSL. • Original legalized valid FSC and GMP certificate, since already submitted certificates are • expired now but valid upon submission. • label in accordance with The Drugs (Labeling and Packing) Rules, 1986.	
	Updated status: The firm has submitted the following: • Original signed Form 5A • Original legalized free sale certificate for the applied product dated 22-09-2024 • Original legalized GMP certificate of the manufacturer dated 22-09-2024 valid for three years from the date of inspection done on 06/2022. • label in accordance with The Drugs (Labeling and Packing) Rules, 1986 **Shortcomings:** • Copy of valid DSL • Original legalized letter of authorization (LOA) since already submitted is **expired now but valid upon submission** • Clarification regarding address of the applicant since the address mentioned on form 5A is not the same as mentioned on copy of DSL.	
	Decision: Deferred for submission of following: • **Copy of valid DSL** • **Original legalized letter of authorization (LOA) since already submitted is expired now but valid upon submission** • **Clarification regarding address of the applicant since the address mentioned on form 5A is not the same as mentioned on copy of DSL.**	
647.	Name and address of Applicant	M/s Bio-Vet Pvt Ltd., Permanent Address: 97-A Jail Road, Lahore. Correspondence Address: Suite 4, Block G2, Near Doctors Hospital Underpass, Canal Road, Johar Town, Lahore, Pakistan.
	Detail of Drug Sale License	Name: M/s Bio-Vet, Address: Bhatti street Dhana Singh Wala House No 332 Mohallah New Campus Road, Johar Town Lahore. Validity: **11 August, 2023.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Jovet Jordan Vet & Agr. Med. Ind. Co. P.O.Box 2760 Amman 11953 Jordan.
	Name and address of marketing authorization holder	M/s Jovet Jordan Vet & Agr. Med. Ind. Co. P.O.Box 2760 Amman 11953 Jordan.
	Name of exporting country	Jordan
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 6360 Dated 06-03-2023
	Fee including differential fee	Rs : 150,000 Dated 28-02-2023(slip No. 79890632)
	Brand Name +Dosage Form + Strength	Colistin 6M Oral Powder
	Composition	Each gram Contains: Colistin as Sulphate…6,000,000 IU
	Finished Product Specification	
	Pharmacological Group	Antibiotic

	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	1Kg
	International availability	Lebanon, Russia, Dubai
	Me-too status	Elecol Powder of M/s Elegance Pharmaceuticals, Distt. Rawalpindi. (Reg. No. 118625)
	Detail of certificates attached	➢ Original Legalized Free Sale Certificate No. 5/5/10/003618 dated 26-04-2018 issued by Ministry of Agriculture Veterinary Department Pharmacy and drug control division, Jordan confirms free sale status of the applied product in country of origin ➢ Original legalized GMP certificate No. 5/5/10/003095 dated 11-04- 2018 issued by Ministry of Agriculture Veterinary Department Pharmacy and drug control division, Jordan confirms GMP status of the manufacturer. ➢ Original legalized letter of authorization (LOA) dated 01-04-2018, issued in the name of applicant by PLH
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated and 36-month real time stability studies data of three batches as per zone IV-A conditions. **Target species:** Poultry, lambs, calves **Shortcomings:** • Copy of valid DSL • Clarification regarding address of the applicant since the address mentioned on form 5A is not the same as mentioned on copy of DSL. • Original legalized valid FSC and GMP certificate, since already submitted certificates are 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) instructions for use; Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision of 339th meeting: Deferred for submission of following: • Copy of valid DSL • Clarification regarding address of the applicant since the address mentioned on form 5A is not the same as mentioned on copy of DSL. • Original legalized valid FSC and GMP certificate, since already submitted certificates are expired now but valid upon submission. • label in accordance with The Drugs (Labeling and Packing) Rules, 1986.	
	Updated status: The firm has submitted the following: • Original legalized free sale certificate for the applied product dated 22-09-2024 • Original legalized GMP certificate of the manufacturer dated 22-09-2024 valid for three years from the date of inspection done on 06/2022. • label in accordance with The Drugs (Labeling and Packing) Rules, 1986 **Shortcomings:** • Copy of valid DSL • Original legalized letter of authorization (LOA) since already submitted is **expired now but valid upon submission** • Clarification regarding address of the applicant since the address mentioned on form 5A is not the same as mentioned on copy of DSL.	
	Decision: Deferred for submission of following: • **Copy of valid DSL** • **Original legalized letter of authorization (LOA) since already submitted is expired now but valid upon submission** • **Clarification regarding address of the applicant since the address mentioned on form 5A is not the same as mentioned on copy of DSL.**	

648.	Name and address of Applicant	M/s Bio-Vet Pvt Ltd., Permanent Address: 97-A Jail Road, Lahore. Correspondence Address: Suite 4, Block G2, Near Doctors Hospital Underpass, Canal Road, Johar Town, Lahore, Pakistan.
	Detail of Drug Sale License	Name: M/s Bio-Vet, Address: Bhatti street Dhana Singh Wala House No 332 Mohallah New Campus Road, Johar Town Lahore. Validity: **11 August, 2023.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Jovet Jordan Vet & Agr. Med. Ind. Co. P.O.Box 2760 Amman 11953 Jordan.
	Name and address of marketing authorization holder	M/s Jovet Jordan Vet & Agr. Med. Ind. Co. P.O.Box 2760 Amman 11953 Jordan.
	Name of exporting country	Jordan
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 6358 Dated 06-03-2023
	Fee including differential fee	Rs : 150,000 Dated 28-02-2023(slip No. 4222019594)
	Brand Name +Dosage Form + Strength	Amoxycillin 50 Powder
	Composition	Each gram contains: Amoxicillin Trihydrate…500mg
	Finished Product Specification	
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	1Kg
	International availability	Saudi Arabia, Dubai
	Me-too status	Amoxinal 50% Water Soluble Powder of M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi (Reg. No. 069626)
	Detail of certificates attached	➢ Original Legalized Free Sale Certificate No. 5/5/10/003617 dated 26-04-2018 issued by Ministry of Agriculture Veterinary Department Pharmacy and drug control division, Jordan confirms free sale status of the applied product in country of origin ➢ Copy of GMP certificate No. 5/5/10/003095 dated 11-04-2018 issued by Ministry of Agriculture Veterinary Department Pharmacy and drug control division, Jordan confirms GMP status of the manufacturer. (**Original in Colistin 6M Oral Powder**) ➢ Scanned copy of legalized letter of authorization (LOA) dated 01-04-2018, issued in the name of applicant by PLH (**Original in Colistin 6M Oral Powder**)
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated and 36-month real time stability studies data of three batches as per zone IV-A conditions. **Target species:** Poultry, Sheep, goats, calves, foals **Shortcomings:** • Form 5A is not attached in the dossier. • Copy of valid DSL • Clarification regarding address of the applicant since the address mentioned on form 5A is not the same as mentioned on copy of DSL. • Original legalized valid FSC and relevant GMP certificate, since already submitted certificates are 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) instructions for use; Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise
	Decision of 339th meeting: Deferred for submission of following: • Original signed Form 5A • Copy of valid DSL • Clarification regarding address of the applicant since the address mentioned on form 5A is not the same as mentioned on copy of DSL. • Original legalized valid FSC and relevant GMP certificate, since already submitted certificates are expired now but valid upon submission. • label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise	
	Updated status: The firm has submitted the following: • Original signed form 5A • Original legalized free sale certificate for the applied product dated 22-09-2024 • label in accordance with The Drugs (Labeling and Packing) Rules, 1986 **Shortcomings:** • Copy of valid DSL • Originally legalized relevant GMP certificate, since already submitted certificates **are expired now but valid upon submission** and the original certificate submitted with reply dated 15-11-2024 is not legalized. • Original legalized letter of authorization (LOA) since already submitted is **expired now but valid upon submission** • Clarification regarding address of the applicant since the address mentioned on form 5A is not the same as mentioned on copy of DSL. • clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise	
	Decision: Deferred for submission of following: • **Copy of valid DSL** • **Originally legalized relevant GMP certificate, since already submitted certificates are expired now but valid upon submission and the original certificate submitted with reply dated 15-11-2024 is not legalized.** • **Original legalized letter of authorization (LOA) since already submitted is expired now but valid upon submission** • **Clarification regarding address of the applicant since the address mentioned on form 5A is not the same as mentioned on copy of DSL.** • **Decision of DRAP Authority regarding manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise.**	
649.	Name and address of Applicant	M/s Fair International Trading Co., A-129, Block 15, Gulistan e Johar Karachi, Pakistan.
	Detail of Drug Sale License	Name: M/s Fair International Address: 11, Al-Syed Arcade, 2nd Floor, Block 5, Gulshan-e-Iqbal, Karachi. Validity: **24-05-2024** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Cenavisa, S.L. Cami Pedra Estela, 43205-REUS, Spain
	Name and address of marketing authorization holder	M/s Cenavisa, S.L. Cami Pedra Estela, 43205-REUS, Spain
	Name of exporting country	Spain
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 18372 Dated 20-07-2023
	Fee including differential fee	Rs: 150,000 Dated 17-07-2023 (slip N0. 2801381030)

	Brand Name +Dosage Form + Strength	Cencoli 4,000,000 IU Oral Solution
	Composition	Each ml Contains: Colistin (as Sulphate)…4,000,000 IU
	Finished Product Specification	Eur. Ph. Specifications
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	1L, 5L
	International availability	Colicen 4,000,000 IU/ml Solution for drinking water (**Cimavet Spain approved**)
	Me-too status	**Could not be confirmed.**
	Detail of certificates attached	➢ Originally legalized COPP No. 2021/271 dated 25-03-2021 certified by Spanish agency of Medicines and Medical Devices, Spain confirms GMP status of the manufacturer and free sale status of the applied product in country of origin. ➢ Original legalized GMP certificate No. ES/002HV/21 dated 20.01.2021 certified by Certified by Spanish agency of Medicines and Medical Devices, Spain ➢ Letter of authorization/ distribution agreement **Not Provided**
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated and 24-month real time stability studies data of three batches at zone IV-A conditions. **Target species:** Cattle (calves), sheep (lambs), chicken, and turkeys **Shortcomings:** • Provide valid notarized original letter of authorization (LOA)/ distribution agreement. • 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. • Clarification regarding address of the applicant, since two different addresses are mentioned on form 5A and DSL.
	Decision of 339th meeting: Deferred for submission of following: • valid notarized original letter of authorization (LOA)/ distribution agreement. • label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Clarification regarding address of the applicant, since two different addresses are mentioned on form 5A and DSL.	
	Updated status: The firm has submitted the following: • Original letter of authorization dated 09-10-2024 **notarized from notary public Pakistan** • label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Declaration that the registered address is "11 Al-Syed Arcade, 2nd floor, block-05, Gulshan-e-Iqbal, Karachi" which is mentioned on the DSL, and the other address "A-129 block-15, Gulistan-e-Johar, Karachi" which is mentioned on form-5A is our postal address for correspondence purpose. **Shortcomings:** valid original letter of authorization (LOA)/ distribution agreement **notarized from country of origin**	
	Decision: Deferred for submission of valid original letter of authorization (LOA)/ distribution agreement notarized from country of origin.	
650.	Name and address of Applicant	M/s Vet Line International, 939-A, Block-J, Phase-1, LDA Avenue-1, Lahore, Pakistan
	Detail of Drug Sale License	Name: M/s Vet Line International Address: 939-A, Block-J, Phase-1, LDA Avenue-1, Lahore. Validity: **13-02-2023**. Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co. Limited.

		189 Taihang Street, Hi-tech zone, Shijiazhuang, Hebei, P.R.China
	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Hi-tech zone, Shijiazhuang, Hebei, P.R.China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24992 Dated 13-10-2023
	Fee including differential fee	Rs : 1,50,000 Dated 09-10-2023
	Brand Name +Dosage Form + Strength	HBNCP Benzyl Penicillin Na 5Mega Injection 20ml
	Composition	Each ml contains: Benzyl Penicillin Sodium…5,000,000 IU
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	20ml
	International availability	N/A
	Me-too status	**Could not be confirmed in the applied strength**
	Detail of certificates attached	➢ Original legalized CoPP No. 2023042805 dated 28-04-2023 issued by Agriculture office of Shijiazhuang High-Tech zone, Huanghe Road No. 151, China confirms free sale status in exporting country as well as GMP status of the manufacturer. ➢ The scope of original legalized GMP certificate No. 03034 dated 08-07-2022 issued by Department of Agriculture and Rural Affairs of Hebei Province **Does Not cover** Manufacturing operations related to Penicillin products ➢ Legalized Power of attorney dated 22-05-2023 between PLH and applicant for the applied product
	Remarks of the Evaluator [XXV]	6 months accelerated and 36 months long term stability studies data has been submitted as per zone-IV-A conditions. **Target species:** Cattle, sheep, calves, poultry, dog, cat **Shortcomings:** • Provide valid copy of DSL • clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise. • Evidence of approval status in any RRA or evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision of 340th meeting: Deferred for submission of following: • valid copy of DSL • Clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise. • Evidence of approval status in any RRA or evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
	Updated status: The firm has submitted the following**:** • Copy of DSL valid till **09-02-2028** • Clarification from the MAH abroad that penicillin formulations are manufactured by our company and have a separate production line. Site layout is also submitted for reference • **Me-too/ generic status:** Penivet-5 injection of M/s Star labs. • **RRA status:** Crystapen 5 Mega Units 3g Powder for Solution for Injection (VMD defra UK)	

	Remarks/Shortcomings: The submitted reference to the generic product could not be confirmed. Moreover, the status of reference product in RRA is expired since 30-03-2021	
	Decision: Deferred for submission of following: • **evidence of approval status in any RRA or evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Decision of DRAP Authority regarding manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise.**	
651.	Name and address of Applicant	M/s Vet Line International, 939-A, Block-J, Phase-1, LDA Avenue-1, Lahore, Pakistan
	Detail of Drug Sale License	Name: M/s Vet Line International Address: 939-A, Block-J, Phase-1, LDA Avenue-1, Lahore. Validity: **13-02-2023**. Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Hi-tech zone, Shijiazhuang, Hebei, P.R.China
	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Hi-tech zone, Shijiazhuang, Hebei, P.R.China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24993 Dated 13-10-2023
	Fee including differential fee	Rs : 1,50,000 Dated 09-10-2023
	Brand Name +Dosage Form + Strength	HBNCP FPro Penicillin 4Mega Injection 20ml
	Composition	Each vial contains: Penicillin G Procaine…3,000,000 IU Penicllin G Sodium…1000,000 IU
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	20ml
	International availability	Not provided
	Me-too status	**Could not be confirmed in the applied combination and strength**
	Detail of certificates attached	➢ Original legalized CoPP No. 2023042804 dated 28-04-2023 issued by Agriculture office of Shijiazhuang High-Tech zone, Huanghe Road No. 151, China confirms free sale status in exporting country as well as GMP status of the manufacturer. ➢ The scope of submitted GMP certificate No. 03034 dated 08-07-2022 issued by Department of Agriculture and Rural Affairs of Hebei Province **Does Not cover** Manufacturing operations related to Penicillin products ➢ Scanned copy of legalized Power of attorney dated 22-05-2023 between PLH and applicant for the applied product (original in **HBNCP Benzyl Penicillin Na 5Mega Injection 20ml** dossier)
	Remarks of the Evaluator [XXV]	6 months accelerated and 36 months long term stability studies data has been submitted as per zone-IV-A conditions. **Target species:** Horses, Cattle, sheep, goats, dog, cat **Shortcomings:** • Provide valid copy of DSL

		• clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise. • Evidence of approval status in any RRA or evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision of 340th meeting: Deferred for submission of following: • valid copy of DSL • Clarification of the manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise. • Evidence of approval status in any RRA or evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
	Updated status: The firm has submitted the following**:** • Copy of DSL valid till **09-02-2028** • Clarification from the MAH abroad that penicillin formulations are manufactured by our company and have a separate production line. Site layout is also submitted for reference • **Me-too/ generic status:** Penivet Forte injection of M/s Star labs. (Reg. No. 017945) • **RRA status:** Fortified Procaine Penicillin for injection 4 mega Troge Medical GmBh **Remarks/Shortcomings:** The submitted reference to the generic product is of different combination than applied (also contains dihydrostreptomycin sulphate). Moreover, the status of reference product in RRA could not be confirmed.	
	Decision: Deferred for submission of following: • **evidence of approval status in any RRA or evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Decision of DRAP Authority regarding manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise.**	
652.	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. Date of Validity: **25-05-2020** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Pucheng Chia Tai Biochemistry Co. Ltd. No.56, Da Shi Xi, Putan Village, Pucheng, Nanping City, Fujian Province, China
	Name and address of marketing authorization holder	M/s Pucheng Chia Tai Biochemistry Co. Ltd. No.56, Da Shi Xi, Putan Village, Pucheng, Nanping City, Fujian Province, China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 6288 Dated 16-05-2019
	Fee including differential fee	**Rs : 50,000** Dated 15-05-2019
	Brand Name +Dosage Form + Strength	Farmcare CTC 20% Water Soluble Powder
	Composition	Each Kg contains: Chlortetracycline HCl…200gm
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled

	Pack size	250gm, 500gm, 1Kg
	International availability	N/A
	Me-too status	Elecylin Powder of M/s Elegance Pharmaceuticals, Rawalpindi. (Reg. No.105028)
	Detail of certificates attached	➢ Original Legalized Free Sale Certificate No. 191100B0/019936 issued by Pucheng Bureau of Agriculture and Rural Affairs, China confirms free sale status in China. Validity: 24-03-2024 ➢ Original legalized GMP certificate No. (2017) Shou Yao GMP Zheng Zi No.13002 issued on 20-02-2019 and valid till **16-01-2022** confirms GMP status ➢ Original legalized Power of attorney dated 19-03-2019.
	Remarks of the Evaluator [XXV]	• 06 months accelerated (Batch No. F1109001, F1109002, F1109003) and 36 months long term (Batch No. F1202001, F1203001, F1203002) stability studies data has been submitted as per zone-IV-A conditions. **For LOD, the samples are OOS at each time point of accelerated stability studies and at 6th month time point for batch F1202001 and at 12th month time point for batches F1203001, F1203002.** **Shortcomings:** • Submitted GMP certificate is expired now but valid upon submission. Submit original valid legalized GMP certificate • 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. • For LOD, the samples are OOS at each time point of accelerated stability studies and at 6th month time point for batch F1202001 and at 12th month time point for batches F1203001, F1203002, clarify.
	Decision of 322nd meeting: Deferred for submission of 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. • Clarification regarding LOD, the samples are OOS at each time point of accelerated stability studies and at 6th month time point for batch F1202001 and at 12th month time point for batches F1203001, F1203002, justify.	
	Updated status: The firm has submitted the following: • Apostille certified GMP certificate of the manufactured valid till 16-12-2026 • Apostille certified free sale certificate for the applied product valid till 17-04-2029 • Apostille certified LOA for the applied product valid till 14-04-2029 • Finished product specifications: **"as per innovator's specifications"** • Clarification regarding stability results that the samples are not OOS because the specification for LOD i.e. ≤ 0.5%_mentioned in stability document is typographical error. The correct specification of LOD is ≤ 5.0% which is also mentioned in FPP specifications. **Shortcomings:** • Differential fee for registration of imported generic drug.	
	Decision: Approved with as per innovator's specifications. The firm shall submit differential fee for registration of imported generic drug before issuance of registration letter.	
653.	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 Pucheng Chia Tai Biochemistry Co. Ltd. No.56, Da Shi Xi, Putan Village, Pucheng, Nanping City, Fujian Province, China
	Name and address of marketing authorization holder	M/s Pucheng Chia Tai Biochemistry Co. Ltd. No.56, Da Shi Xi, Putan Village, Pucheng, Nanping City, Fujian Province, China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 6287 Dated 16-05-2019
	Fee including differential fee	**Rs : 50,000** Dated 15-05-2019
	Brand Name +Dosage Form + Strength	CoxRival 12% Premix
	Composition	Each Kg contains: Salinomycin Sodium…120gm
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	25Kg
	International availability	N/A
	Me-too status	Salinafarm 120 Powder of M/s Mylab (Pvt) Ltd, Khankah Sharif, Bahawalpur. (Reg. No. 101465)
	Detail of certificates attached	➢ Photocopy of Free Sale Certificate issued by Pucheng Bureau of Agriculture ➢ Photocopy of GMP certificate No. (2017) Shou Yao GMP Zheng Zi No. 13002 issued on 20-02-2019 and valid till **16-01-2-22.** ➢ Original legalized Power of attorney dated 19-03-2019 attached in Farmcare CTC 20% Water Soluble Powder dossier.
	Remarks of the Evaluator [XXV]	06 months accelerated and **18 months** long term stability studies data has been submitted as per zone-IV-A conditions. **Shortcomings:** • Submitted copy of FSC, provide legalized original valid FSC. • 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. • Submit long term stability studies data as per zone-IV-A conditions upto claimed shelf life.
	Decision of 322nd meeting: Deferred for submission of following: • Legalized original valid FSC. • 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.	

	• Long term stability studies data as per zone-IV-A conditions upto claimed shelf life (2 years).	
	Updated status: The firm has submitted the following: • Apostille certified GMP certificate of the manufactured valid till 16-12-2026 • Apostille certified free sale certificate for the applied product valid till 17-04-2029 • Apostille certified LOA for the applied product valid till 14-04-2029 • Finished product specifications: **"as per innovator's specifications"** • 2-year long term stability studies data as per zone-IV-A conditions **Shortcomings:** Differential fee for registration of imported generic drug.	
	Decision: Approved with as per innovator's specifications. The firm shall submit differential fee for registration of imported generic drug before issuance of registration letter.	
654.	Name and address of Applicant	M/s Neovet Pharma Pvt Ltd. Street No. 6, Plot No. A 12/37, Commercial Area Landhi, Cattle Colony Karachi
	Detail of Drug Sale License	Name: M/s Neovet Pharma Pvt Ltd Address: Plot No. A-12,37, 1st floor, Road No. 6, Commercial Area, Cattle Colony, Malir, Landhi Karachi Validity: **12-07-2023.** Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co. Limited. 189 Taihang Street, Shijiazhuang,Hebei, P.R.China 050035
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy. No 25224 Dated 10-09-2021
	Fee including differential fee	Rs : 150,000 Dated 06-09-2021 (slip No.07196659530)
	Brand Name +Dosage Form + Strength	Oligovit-M 100ml Injection
	Composition	Each ml contains: Vitamin A, Retinol Palmitate…15,000 IU Vitamin D3, Cholecalciferol...7500 IU Vitamin E, Tocopherol Acetate...20mg Thiamine HCl...10mg Riboflavine Sodium Phosphate...5mg Pyridoxine HCl...3mg Cyanocobalamin...60mcg D-Panthenol...25mg Nicotinamide...50mg Folic Acid...150mg Biotin...125mg **Amino Acids...12mg** Water for Injection...1ml
	Finished Product Specification	Inhouse specifications
	Pharmacological Group	Vitamin supplements
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Original embassy attested CoPP No. 2021042910 certified by Agriculture office of Shijiazhuang High-tech zone Huanghe Road No. 151, China confirming the free sale status in exporting country as well as GMP status of the manufacturer Vaidity: 28-04-2026

		➢ Photocopy of agency agreement dated 06-05-2021 between PLH and the applicant; valid for 5 years
	Remarks of the Evaluator [XXV]	The firm has provided 06-month accelerated and 36-month real time stability studies data as per zone-IV-A conditions. **Shortcomings:** • copy of valid DSL • notarized original valid Letter of Authorization/ Sole agency certificate since already submitted is copy • 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. • Specify which amino acids are included in the formulation and accordingly, provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision of 330th meeting: Deferred for submission of following: • copy of valid DSL • notarized original valid Letter of Authorization/ Sole agency certificate. • label in accordance with The Drugs (Labeling and Packing) Rules, 1986 • Specify which amino acids are included in the formulation and accordingly, provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm	
	Updated status: The firm has submitted the following • copy of DSL **valid till 12-07-2028** • scanned copy of agency agreement dated 06-05-2021 between PLH and the applicant; valid for 5 years • label in accordance with The Drugs (Labeling and Packing) Rules, 1986 • **Me-too/ generic status**: Multivitamin Solution for Injection of M/s Chakwal Pharma International, Lahore (Reg. No. 103799) • Applied formulation: Each ml contains: Vitamin A, Retinol Palmitate…15,000 IU Vitamin D3, Cholecalciferol...7500 IU Vitamin E, Tocopherol Acetate...20mg Thiamine HCl...10mg Riboflavine Sodium Phosphate...5mg Pyridoxine HCl...3mg Cyanocobalamin...60mcg D-Panthenol...25mg Nicotinamide...50mg Folic Acid...150mg Biotin...125mg **Methionine...6mg** **Lysine.....6mg** **Remarks of the evaluator:** The submitted reference to the generic product is of different strength than the applied formulation **Shortcomings:** 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 submission of evidence of approval of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or in any RRA.	
655.	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 32615 Dated 08-12-2020
	Fee including differential fee	Rs : 1,00,000 Dated 08-12-2020
	Brand Name +Dosage Form + Strength	Permethrin Pharma Insecticide Shampoo
	Composition	Each 100ml contains: Permethrin…1g
	Finished Product Specification	Inhouse
	Pharmacological Group	Pyrethrines
	Shelf life	2 Years
	Demanded Price	Decontrolled
	Pack size	100ml, 250ml
	International availability	N/A
	Me-too status	Could not be confirmed
	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 [XXV]	6 months accelerated and 24 months long term stability studies data has been submitted as per zone-IV-A conditions. **Shortcomings:** • Provide valid copy of DSL • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.
	Decision of 326th meeting: Deferred for following: • valid copy of DSL • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Label in accordance with The Drugs (Labeling and Packing) Rules, 1986	
	Updated status: The firm has submitted the following: • copy of DSL valid till **07-11-2027** • Label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Link for verification of approval status of Permethrin Pharma in EU; **authorized in Bulgaria** (https://medicines.health.europa.eu/veterinary/en/search-medicines?keys=permethrin)	
	Decision of 336th meeting: Deferred for availability of the said formulation in three EU countries, any reference country or PICs member country or ML-4 country.	

	Updated status: The firm has submitted the reference of Lyclear Crème Rinse 1% w/w cutaneous solution for hair application, registered in **Ireland**. Our formulation is also a cutaneous solution used as shampoo for dogs for removing/ killing lice from their hair. **Remarks/shortcomings:** The reference formulation approved in Ireland is for human use.	
	Decision: Deferred for submission of evidence of approval of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or in any RRA.	
656.	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: 22-10-2024. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Univet Ltd., Tullyvin, Cootehil, County Cavan, H16 T 183, Ireland
	Name and address of marketing authorization holder	M/s Univet Ltd., Tullyvin, Cootehil, County Cavan, H16 T 183, Ireland
	Name of exporting country	Ireland
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 18907 Dated 27-07-2023
	Fee including differential fee	Rs: 150,000 Dated 20-06-2023 (slip N0. 4693817453)
	Brand Name +Dosage Form + Strength	Terrixine DC 250mg Intramammary Suspension For Dry Cows
	Composition	Each Unit contains: Cefalonium dihydrate as Cefalonium Base…250mg
	Finished Product Specification	Eur. Ph. specifications
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	3gm
	International availability	Terrixine DC 250mg Intramammary Suspension For Dry Cows (**Ireland approved**)
	Me-too status	Not registered with DRAP
	Detail of certificates attached	➢ Scanned copy of legalized COPP dated 15-05-2023 certified by HPRA Ireland confirms GMP status of the manufacturer and free sale status of the applied product in country of origin. ➢ Scanned copy of legalized GMP certificate No. 29062/V10864 dated 01.02.2021 certified by HPRA Ireland having the scope of Beta lactam production lines. ➢ Letter of authorization/ distribution agreement **Not Provided**
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated and 24-month real time stability studies data of three batches at zone IV-A conditions. **Shortcomings:** • Provide valid notarized original letter of authorization (LOA)/ distribution agreement. • 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. • Confirmation whether cephalosporin and penicillin containing products are manufactured in segregated

		facilities or otherwise.
	Decision of 339th meeting: Deferred for submission of following: □□valid notarized original letter of authorization (LOA)/ distribution agreement. □□label in accordance with The Drugs (Labeling and Packing) Rules, 1986. □□Confirmation whether cephalosporin and penicillin containing products are manufactured in segregated facilities or otherwise.	
	Updated status: The firm has submitted the following: • Notarized original letter of authorization (LOA)/ distribution agreement valid till 10-09-2029 • label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Declaration that **cephalosporin and penicillin containing products are manufactured in the same facility,** but we solely manufacture veterinary medicinal products, so there is no requirement to have segregated facilities. we follow the principles outlined in the FDA guidance (manufacturing considerations for penicillin or cephalosporin animal drugs/ FDA). Univet **have validated cleaning procedures set up to prevent cross-contamination**. The firm has also informed about typographical error in brand name, the correct brand name is **Terrexine**	
	Decision: Deferred till decision of DRAP Authority regarding manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise.	
657.	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: 22-10-2024. Status: Drug License by way of Wholesale (Form No.7).
	Name and address of manufacturer	M/s Univet Ltd., Tullyvin, Cootehil, County Cavan, H16 T 183, Ireland
	Name and address of marketing authorization holder	M/s Univet Ltd., Tullyvin, Cootehil, County Cavan, H16 T 183, Ireland
	Name of exporting country	Ireland
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 18908 Dated 27-07-2023
	Fee including differential fee	Rs: 150,000 Dated 20-06-2023 (slip N0. 6264313062)
	Brand Name +Dosage Form + Strength	Terrixine LC 250mg Intramammary Suspension For Lactating Cows
	Composition	Each gram contains: Cephalexin Monohydrate…20mg Kanamycin Sulphate…13.33mg
	Finished Product Specification	Eur. Ph. specifications
	Pharmacological Group	Antibiotic
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	10gm
	International availability	Terrixine LC 250mg Intramammary Suspension for Lactating Cows (**Ireland approved**) Cephalexin Monohydrate…200mg/syringe Kanamycin Sulphate…100,000IU / syringe
	Me-too status	**Terrexine Intramammary Suspension of M/s Orient Animal Health (Pvt) Ltd., Karachi (Reg. No. 048128)**
	Detail of certificates attached	➢ Scanned copy of legalized COPP dated 15-05-2023 certified by HPRA Ireland confirms GMP status of the manufacturer and free sale status of the applied product in country of origin. ➢ Scanned copy of legalized GMP certificate No. 29062/V10864 dated 01.02.2021 certified by HPRA

		Ireland having the scope of Beta lactam production lines. ➢ Letter of authorization/ distribution agreement **Not Provided**
	Remarks of the Evaluator [XXV]	Firm has provided 06-month accelerated and 24-month real time stability studies data of three batches at zone IV-A conditions. **Shortcomings:** • Provide valid notarized original letter of authorization (LOA)/ distribution agreement. • 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. • Confirmation whether cephalosporin and penicillin containing products are manufactured in segregated facilities or otherwise. • Provide conversion of Kanamycin sulphate from IU to grams.
	Decision of 339th meeting: Deferred for submission of following: • valid notarized original letter of authorization (LOA)/ distribution agreement. • label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Confirmation whether cephalosporin and penicillin containing products are manufactured in segregated facilities or otherwise. • conversion of Kanamycin sulphate from IU to grams.	
	Updated status: The firm has submitted the following: • Notarized original letter of authorization (LOA)/ distribution agreement valid till 10-09-2029 • label in accordance with The Drugs (Labeling and Packing) Rules, 1986. • Declaration that **cephalosporin and penicillin containing products are manufactured in the same facility,** but we solely manufacture veterinary medicinal products, so there is no requirement to have segregated facilities. we follow the principles outlined in the FDA guidance (manufacturing considerations for penicillin or cephalosporin animal drugs/ FDA). Univet **have validated cleaning procedures set up to prevent cross-contamination**. • conversion of Kanamycin sulphate (100000 IU = 133mg) The firm has also informed about typographical error in brand name, the correct brand name is **Terrexine**	
	Decision: Deferred till decision of DRAP Authority regarding manufacturing facility, whether Cephalosporin & Penicillin formulations are manufactured in same section or otherwise.	
658.	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 Lifecome Biochemistry Co., Ltd. No.19, Nanpu Ecological Indsutrial Park, Pucheng, Fujian, P.R.China
	Name and address of marketing authorization holder	M/s Lifecome Biochemistry Co., Ltd. No.19, Nanpu Ecological Indsutrial Park, Pucheng, Fujian, P.R.China
	Name of exporting country	China
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 24962 Dated 24-09-2020
	Fee including differential fee	**Rs : 50,000** Dated 23-09-2020
	Brand Name +Dosage Form + Strength	Flavopak 80 Premix
	Composition	Each Kg contains: Bambermycin…80gm

	Finished Product Specification	Inhouse
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	25Kg
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	➢ Original Legalized Free Sale Certificate No. 201100B0/022161 issued by Animal Husbandry Bureau of Zhumadian City, Henan Province China Date of issuance: 31-03-2020 ➢ Original Legalized GMP Certificate No. (2019) GMP13004 issued by Fujian Province Department of Agriculture and Rural Affairs Date of issuance: 02-09-2020 Validity: 01-09-2024 ➢ Original Legalized Power of Attorney dated 31-03-2020 for the applied product
	Remarks of the Evaluator [XXV]	**Shortcomings:** • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved 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. • Differential fee Rs. 50,000/- for registration of generic drug product. • Provide long term stability studies data as per zone-IV-A conditions upto the claimed shelf life.

Decision of 326th meeting: Deferred for following:

- Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved 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.
- Differential fee Rs. 50,000/- for registration of generic drug product.
- Long term stability studies data as per zone-IV-A conditions upto the claimed shelf life.

Updated status: The firm has submitted the following:

Sr. No.	Observation	Firm's response
i	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	Flavomycin 80 has been **approved by EU** under authorization number 0022-2444 with date of authorization status 12/06/2023. **Authorized in Bulgaria** Reference: https://medicines.health.europa.eu/veterinary/en/600000098550 accessed dated 31-05-2024
ii	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	Not registered in DRAP

		iii	Differential fee Rs. 50,000/- for registration of generic drug product.	N/A
		iv	Long term stability studies data as per zone-IV-A conditions upto the claimed shelf life.	Submitted
	Decision of 336th meeting: Deferred for availability of the said formulation in three EU countries, any reference country or PICs member country or ML-4 country.			
	Updated status: The firm has submitted the following: • reference of approval in EU with authorization No. 0022-2444 is for authorization **only in Bulgaria**. • reference of Australian Pesticides and Veterinary Medicines Authority (APVMA) approval is of Public Chemical Registration Information System (APVMA PubCRIS**),** only for active constituent. • The reference of approval in USFDA Flavomycin 4 is of different strength **(8.8gm per kg**) than the applied formulation.			
	Decision: Deferred for submission of evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.			
659.	Name and address of Applicant		M/s Tarobina Corporation, 226-Ahmad Block, New Garden Town, Lahore, Pakistan	
	Detail of Drug Sale License		Name: M/s Tarobina Corporation, Address: 226-Ahmad Block, New Garden Town, Lahore, Pakistan **Validity: 15-03-2028.** Status: License to sell drugs as a Distributor (Form No.11).	
	Name and address of manufacturer		M/s Alke Saglik Urunleri San.Tic.A.S. Merkez Organize Sanayi Bolgesic2. Kisim 10. Cadde No:7 Tokat Turkey	
	Name and address of marketing authorization holder		M/s Alke Saglik Urunleri San.Tic.A.S. Sahrayicedid Mah. Batman Sok, Royal Plaza No: 18/6 Kadikoy-Istanbul-Turkey	
	Name of exporting country		Turkey	
	Type of Form		Form-5A	
	Diary No. & Date of R& I		Dy.No 17947 Dated 28-06-2021	
	Fee including differential fee		Rs.150,000/- Dated 22-06-2021	
	Brand Name +Dosage Form + Strength		Neozid Powder for Oral Solution	
	Composition		Each gram contains: Neomycin as Sulphate…500mg	
	Finished Product Specification		Inhouse	
	Pharmacological Group		Antibacterial	
	Shelf life		72 months	
	Demanded Price		Decontrolled	
	Pack size		1000gm	
	International availability		N/A	
	Me-too status		**Could not be confirmed**	
	Detail of certificates attached		▪ Originally legalized COPP No. 22.03.2002-11/1023 dated 07-12-2020 issued by General directorate of Food and Control, Ministry of Agriculture and Forestry Republic of Turkey confirms free sale status of the product in exporting country and GMP status of the manufacturing site. **Validity: 21-03-2022** ▪ Scanned copy of legalized GMP certificate No. GMP/TR/V/Yi/S0149/2019 dated 21-05-2019 (**Original in Fenerol 30% oral solution)** issued by General directorate	

		of Food and Control, Ministry of Food, Agriculture and Livestock Republic of Turkey. **Validity: 14-02-2022** ▪ Copy of legalized distribution agreement (**Original in Fenerol 30% oral solution)** dated 28-09-2020 between the MAH and the applicant. ➢ **Validity: 5 years**
	Remarks of the Evaluator [XXV]	Provided 06-month accelerated and **48-month** real time stability studies data of three batches as per zone IV-A conditions. **Shortcomings:** ➢ Provide original legalized valid CoPP and GMP certificate since the already submitted are **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 real time stability studies data of three batches as per zone IV-A conditions **upto claimed shelf life.**
	Decision of 330th meeting: Deferred for following: • original legalized valid COPP and relevant GMP certificate • evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • real time stability studies data of three batches as per zone IV-A 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.	
	Updated status: The firm has submitted the following: • Scanned copies of CoPP confirming free sale status in country of origin and GMP certificate. • The firm has agreed with 48 months shelf life of the applied product. **Shortcomings:** • evidence of applied formulation/drug already approved by DRAP (generic / me-too status), **in the applied strength**, alongwith registration number, brand name and name of firm.	
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status), in the applied strength, alongwith registration number, brand name and name of firm.	
660.	Name and address of Applicant	M/s Tarobina Corporation, 226-Ahmad Block, New Garden Town, Lahore, Pakistan
	Detail of Drug Sale License	Name: M/s Tarobina Corporation, Address: 226-Ahmad Block, New Garden Town, Lahore, Pakistan **Validity: 15-03-2028.** Status: License to sell drugs as a Distributor (Form No.11).
	Name and address of manufacturer	M/s Alke Saglik Urunleri San.Tic.A.S. Merkez Organize Sanayi Bolgesic2. Kisim 10. Cadde No:7 Tokat Turkey
	Name and address of marketing authorization holder	M/s Alke Saglik Urunleri San.Tic.A.S. Sahrayicedid Mah. Batman Sok, Royal Plaza No: 18/6 Kadikoy-Istanbul-Turkey
	Name of exporting country	Turkey
	Type of Form	Form-5A
	Diary No. & Date of R& I	Dy.No 17937 Dated 28-06-2021
	Fee including differential fee	Rs.150,000/- Dated 22-06-2021
	Brand Name +Dosage Form + Strength	Fenerol 30% Oral Solution
	Composition	Each ml Contains: Florfenicol…300mg
	Finished Product Specification	Inhouse
	Pharmacological Group	Antibacterial

	Shelf life	24 months
	Demanded Price	Decontrolled
	Pack size	1000ml
	International availability	N/A
	Me-too status	**Could not be confirmed**
	Detail of certificates attached	▪ Originally legalized COPP No. 13.04.2009-21/019 dated 24-11-2020 issued by General directorate of Food and Control, Ministry of Agriculture and Forestry Republic of Turkey confirms free sale status of the product in exporting country and GMP status of the manufacturing site. **Validity: 12-04-2024** ▪ Original legalized GMP certificate No. GMP/TR/V/Yi/S0149/2019 dated 21-05-2019 issued by General directorate of Food and Control, Ministry of Food, Agriculture and Livestock Republic of Turkey. **Validity: 14-02-2022** ▪ Original legalized distribution agreement dated 28-09-2020 between the MAH and the applicant. ➢ **Validity: 5 years**
	Remarks of the Evaluator [XXV]	Provided 06months accelerated and 24months real time stability studies data of three batches as per zone IV-A conditions. **Shortcomings:** ➢ 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.
	Decision of 330th meeting: Deferred for following: • original legalized valid GMP certificate • 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.	
	Updated status: The firm has submitted the following: • Scanned copy of GMP certificate. **Shortcomings:** • evidence of applied formulation/drug already approved by DRAP (generic / me-too status), **in the applied strength**, alongwith registration number, brand name and name of firm.	
	Decision: Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status), in the applied strength, alongwith registration number, brand name and name of firm.	

Agenda of Ms. Saima Hussain

Routine Cases of Form 5-F

661.	Name, address of Applicant / Marketing Authorization Holder	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 21698 dated 01-09-2023

	Details of fee submitted	Rs.30,000/- vide slip no. 3070852160 dated 04-08-2023
	The proposed proprietary name / brand name	Tacrowin 0.1% Ointment
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gm contains: Tacrolimus (as Monohydrate) ……1mg (0.1%w/w)
	Pharmacotherapeutic Group of (API)	L04AD02, Antineoplastic and Immuno-modulating Agents, Calcineurin inhibitors.
	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	MHRA Approved (Tacrolimus Monohydrate 0.1% Ointment)
	For generic drugs (me-too status)	Aimus Ointment of M/s. Aims Pharmaceuticals (Reg.no. 069939)

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	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 drug product manufacturer.
2.	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".*
3.	3.2.S.7	Submit readable copy of stability datasheet of drug substance.
4.	3.2.P.2	Justify for using water in the applied formulation of ointment since the innovator/reference product has not been used water in their formulation.
5.	3.2.P.2.2.1	Justify for not including the microbiological analysis and pH test while performing the pharmaceutical equivalence against the comparator product.
6.	3.2.P.5.1	Justify for not including the microbiological analysis and content uniformity test in the specification of drug product.
7.	3.2.P.5.3	Assay method given in section 3.2.P.5.2 is different from the assay method on which verification has been performed ,clarification is required in this regard.
8.	3.2.P.5.4	Justify for not performing content uniformity and pH determination test while the batch analysis of finished product.
9.	3.2.P.6	Submit COA of reference standard actually used in the analysis of drug product in section 3.2.P.5.4.
10.	3.2.P.8	• Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired. • Justify for not performing microbiological analysis, content uniformity and pH determination test while conducting the stability study of drug product.
11.	3.2.R.1.1	Provide Batch Manufacturing Record (BMR) of all stability batches.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

662.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 22429 dated 12-09-2023
	Details of fee submitted	Rs.30,000/- vide slip no.969213934 dated 02-09-2023
	The proposed proprietary name / brand name	Esobrain 20mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Enteric Coated Tablet contains: Esomeprazole as Magnesium Trihydrate….20mg
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Reference to Finished product specifications	Innovator's specification (Firm claimed Innovator's spec. while the drug product monograph is available in BP)
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved (Esomeprazole (as Esomeprazole Magnesium Trihydrate) Gastro Resistant 20mg and 40mg Tablet)
	For generic drugs (me-too status)	Ulcez Tablet 20mg of M/s. Epla (REg.no. 076084)

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	1.5.6	You have mentioned innovator's specification in section 1.5.6 in module 1 while the drug product monograph is available in BP. Revise the specifications along with submission of requisite fee.
2.	3.2.S.2	According to the submitted drug substance part, you have imported Esomeprazole Magnesium, so, provide evidence of reference product in which Esomeprazole Magnesium is used in the formulation of tablet, since the innovator product used Esomeprazole Magnesium Trihydrate in the NEXIUM 24HR Delayed Release Tablet.
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 drug product manufacturer.
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".*
5.	3.2.S.4.4	Justify for not performing the test of crystallinity and color of solution while the batch analysis of drug substance by drug product manufacturer, since these tests are recommended by USP.
6.	3.2.P.5.2	As per the BP monograph of "*Esomeprazole Gastro Resistant Tablet",* the dissolution of applied formulation is performed in two stages i.e. first stage of dissolution is performed at pH 4.5 and the final stage has to be performed at pH 6.8, while the dissolution method given by you in relevant section is not in accordance with BP monograph, so clarification is required in this regard.
7.	3.2.P.5.3	Justify for using esomeprazole magnesium as reference standard while verification studies of drug product and stability studies of drug product when the pharmacopeial monograph recommends omeprazole reference standard in the assay of esomeprazole gastro resistant tablet.

8.	3.2.P.8	Dissolution method outlined in section 3.2.P.5.2 revealed that the test will be performed on HPLC, while the raw data sheets of stability studies indicate that the dissolution test was performed on UV instrument, clarify the ambiguity regarding the instrument/technique which has been actually used for dissolution testing of drug product.
9.	3.2.R.1.1	Provide Batch Manufacturing Record (BMR) of all stability batches.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

663.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 22436 dated 12-09-2023
	Details of fee submitted	Rs.30,000/- vide slip no.66229400 dated 02-09-2023
	The proposed proprietary name / brand name	Esobrain 40mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Enteric Coated Tablet contains: Esomeprazole as Magnesium Trihydrate….40mg
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Reference to Finished product specifications	Innovator's specification (Firm claimed Innovator's spec. while the drug product monograph is available in BP)
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA Approved (Esomeprazole (as Esomeprazole Magnesium Trihydrate) Gastro Resistant 20mg and 40mg Tablet)
	For generic drugs (me-too status)	Ulcez Tablet 40mg of M/s. Epla (REg.no. 076085)

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	1.5.6	You have mentioned innovator's specification in section 1.5.6 in module 1 while the drug product monograph is available in BP. Revise the specifications along with submission of requisite fee.
2.	3.2.S.2	According to the submitted drug substance part, you have imported Esomeprazole Magnesium, so, provide evidence of reference product in which Esomeprazole Magnesium is used in the formulation of tablet, since the innovator product used Esomeprazole Magnesium Trihydrate in the NEXIUM 24HR Delayed Release Tablet.
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 drug product manufacturer.
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".*

5.	3.2.S.4.4	Justify for not performing the test of crystallinity and color of solution while the batch analysis of drug substance by drug product manufacturer, since these tests are recommended by USP.
6.	3.2.P.5.2	As per the BP monograph of "*Esomeprazole Gastro Resistant Tablet",* the dissolution of applied formulation is performed in two stages i.e. first stage of dissolution is performed at pH 4.5 and the final stage has to be performed at pH 6.8, while the dissolution method given by you in relevant section is not in accordance with BP monograph, so clarification is required in this regard.
7.	3.2.P.5.3	Justify for using esomeprazole magnesium as reference standard while verification studies of drug product and stability studies of drug product when the pharmacopeial monograph recommends omeprazole reference standard in the assay of esomeprazole gastro resistant tablet.
8.	3.2.P.8	Dissolution method outlined in section 3.2.P.5.2 revealed that the test will be performed on HPLC, while the raw data sheets of stability studies indicate that the dissolution test was performed on UV instrument, clarify the ambiguity regarding the instrument/technique which has been actually used for dissolution testing of drug product.
9.	3.2.R.1.1	Provide Batch Manufacturing Record (BMR) of all stability batches.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

664.	Name, address of Applicant / Marketing Authorization Holder	M/s Sami Pharmaceuticals Pvt Limited. F-95, S.I.T.E, Karachi, Pakistan
	Name, address of Manufacturing site.	M/s Sami Pharmaceuticals Pvt Limited. F-95, S.I.T.E, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 22480 dated 13-09-2023
	Details of fee submitted	Rs.30,000/- vide slip no.66229400 dated 02-09-2023
	The proposed proprietary name / brand name	NovoTEpH DR (Esomeprazole)10mg Sachet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet contains: Enteric coated granules of Esomeprazole Magnesium Trihydrate eq. to Esomeprazole….10mg
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	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	USFDA Approved (Nexium gastro resistant granules for oral suspension packaging in triplex laminated Sachet foil with secondary packaging of unit carton.
	For generic drugs (me-too status)	M/s. Winthrox Laboratories product Esowin Sachet (Reg.no. 086891)

Evaluation by PEC-XV:

S.no.	Observations/Deficiencies/ Short-comings	Reply of Firm
1.	Please clarify regarding the address of manufacturing site of esomeprazole pellets, since the address of manufacturing site of both pellets and Finished product is same.	Firm clarified that same plant F-95 is used for manufacturing of both API and finish product i.e. Esomeprazole pellets and NovoTEpH DR Sachet because we have both DML for F-95 plant i.e. DML on basis of formulations and DML for semi-basic manufacturing.

2.	Justify for not including the dissolution test performed at acid resistant stage in the specification of drug substance.	Firm replied that we derived the specification of applied product from the USP Monograph for esomeprazole magnesium delayed release capsules (Test-1), in which the USP recommends testing the pellets in an acidic medium without requiring quantification of the release. Accordingly, we apply the same procedure to the sachet.
3.	Please provide the analytical method verification report and batch analysis report of drug substance performed by the drug product manufacturer at the manufacturing site of finished product.	Firm submitted the analytical method verification report and batch analysis report of drug substance performed by the drug product manufacturer at the manufacturing site of finished product.

Decision: Approved.

665.	Name, address of Applicant / Marketing Authorization Holder	M/s Relizon Pharmaceuticals. Plot no.118 Sunder Industrial Area, Raiwind Road, Lahore
	Name, address of Manufacturing site.	M/s Relizon Pharmaceuticals. Plot no.118 Sunder Industrial Area, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 22825 dated 18-09-2023
	Details of fee submitted	Rs.30,000/- vide slip no. 1003575822 dated 24-07-2023
	The proposed proprietary name / brand name	Osevir Oral Dry Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml of suspension contains: Oseltamivir Phosphate …..6mg
	Pharmacotherapeutic Group of (API)	Neuraminidase Inhibitor
	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	USFDA Approved (Tamiflu 6mg/ml oral dry suspension).
	For generic drugs (me-too status)	M/s. Brookes Pharmaceuticals product Osemvir Powder for dry Suspension (Reg.no. 042290)

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	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 drug product manufacturer.
2.	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".*
3.	3.2.S.7	Submit stability data of drug substance till the claimed re-test, since you have only submitted the data of three months.
4.	3.2.P.2	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.

5.	3.2.P.2.2.1	• Justify the label claim of applied product mentioned on the pharmaceutical equivalence report i.e. Osevir 250mg/5ml, while the label claim of comparator product is Osemvir 6mg/ml dry suspension. • Justify for not including the test of deliverable volume and pH test while performing the pharmaceutical equivalence of oral suspension dosage form against the reference product.
6.	3.2.P.5.2	Provide detailed method of sample solution preparation for assay testing of the drug product in section 3.2.P.5.2 specifying the exact volume of water in which reconstitution is carried out.
7.	3.2.P.5.4	Submit Batch analysis report of all three trail batches of drug product.
8.	3.2.P.6	Submit COA of reference standard actually used in the analysis of drug product in section 3.2.P.5.4.
9.	3.2.P.8	• Submit data in section 3.2.P.8.1 as per the guidance document approved by Registration Board which specifies that "Summary of additional stability studies (if applicable) e.g. in-use studies for drug products which are to be reconstituted before use, along with proposed in-use storage statement and in-use shelf-life shall be provided". • Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.
10.	3.2.R.1.1	Provide Batch Manufacturing Record (BMR) of all stability batches.
11.	Provide details of volume of diluent taken for reconstitution of oral suspension in the relevant section.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

666.	Name, address of Applicant / Marketing Authorization Holder	M/s Hisun Pharmaceutical Industries.Plot No. 37-A, R-2, Industrial Estate Gadoon, Sawabi, Kpk, Pakistan
	Name, address of Manufacturing site.	M/s Hisun Pharmaceutical Industries.Plot No. 37-A, R-2, Industrial Estate Gadoon, Sawabi, Kpk, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 22824 dated 18-09-2023
	Details of fee submitted	Rs.30,000/- vide slip no. 82277837919 dated 23-01-2023
	The proposed proprietary name / brand name	Tramsun 50mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet contains: Tramadol HCl……50mg
	Pharmacotherapeutic Group of (API)	Analgesic (ATC code: N02AX02)
	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 (Tramadol hydrochloride 50mg tablet)
	For generic drugs (me-too status)	M/s. Sami Pharma of product Tonoflex Tablet 50mg

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	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 both drug substance manufacturer and drug product manufacturer.
2.	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".*
3.	3.2.S.7	• Submit stability data of drug substance performed at long term condition till the claimed re-test, since you have only submitted the data of six months. • Clarification is required for not performing all the test recommended by USP Monograph while conducting the stability studies of drug substance. Furthermore, USP recommend water determination test for the drug substance while the drug substance manufacturer performed "Loss on drying test" during the stability studies of drug substance.
4.	3.2.P.2.2.1	Justify for not performing the content uniformity test as recommended by USP Monograph of Tramadol HCl Tablet while establishing the pharmaceutical equivalence of applied product against the comparator product.
5.	3.2.P.5.1	Justify for not adopting the same acceptance criteria for dissolution test as recommended by the USP Monograph of Tramadol Tablet.
6.	3.2.P.5.2	Analytical procedure given in section 3.2.P.5.2 is different from the testing methods recommended by the USP,justify how the applied product complied USP specifications.
7.	3.2.P.5.4	Submit Batch analysis report of all three trail batches of drug product.
8.	3.2.P.6	Submit COA of reference standard actually used in the analysis of drug product in section 3.2.P.5.4.
9.	3.2.P.8	• According to the stability data sheets, all three trial batches were manufactured in October 2022. In contrast, the submitted chromatogram indicates that the assay was performed in April 2022, which is earlier than the manufacturing date. Clarify the discrepancy observed in the dates. • Justify for not adopting the same acceptance criteria for dissolution test as recommended by the USP Monograph of Tramadol Tablet. • Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired.
10.	3.2.R.1.1	Provide Batch Manufacturing Record (BMR) of all stability batches.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

667.	Name, address of Applicant / Marketing Authorization Holder	M/s Platinum Pharmaceuticals Pvt. Ltd. A-20, North western Industrial Zone, Bin Qasim Karachi.
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals Pvt. Ltd. A-20, North western Industrial Zone, Bin Qasim Karachi.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 22954 dated 19-09-2023
	Details of fee submitted	Rs.30,000/- vide slip no. 1830373208 dated 22-08-2023
	The proposed proprietary name / brand name	Tofacitinib 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: 10 mg tofacitinib (equivalent to 16.16 mg tofacitinib citrate)
	Pharmacotherapeutic Group of (API)	Janus Kinase (JAK) Inhibitor
	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	USFDA Approved (Xeljanz 5mg and 10mg Tablet)
	For generic drugs (me-too status)	Tofajak 10mg Tablet of M/s. Hiranis Pharma (Reg.no. 117960)

Evaluation by PEC-XV:

S.no.	Observations/Deficiencies/ Short-comings	Reply of the Firm
1.	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.	Firm submitted drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.
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".*	Firm submit the analytical method verification report of drug substance performed by drug product manufacturer.
3.	Submit stability data of drug substance till the claimed re-test date since you have submitted only 6 month data of long term stability studies.	Firm submit the stability data of drug substance till claimed re-test date.
4.	Justify for not keeping the dissolution conditions in accordance with innovator product as evident from the procedure given in the CDP protocol.	Firm replied that they follow USFDA dissolution database for setting the dissolution conditions and acceptance criteria. However, they also update the dissolution limit in accordance with innovator product and accordingly submit the performance report of 22nd month time point of stability study.
5.	Justify for not adopting the dissolution acceptance criteria and dissolution conditions in accordance with the innovator product approved in USFDA.Further, Please specify the reference of acceptance criteria of dissolution test.	Firm replied that they follow USFDA dissolution database for setting the dissolution conditions and acceptance criteria. However, they also update the dissolution limit in accordance with innovator product and accordingly submit the performance report of 22nd month time point of stability study.
6.	Submit documents for the procurement of API including copy of commercial invoice attested	Firm submitted the requisite documents.

	by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	
7.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired.	Firm submitted the GMP certificate of API manufacturer.
8.	Provide Batch Manufacturing Record (BMR) of all stability batches.	Submitted.

Decision: Approved. Manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of this drug.

668.	Name, address of Applicant / Marketing Authorization Holder	M/s Platinum Pharmaceuticals Pvt Ltd. A-20, North western Industrial Zone, Bin Qasim Karachi
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals Pvt Ltd. A-20, North western Industrial Zone, Bin Qasim Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 22953 dated 19-09-2023
	Details of fee submitted	Rs.30,000/- dated 22-08-2023
	The proposed proprietary name / brand name	Tofacitinib 5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: 5 mg tofacitinib (equivalent to 8.08 mg tofacitinib citrate)
	Pharmacotherapeutic Group of (API)	Janus Kinase (JAK) Inhibitor
	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	USFDA Approved (Xeljanz 5mg and 10mg Tablet)
	For generic drugs (me-too status)	Tofajak 5mg Tablet of M/s. Hiranis Pharma (Reg.no. 110057)

Evaluation by PEC-XV:

S.no.	Observations/Deficiencies/ Short-comings	Reply of the Firm
1.	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.	Firm submitted drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.
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*	Firm submit the analytical method verification report of drug substance performed by drug product manufacturer.

	well as non-compendial drug substance(s) shall be submitted".	
3.	Submit stability data of drug substance till the claimed re-test date since you have submitted only 6 month data of long term stability studies.	Firm submit the stability data of drug substance till claimed re-test date.
4.	Justify for not keeping the dissolution conditions in accordance with innovator product as evident from the procedure given in the CDP protocol.	Firm replied that they follow USFDA dissolution database for setting the dissolution conditions and acceptance criteria. However, they also update the dissolution limit in accordance with innovator product and accordingly submit the performance report of 22nd month time point of stability study.
5.	Justify for not adopting the dissolution acceptance criteria and dissolution conditions in accordance with the innovator product approved in USFDA.Further, Please specify the reference of acceptance criteria of dissolution test.	Firm replied that they follow USFDA dissolution database for setting the dissolution conditions and acceptance criteria. However, they also update the dissolution limit in accordance with innovator product and accordingly submit the performance report of 22nd month time point of stability study.
6.	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Firm submitted the requisite documents.
7.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired.	Firm submitted the GMP certificate of API manufacturer.
8.	Provide Batch Manufacturing Record (BMR) of all stability batches.	Submitted.

Decision: Approved.

669.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 23615 dated 25-09-2023
	Details of fee submitted	Rs.30,000/- vide slip no. 01059753 dated 08-09-2023
	The proposed proprietary name / brand name	Artec 50mg/200mcg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Modified Release Tablet Contains: Diclofenac Sodium…50mg (Enteric coated core) Misoprostol…200mcg (Immediate release core)
	Pharmacotherapeutic Group of (API)	NSAIDs/Prostaglandin analogue
	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 (ARTHROTEC 50MG;0.2MG/ 75MG;0.2MG)
	For generic drugs (me-too status)	Rotec 50mg/200mcg Tablet of M/s. Searle Pakistan

Evaluation by PEC-XV:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Provide raw data sheets and chromatograms of analytical method verification report as the submitted report did not specify the assay procedures.	Firm submitted the raw data sheets and chromatograms of analytical method verification report.
2.	The comparative dissolution profile report of the drug product shows that more than 90% of the drug is released within 30 minutes in a pH 6.8 medium, while the USP monograph for the product specifies an acceptance limit of not less than 75% (Q) within 45 minutes. Please justify the release behavior of the product in pH 6.8 in comparison to the acceptance limits outlined in the USP monograph.	Firm claimed that the release behavior of applied product at pH 6.8 is within acceptance limit recommended by USP i.e. NLT 75%(Q) within 45minutes.
3.	• According to the Clearance certificate of misoprostol and Approval of loan letter, the material which has been imported was Misoprostol while the API used in the formulation is Misoprostol 1% HPMC Dispersion, clarification is required in this regard. • Provide Reference of previous approval of applications with stability study data of the firm (if any). • Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Submit valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	Firm submitted all the supporting documents which has been required along with stability data.

Decision: Approved.

670.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 23616 dated 25-09-2023
	Details of fee submitted	Rs.30,000/- vide slip no. 8244128496 dated 08-09-2023
	The proposed proprietary name / brand name	Artec 75mg/200mcg Tablet

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Modified Release Tablet Contains: Diclofenac Sodium…75mg (Enteric coated core) Misoprostol…200mcg (Immediate release core)
	Pharmacotherapeutic Group of (API)	NSAIDs/Prostaglandin analogue
	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 (ARTHROTEC 50MG;0.2MG/ 75MG;0.2MG)
	For generic drugs (me-too status)	Rotec 75mg/200mcg Tablet of M/s. Searle Pakistan

Evaluation by PEC-XV:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Provide raw data sheets and chromatograms of analytical method verification report as the submitted report did not specify the assay procedures.	Firm submitted the raw data sheets and chromatograms of analytical method verification report.
2.	The comparative dissolution profile report of the drug product shows that more than 90% of the drug is released within 30 minutes in a pH 6.8 medium, while the USP monograph for the product specifies an acceptance limit of not less than 75% (Q) within 45 minutes. Please justify the release behavior of the product in pH 6.8 in comparison to the acceptance limits outlined in the USP monograph.	Firm claimed that the release behavior of applied product at pH 6.8 is within acceptance limit recommended by USP i.e. NLT 75%(Q) within 45minutes.
3.	• According to the Clearance certificate of misoprostol and Approval of loan letter, the material which has been imported was Misoprostol while the API used in the formulation is Misoprostol 1% HPMC Dispersion, clarification is required in this regard. • Provide Reference of previous approval of applications with stability study data of the firm (if any). • Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Submit valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.	Firm submitted all the supporting documents which has been required along with stability data.

Decision: Approved.

671.	Name, address of Applicant / Marketing Authorization Holder	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 23747 dated 26-09-2023
	Details of fee submitted	Rs.75,000/- vide slip no. 525639990 dated 07-09-2023
	The proposed proprietary name / brand name	Cefta 400mg Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftaroline Fosamil as Acetic acid Solvate Monohydrate ….400mg
	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use
	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	USFDA Approved
	For generic drugs (me-too status)	NA

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.1	• As per the review literature, the salt form of the drug substance in the innovator brand is ceftaroline fosamil acetic acid solvate monohydrate. However, the drug substance in the applied product is ceftaroline fosamil, according to the information provided in the substance section. A justification is needed for the use of a chemically different API compared to the innovator product. • Further, neither the physicochemical characteristics nor the CAS no. and molecular formula of API is similar to the API used by innovator product, clarification is required in this regard.
2.	3.2.S.4.1-3.2.S.4.2	• Submit specification and detailed analytical procedure of drug substance used by drug product manufacturer. • Justify for not including the test of specific optical rotation, sulphate ion test, sodium ion test, arsenic quantification test and particle size distribution test in the specification of drug substance by drug substance manufacturer, since these tests are included in the specification of innovator product. • The analytical procedure provided in section 3.2.S.4.2 specifies the assay limit as NLT 68.5% (on a dried basis), while the assay limit mentioned in the API's COA is 54.8% to 67.0% (on an anhydrous and acetic acid-free basis). Please clarify the discrepancy observed between the assay limits in these two sections.
3.	3.2.S.4.3	Submit analytical method verification report of drug substance performed by drug product manufacturer.
4.	3.2.S.4.4	COA of API reflects that the API is the sterile blend of ceftaroline fosamil monoacetate monohydrate buffered with L-Arginine, however, neither the stated salt form nor the inclusion of L-Arginine is confirmed from the documents submitted in section 3.2.S.1 and 3.2.S.2.
5.	3.2.S.7	Justify for not including the L-Arginine content test while performing the stability of drug substance.
6.	3.2.P.1 (c)	Provide details of type and quantity of diluents used for reconstitution for of applied product.
7.	3.2P.2.2.1	Justify for not performing the test of clarity of solution, constitution time, uniformity of dosage units ,container/closure integrity, extractable volume and particulate contamination test while evaluating the pharmaceutical equivalence of applied product with reference product.

8.	3.2.P.5.1	• Justify for not including the test of clarity of solution, constitution time, uniformity of dosage units, container/closure integrity, extractable volume and particulate contamination 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.
9.	3.2.P.5.2	Justify for using different assay method from that given by the drug substance manufacturer in section 3.2.S.4.2,since you have been imported ready to fill bulk of finished product.
10.	3.2.P.5.3	Clarification is needed on whether the assay for the drug product quantifies ceftaroline fosamil or ceftaroline, as the chromatograms and data sheets from the validation report indicate that the eluted peak and calculated amount correspond to ceftaroline.
11.	3.2.P.5.4	Submit bath analysis report of drug of all three trial batches.
12.	3.2.P.6	Justify, how ceftaroline fosamil separately eluted using the reference standard of ceftaroline fosamil with arginine.
13.	3.2.P.8	• Justify for not performing test of clarity of solution, constitution time, uniformity of dosage units, container/closure integrity, extractable volume and particulate contamination test during the stability study of drug product. • Submit the remaining stability data of drug product, since you have submitted only three-month stability data. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. • Documents for the procurement of API with approval from DRAP (in case of import).
14.	3.2.R.1.1	Justify the dispensed quantity of ceftaroline fosamil injection with respect to the potency of active.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

672.	Name, address of Applicant / Marketing Authorization Holder	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 23748 dated 26-09-2023
	Details of fee submitted	Rs.75,000/- vide dated 07-09-2023
	The proposed proprietary name / brand name	Cefta 600mg Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftaroline Fosamil as Acetic acid Solvate Monohydrate ….600mg
	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use
	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	USFDA Approved
	For generic drugs (me-too status)	Zinforo 600mg Injection of M/s. Pfizer,Pakistan (Reg.no. 110515)
Evaluation by PEC-XV:		

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.1	• As per the review literature, the salt form of the drug substance in the innovator brand is ceftaroline fosamil acetic acid solvate monohydrate. However, the drug substance in the applied product is ceftaroline fosamil, according to the information provided in the substance section. A justification is needed for the use of a chemically different API compared to the innovator product. • Further, neither the physicochemical characteristics nor the CAS no. and molecular formula of API is similar to the API used by innovator product, clarification is required in this regard.
2.	3.2.S.4.1-3.2.S.4.2	• Submit specification and detailed analytical procedure of drug substance used by drug product manufacturer. • Justify for not including the test of specific optical rotation, sulphate ion test, sodium ion test, arsenic quantification test and particle size distribution test in the specification of drug substance by drug substance manufacturer, since these tests are included in the specification of innovator product. • The analytical procedure provided in section 3.2.S.4.2 specifies the assay limit as NLT 68.5% (on a dried basis), while the assay limit mentioned in the API's COA is 54.8% to 67.0% (on an anhydrous and acetic acid-free basis). Please clarify the discrepancy observed between the assay limits in these two sections.
3.	3.2.S.4.3	Submit analytical method verification report of drug substance performed by drug product manufacturer.
4.	3.2.S.4.4	COA of API reflects that the API is the sterile blend of ceftaroline fosamil monoacetate monohydrate buffered with L-Arginine, however, neither the stated salt form nor the inclusion of L-Arginine is confirmed from the documents submitted in section 3.2.S.1 and 3.2.S.2.
5.	3.2.S.7	Justify for not including the L-Arginine content test while performing the stability of drug substance.
6.	3.2.P.1 (c)	Provide details of type and quantity of diluents used for reconstitution for of applied product.
7.	3.2P.2.2.1	Justify for not performing the test of clarity of solution, constitution time, uniformity of dosage units ,container/closure integrity, extractable volume and particulate contamination test while evaluating the pharmaceutical equivalence of applied product with reference product.
8.	3.2.P.5.1	• Justify for not including the test of clarity of solution, constitution time, uniformity of dosage units, container/closure integrity, extractable volume and particulate contamination 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.
9.	3.2.P.5.2	Justify for using different assay method from that given by the drug substance manufacturer in section 3.2.S.4.2,since you have been imported ready to fill bulk of finished product.
10.	3.2.P.5.3	Clarification is needed on whether the assay for the drug product quantifies ceftaroline fosamil or ceftaroline, as the chromatograms and data sheets from the validation report indicate that the eluted peak and calculated amount correspond to ceftaroline.
11.	3.2.P.5.4	Submit bath analysis report of drug of all three trial batches.
12.	3.2.P.6	Justify, how ceftaroline fosamil separately eluted using the reference standard of ceftaroline fosamil with arginine.
13.	3.2.P.8	• Justify for not performing test of clarity of solution, constitution time, uniformity of dosage units, container/closure integrity, extractable volume and particulate contamination test during the stability study of drug product.

		• Submit the remaining stability data of drug product, since you have submitted only three-month stability data. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. • Documents for the procurement of API with approval from DRAP (in case of import).
14.	3.2.R.1.1	Justify the dispensed quantity of ceftaroline fosamil injection with respect to the potency of active.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

673.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 24576 dated 06-10-2023
	Details of fee submitted	Rs.30,000/- slip no. 2467456096 dated 01-09-2023
	The proposed proprietary name / brand name	Nebicard-V 5/80 mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Nebivolol as Hcl…5mg Valsartan…80mg
	Pharmacotherapeutic Group of (API)	Beta Blocking agent/ACE Inhibitors
	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	USFDA Approved (Byvalson 5mg/80mg Tablet)
	For generic drugs (me-too status)	Nebilol-V Tablet 5mg+80mg of M/s. Genix Pharma Reg.no.

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	3.2. P.2.2.1	When the drug released more than 80% within 30 minutes without surfactant in all three medias as revealed by the CDP reports, than justify the used of surfactant in the adopted dissolution medium.	Firm claimed that they used surfactant as recommended by USFDA approved innovator product.

Decision: Approved.

674.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 24577 dated 06-10-2023

	Details of fee submitted	Rs.30,000/- vide slip no. 2603752808 dated 01-09-2023
	The proposed proprietary name / brand name	Nebivol-HCT 5/12.5 mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Nebivolol as Hcl…5mg Hydrochlorothiazide….12.5mg
	Pharmacotherapeutic Group of (API)	Beta Blocking agent/Thiazide Type Diuretics
	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	Lobivon Plus 5mg/ 12.5mg film coated tablets (CIMA Approved)
	For generic drugs (me-too status)	NA

Evaluation by PEC-XV:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Public assessment report of reference product revealed that "*Dissolution profile of batches in 0.1N HCl have more than 85% of drug dissolved at 15 minutes"* than justify the obtained percentage release of both comparator and test product while performing the CDP, at the same pH i.e. more than 85% release achieved after 20 minutes.	Firm replied that the CDP results obtained at 15 minutes time point is above 75% which was considered as baseline benchmark for the immediate release dosage form.
2.	Please provide a rationale for selecting pH 6.8 as the dissolution medium for both active ingredients, despite literature indicating that 0.1N HCl is the recommended dissolution medium for tablets containing nebivolol or hydrochlorothiazide as single active ingredients.	Firm replied that we following the public assessment report of medicine evaluation board in Netherland regards the product Lobiretic 5mg/12.5mg Film coated Tablet & Lobiretic 5mg/25mg Film coated Tablet. In their report they are not recommended the medium for dissolution we rely on the results of CDP of our product and selecting pH 6.8 as the dissolution medium for both active ingredients.

Decision: Approved.

675.	Name, address of Applicant / Marketing Authorization Holder	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Status of the applicant	☐ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 24578 dated 06-10-2023
	Details of fee submitted	Rs.30,000/- dated 01-09-2023
	The proposed proprietary name / brand name	Nebivol-HCT 5/25 mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Nebivolol as Hcl…5mg Hydrochlorothiazide….25mg
	Pharmacotherapeutic Group of (API)	Beta Blocking agent/Thiazide Type Diuretics
	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	Lobivon Plus 5mg/ 25mg film coated tablets (CIMA Approved)
	For generic drugs (me-too status)	NA

Evaluation by PEC-XV:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Public assessment report of reference product revealed that "*Dissolution profile of batches in 0.1N HCl have more than 85% of drug dissolved at 15 minutes"* than justify the obtained percentage release of both comparator and test product while performing the CDP, at the same pH i.e. more than 85% release achieved after 20 minutes.	Firm replied that the CDP results obtained at 15 minutes time point is above 75% which was considered as baseline benchmark for the immediate release dosage form.
2.	Please provide a rationale for selecting pH 6.8 as the dissolution medium for both active ingredients, despite literature indicating that 0.1N HCl is the recommended dissolution medium for tablets containing nebivolol or hydrochlorothiazide as single active ingredients.	Firm replied that we following the public assessment report of medicine evaluation board in Netherland regards the product Lobiretic 5mg/12.5mg Film coated Tablet & Lobiretic 5mg/25mg Film coated Tablet. In their report they are not recommended the medium for dissolution we rely on the results of CDP of our product and selecting pH 6.8 as the dissolution medium for both active ingredients.

Decision: Approved.

676.	Name, address of Applicant / Marketing Authorization Holder	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Plot No. 221-223, Sector 23, Korangi Industrial Area, Karachi, Pakistan
	Name, address of Manufacturing site.	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Plot No. 221-223, Sector 23, Korangi Industrial Area, Karachi, Pakistan
	Status of the applicant	☐ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 24689 dated 10-10-2023
	Details of fee submitted	Rs.30,000/- dated 25-04-2022 & Rs.45,000/- dated 12-05-2023
	The proposed proprietary name / brand name	Vextro 200mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Tedizolid Phosphate ….200mg
	Pharmacotherapeutic Group of (API)	Oxazolidinone Antibiotic J01XX1
	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	USFDA Approved (Tedizolid Phosphate SIVEXTRO 200mg of M/s. CUBIST PHARMS LLC)
	For generic drugs (me-too status)	NA

Evaluation by PEC-XV:

SIVEXTRO is an oxazolidinone-class antibacterial drug indicated in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria. (1) To reduce the development of drug-resistant bacteria and maintain the effectiveness of SIVEXTRO and other antibacterial

drugs, SIVEXTRO should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.	Firm submitted the specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.
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".*	Firm submitted the analytical verification report of drug substance performed by drug product manufacturer.
3.	Justify the dissolution behavior of applied product in all their media in comparison of BCS classification of applied product i.e. BCS-IV.	Firm again submitted the CDP report in which drug released more than 80% within 15 minutes in all three media, results of CDP did not technically support the solubility properties of drug substance that is mentioned in the review literature of innovator product. According to the review literature of innovator "Tedizolid phosphate is technically a Biopharmaceutical Classification System (BCS) Class IV compound, with poor solubility below pH 4 and poor permeability of the phosphate prodrug moiety".
4.	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Submitted
5.	Provide Batch Manufacturing Record (BMR) of all stability batches.	Submitted

Decision: Deferred for clarification as API is in BCS Class IV and firm submitted release of more than 80% within 15 minutes in all 3 media during CDP studies.

677.	Name, address of Applicant / Marketing Authorization Holder	M/s Platinum Pharmaceuticals Pvt Ltd. A-20, North western Industrial Zone, Bin Qasim Karachi
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals Pvt Ltd. A-20, North western Industrial Zone, Bin Qasim Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 24684 dated 10-10-2023
	Details of fee submitted	Rs.30,000/- vide slip no. 98015498 dated 19-09-2023
	The proposed proprietary name / brand name	Fusidic Acid 2% and Hydrocortisone Acetate 1% Cream

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tube of cream contains: Fusidic acid 2% +Hydrocortisone Acetate 1%
	Pharmacotherapeutic Group of (API)	Others antibiotic for topical use/Dermatological Corticosteroids weak
	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	MHRA Approved (Fucidin H Cream)
	For generic drugs (me-too status)	Fudic-H cream, Manufacturer: Shaigan Pharmaceuticals (Pvt.) Limited

Evaluation by PEC-XV:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the both Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.	Firm submitted the drug substance specification and analytical procedures used for routine testing of the both Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.
2.	Submit data of verification of analytical procedure of both drug substances 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".*	Firm submitted the analytical verification report of both drug substances performed by drug product manufacturer.
3.	Submit COA of reference standard actually used in the analysis of both drug substances in section 3.2.S.5.	Submitted.
4.	Submit stability data of drug substance till the claimed re-test date since you have only submitted the six month data of long term stability study.	Submitted
5.	Provide justification for not performing microbiological quality analysis and antimicrobial preservative content testing when evaluating the pharmaceutical equivalence of the test product against the comparator product.	Firm submitted the revised pharmaceutical equivalence of the test product against the comparator product including the result of microbiological quality analysis and antimicrobial preservative content testing.
6.	Justify for not including the microbiological quality analysis and antimicrobial preservative content test while performing the batch analysis of drug product.	Firm submitted the revised batch analysis report including the results of microbiological quality analysis and antimicrobial preservative content test.
7.	Justify for not performing the microbiological quality analysis and antimicrobial preservative content test while conducting the stability study of drug product.	Firm submitted the revised stability reports including the results of microbiological quality analysis and antimicrobial preservative content test.
8.	Submit documents for the procurement of API including copy of commercial invoice	Submitted

	attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	
9.	Provide Batch Manufacturing Record (BMR) of all stability batches.	Submitted

Decision: Approved.

678.	Name, address of Applicant / Marketing Authorization Holder	M/s Himark Laboratories Pvt Ltd. Plot 37-A, Sundar Industrial Estate, Lahore
	Name, address of Manufacturing site.	M/s Himark Laboratories Pvt Ltd. Plot 37-A, Sundar Industrial Estate, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No 25280 dated 17-10-2023
	Details of fee submitted	Rs.30,000/- dated 02-10-2023
	The proposed proprietary name / brand name	Declor 5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Desloratadine…5mg
	Pharmacotherapeutic Group of (API)	Antihistamines -H1 antagonists
	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	Desloratadine Tablet 5mg by Accord Healthcare Limited, United Kingdom (Approved in MHRA)
	For generic drugs (me-too status)	Neo-Antial Tablet 5mg Reg No. 061440 (SAMI Pharmaceuticals)

Evaluation by PEC-XV:

S.no.	Section	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.4	Justify for not performing the water content test while performing the batch analysis of drug substance by drug product manufacturer.
2.	3.2.P.2.2.1	You have submitted the CDP report of sitagliptin tablet instead of desloratadine tablet clarification is required in this required.
3.	3.2.P.8	• Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. • Submit Compliance Record of HPLC software 21CFR & audit trail reports on product testing.
4.	2.3.R.1.1	Provide Batch Manufacturing Record (BMR) of three stability batches.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.		
679.	Name, address of Applicant / Marketing Authorization Holder	M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi
	Name, address of Manufacturing site.	M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No 25794 dated 25-10-2023
	Details of fee submitted	Rs.75,000/- dated 04-10-2023
	The proposed proprietary name / brand name	Refine 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Finerenone…10mg
	Pharmacotherapeutic Group of (API)	Non- steroidal mineralocorticoid receptor antagonist
	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	USFDA Approved (Kerendia Tablet 10mg & 20mg)
	For generic drugs (me-too status)	NA

Evaluation by PEC-XV:

Kerendia is a non-steroidal mineralocorticoid receptor antagonist (MRA) indicated to reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D). DOSAGE AND ADMINISTRATION: The recommended starting dosage is 10 mg or 20 mg orally once daily based on estimated glomerular filtration rate (eGFR) and serum potassium thresholds. (2.1) • Increase dosage after 4 weeks to the target dose of 20 mg once daily, based on eGFR and serum potassium thresholds. (2.3) • Tablets may be taken with or without food.

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.P.2.2.1	The disintegration results for both the reference product and the test product, as presented in section 3.2.P.2.2.1, were not comparable. The reference tablets disintegrated after 6 minutes, while the test tablets disintegrated after only 1 minute. Please provide a justification for these results.
2.	3.2.P.5.1	• Please provide the reference of disintegration limit adopted for the applied drug product. • Adapt the acceptance limit of dissolution in term of Q, since the innovator product approved in USFDA specify the limit with Q value i.e. (Q) at 15 minutes.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.		
680.	Name, address of Applicant / Marketing Authorization Holder	M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi
	Name, address of Manufacturing site.	M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 25795 dated 25-10-2023

	Details of fee submitted	Rs.75,000/- dated 04-10-2023
	The proposed proprietary name / brand name	Refine 20mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Finerenone…20mg
	Pharmacotherapeutic Group of (API)	Non- steroidal mineralocorticoid receptor antagonist
	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	USFDA Approved (Kerendia Tablet 10mg & 20mg)
	For generic drugs (me-too status)	NA

Evaluation by PEC-XV:

Kerendia is a non-steroidal mineralocorticoid receptor antagonist (MRA) indicated to reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D). DOSAGE AND ADMINISTRATION: The recommended starting dosage is 10 mg or 20 mg orally once daily based on estimated glomerular filtration rate (eGFR) and serum potassium thresholds. (2.1) • Increase dosage after 4 weeks to the target dose of 20 mg once daily, based on eGFR and serum potassium thresholds. (2.3) • Tablets may be taken with or without food.

S.no.	Sections	Observations/Deficiencies/ Short-comings
3.	3.2.P.2.2.1	The disintegration results for both the reference product and the test product, as presented in section 3.2.P.2.2.1, were not comparable. The reference tablets disintegrated after 6 minutes, while the test tablets disintegrated after only 1 minute. Please provide a justification for these results.
4.	3.2.P.5.1	• Please provide the reference of disintegration limit adopted for the applied drug product. • Adapt the acceptance limit of dissolution in term of Q, since the innovator product approved in USFDA specify the limit with Q value i.e. (Q) at 15 minutes.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

681.	Name, address of Applicant / Marketing Authorization Holder	M/s Platinum Pharmaceuticals Pvt Ltd. A-20, North western Industrial Zone, Bin Qasim Karachi
	Name, address of Manufacturing site.	M/s Platinum Pharmaceuticals Pvt Ltd. A-20, North western Industrial Zone, Bin Qasim Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No 25790 dated 25-10-2023
	Details of fee submitted	Rs.30,000/- dated 19-09-2023
	The proposed proprietary name / brand name	Fusidic Acid+ Betamethasone Cream
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Cream Contains: Fusidic Acid…2% Betamethasone Valerate…0.1%
	Pharmacotherapeutic Group of (API)	Corticosteroids
	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	Fucibet Cream, Manufacturer: Leo laboratories limited UK (MHRA-UK Approved)
	For generic drugs (me-too status)	Fosedic B Cream, Manufacturer: Pearl pharmaceuticals (Pvt.) Limited

Evaluation by PEC-XV:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the both Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.	Firm submitted the drug substance specification and analytical procedures used for routine testing of the both Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.
2.	Submit data of verification of analytical procedure of both drug substances 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".*	Firm submitted the analytical verification report of both drug substances performed by drug product manufacturer.
3.	Submit COA of reference standard actually used in the analysis of both drug substances in section 3.2.S.5.	Submitted.
4.	Submit stability data of drug substance till the claimed re-test date since you have only submitted the six month data of long term stability study.	Submitted
5.	Provide justification for not performing microbiological quality analysis and antimicrobial preservative content testing when evaluating the pharmaceutical equivalence of the test product against the comparator product.	Firm submitted the revised pharmaceutical equivalence of the test product against the comparator product including the result of microbiological quality analysis and antimicrobial preservative content testing.
6.	Justify for not including the microbiological quality analysis and antimicrobial preservative content test while performing the batch analysis of drug product.	Firm submitted the revised batch analysis report including the results of microbiological quality analysis and antimicrobial preservative content test.
7.	Justify for not performing the microbiological quality analysis and antimicrobial preservative content test while conducting the stability study of drug product.	Firm submitted the revised stability reports including the results of microbiological quality analysis and antimicrobial preservative content test.
8.	Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product.	Submitted

9.	Provide Batch Manufacturing Record (BMR) of all stability batches.	Submitted

Decision: Approved.

682.	Name, address of Applicant / Marketing Authorization Holder	M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan
	Name, address of Manufacturing site.	M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No 26285 dated 31-10-2023
	Details of fee submitted	Rs.30,000/- dated 25-09-2023
	The proposed proprietary name / brand name	Nebovo 2.5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Uncoated Tablet Contains: Nebivolol as HCl…2.5mg
	Pharmacotherapeutic Group of (API)	Beta blocking agents, selective
	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	BYSTOLIC 2.5mg Tablets of Allergan Sales, LLC, an AbbVie company. USA approved by USFDA.
	For generic drugs (me-too status)	Nebix 2.5mg Tablets of M/s Highnoon Laboratories Ltd.

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	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 drug product manufacturer.
2.	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".*
3.	3.2.P.5.4	Submit batch analysis report of drug product.
4.	3.2.P.8	• Justify for not adopting the acceptance value of content uniformity test as recommended in general chapter of USP *<905> UNIFORMITY OF DOSAGE UNITS.* • Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

683.	Name, address of Applicant / Marketing Authorization Holder	M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan
	Name, address of Manufacturing site.	M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 26284 dated 31-10-2023
	Details of fee submitted	Rs.30,000/- dated 25-09-2023
	The proposed proprietary name / brand name	Nebovo 5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Uncoated Tablet Contains: Nebivolol as HCl…5mg
	Pharmacotherapeutic Group of (API)	Beta blocking agents, selective
	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	BYSTOLIC 5mg Tablets of Allergan Sales, LLC, an AbbVie company. USA approved by USFDA.
	For generic drugs (me-too status)	Nabil 5mg Tablet by M/s Getz Pharma, Reg. No. 061345

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	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 drug product manufacturer.
2.	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".*
3.	3.2.P.5.4	Submit batch analysis report of drug product.
4.	3.2.P.8	• Justify for not adopting the acceptance value of content uniformity test as recommended in general chapter of USP <*905*> *UNIFORMITY OF DOSAGE UNITS.* • Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

684.	Name, address of Applicant / Marketing Authorization Holder	M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan

	Name, address of Manufacturing site.	M/s Wenovo Pharmaceuticals Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 26284 dated 31-10-2023
	Details of fee submitted	Rs.30,000/- dated 25-09-2023
	The proposed proprietary name / brand name	Nebovo 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Uncoated Tablet Contains: Nebivolol as HCl…10mg
	Pharmacotherapeutic Group of (API)	Beta blocking agents, selective
	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	BYSTOLIC 10mg Tablets of Allergan Sales, LLC, an AbbVie company. USA approved by USFDA.
	For generic drugs (me-too status)	Bynevol 10mg Tablet by Atco Laboratories, Reg. No. 081562

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	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 drug product manufacturer.
2.	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".*
3.	3.2.P.5.4	Submit batch analysis report of drug product.
4.	3.2.P.8	• Justify for not adopting the acceptance value of content uniformity test as recommended in general chapter of USP *<905> UNIFORMITY OF DOSAGE UNITS.* • Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

685.	Name, address of Applicant / Marketing Authorization Holder	M/s. Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Name, address of Manufacturing site.	M/s. Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No 26688 dated 06-11-2023
	Details of fee submitted	Rs 75,000/- dated 06-10-2023
	The proposed proprietary name / brand name	Elagolixin 150mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Elagolix Sodium Eq. to Elagolix…150mg
	Pharmacotherapeutic Group of (API)	gonadotropin-releasing hormone (GnRH) receptor antagonist
	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	ORLISSA 150mg & 200mg TABLET Manufactured by AbbVie Inc. approved by USFDA
	For generic drugs (me-too status)	NA

Evaluation by PEC-XV:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Justify, why the specification for the drug substance used by the drug product manufacturer differs from the specification recommended by the drug substance manufacturer.	Firm submitted the revised specification of drug substance performed by the drug product manufacturer.
2.	Innovator literature that they have performed the assay of drug substance on HPLC than justify for adopting potentiometric titration method for performing the assay of drug substance.	Firm claimed that the drug substance manufacturer recommends performance of assay via potentiometric titration ,therefore the drug product manufacturer using the potentiometric titration method for performing the assay of drug substance.
3.	Provide COA of same lot of API that had been used in the manufacturing of trial batches of applied product.	Submitted
4.	• Justify for using water as a dissolution medium despite innovator literature recommending pH 6.8 phosphate buffer as the dissolution medium for elagolix tablets. • Innovator review literature evident that the recommended acceptance criterion for the dissolution test is NLT (Q) in 45 minutes than justify adopting an acceptance criterion of NLT 80% (Q) within 30 minutes for the applied product.	Firm claimed that they are using phosphate buffer pH 6.8 as the dissolution medium for elagolix tablets, accordingly revised analytical procedure along with performance report is submitted as an evidence. Firm claimed that during the development of our dissolution method, we observed that our product releases more than 85% of the API within 30 minutes .Scientifically, there is no justification for extending the dissolution process for an additional 15 minutes Increasing the sampling time from 30 minutes to 45 minutes without necessity would compromise the method's discriminatory power, potentially masking failures and eliminating the possibility of identifying substandard batches.

Decision: Approved.

686.	Name, address of Applicant / Marketing Authorization Holder	M/s. Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Name, address of Manufacturing site.	M/s. Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 26689 dated 06-11-2023
	Details of fee submitted	Rs 75,000/- dated 06-10-2023
	The proposed proprietary name / brand name	**Elagolixin 200mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Elagolix Sodium Eq. to Elagolix…200mg
	Pharmacotherapeutic Group of (API)	gonadotropin-releasing hormone (GnRH) receptor antagonist
	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	ORLISSA 150mg & 200mg TABLET Manufactured by AbbVie Inc. approved by USFDA
	For generic drugs (me-too status)	NA

Evaluation by PEC-XV:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
5.	Justify, why the specification for the drug substance used by the drug product manufacturer differs from the specification recommended by the drug substance manufacturer.	Firm submitted the revised specification of drug substance performed by the drug product manufacturer.
6.	Innovator literature that they have performed the assay of drug substance on HPLC than justify for adopting potentiometric titration method for performing the assay of drug substance.	Firm claimed that the drug substance manufacturer recommends performance of assay via potentiometric titration ,therefore the drug product manufacturer using the potentiometric titration method for performing the assay of drug substance.
7.	Provide COA of same lot of API that had been used in the manufacturing of trial batches of applied product.	Submitted
8.	• Justify for using water as a dissolution medium despite innovator literature recommending pH 6.8 phosphate buffer as the dissolution medium for elagolix tablets. • Innovator review literature evident that the recommended acceptance criterion for the dissolution test is NLT (Q) in 45 minutes than justify adopting an acceptance criterion of NLT 80% (Q) within 30 minutes for the applied product.	Firm claimed that they are using phosphate buffer pH 6.8 as the dissolution medium for elagolix tablets, accordingly revised analytical procedure along with performance report is submitted as an evidence. Firm claimed that during the development of our dissolution method, we observed that our product releases more than 85% of the API within 30 minutes .Scientifically, there is no justification for extending the dissolution process for an additional 15 minutes Increasing the sampling time from 30 minutes to 45 minutes without necessity would compromise the method's discriminatory power, potentially masking failures and eliminating the possibility of identifying substandard batches.

Decision: Approved

687.	Name, address of Applicant / Marketing Authorization Holder	M/s. Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Name, address of Manufacturing site.	M/s. Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 27481 dated 23-11-2023
	Details of fee submitted	Rs 75,000/- dated 03-11-2023
	The proposed proprietary name / brand name	**Crisaderm 2% Ointment**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Gram Contains: Crisaborole…20mg
	Pharmacotherapeutic Group of (API)	phosphodiesterase 4 inhibitor
	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	EUCRISA crisaborole 2% Ointment manufactured by ANACOR PHARMA Inc. approved by USFDA
	For generic drugs (me-too status)	NA

Evaluation by PEC-XV:

EUCRISA is a phosphodiesterase 4 inhibitor indicated for topical treatment of mild to moderate atopic dermatitis in patients 2 years of age and older.

DOSAGE AND ADMINISTRATION: Apply a thin layer twice daily to affected areas. • For topical use only. • Not for ophthalmic, oral, or intravaginal use.

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Justify maintaining the acceptance criterion for the LOD test at NMT 0.5% for the drug substance by the drug product manufacturer, despite the drug substance manufacturer specifying an acceptance criterion of NMT 3.0% for the LOD test.	Firm replied that limit of LOD test is 0.5% as per the documents of drug substance manufacturer i.e.M/s. Azico Biophore.
2.	Please clarify the ambiguity regarding the drug substance manufacturer. The batch analysis report indicates that the drug substance was manufactured by M/s. Azico Biophore India Pvt. Ltd., while the rest of Module III specifies M/s. Fujian Jinshan Zhundian Pharmaceutical Co., Ltd., Fujian Province, China, as the manufacturer of the drug substance for the applied product.	Firm clarified that they had mistakenly submitted the DMF of M/s. Fujian Jinshan Zhundian Pharmaceutical Co., Ltd., Fujian Province, China, now they are submitting complete DMF of manufacturer M/s. Azico Biophore India Pvt. Ltd.
3.	Justify for not including the microbiological analysis test, antioxidant content test, appearant viscosity and uniformity in containers test in the specification of drug product since these tests are recommended for semisolid dosage form in USP general chapter *TOPICAL AND TRANSDERMAL DRUG PRODUCTS—PRODUCT QUALITY TESTS* <3>.	Firm submitted revised specification of drug product including microbiological analysis test, antioxidant content test, appearant viscosity and uniformity in containers test.
4.	The import invoice for the drug substance indicates that it was imported from M/s. Azico Biophore India Pvt. Ltd. However, the submitted drug substance documentation pertains entirely to M/s. Fujian Jinshan Zhundian Pharmaceutical Co., Ltd., Fujian Province, China, except for the Certificate of	Firm submitted the procurement document mentioning M/s. Azico Biophore India Pvt. Ltd. as drug substance manufacturer.

	Analysis (COA) of the drug substance. Clarification on this discrepancy is required.	

Decision: Approved.

688.	Name, address of Applicant / Marketing Authorization Holder	M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura
	Name, address of Manufacturing site.	M/s Jenner Pharmaceuticals Pvt Ltd. 26-km, Lahore Sharaqpur Road, Sheikhupura
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No 26687 dated 06-11-2023
	Details of fee submitted	Rs. 30,000/- dated 24-10-2023
	The proposed proprietary name / brand name	**Jencil 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Uncoated Tablet Contains: Propylthiouracil…50mg
	Pharmacotherapeutic Group of (API)	Thiocarbamide compound/antithyroid drug
	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	Propylthiouracil 50mg Tablet of M/s. ENDO Operations approved by USFDA
	For generic drugs (me-too status)	

Evaluation by PEC-XV:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	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 submitted the stability data of drug substance performed at zone-IV-A conditions.
2.	Explain the release behaviour of the drug product across all three media in terms of the Biopharmaceutics Classification System (BCS) classification and the solubility characteristics of the drug substance.	Firm replied that propylthiouracil belong to BCS class-I drug as per the WHO guidelines attached as reference.
3.	The loan letter for the active ingredient indicates that it was obtained on March 15, 2023, whereas the trial batches were manufactured back in November 2022. Please clarify how the trial batches were produced prior to securing the loan of the active ingredient. Additionally, according to the commercial invoice attached to the stability data, the batch of active ingredient used in these trial batches expired in August 2023,than,Please explain how the expiry date of the trial batches has been claimed until November 2024.	Firm replied that request letter for loan of API was raised on 10-10-2022 and material received on 01-11-2022.After receiving material on 01-11-2022 we manufactured trail batches on 18-11-2022.DRAP was intimated on 16-03-2023 along with Loan request and material received letters. Further, firm replied that we can use API for formulation of the product before date of expiration and expiry of formulated product will be according to stability data of the product.

Decision: Approved.

689.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No 22437 dated 12-09-2023
	Details of fee submitted	Rs.30,000/- dated 10-07-2023
	The proposed proprietary name / brand name	**Terbiwen 250mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Uncoated Tablet Contains: Terbinafine as HCl…250mg
	Pharmacotherapeutic Group of (API)	Antifungal
	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
	For generic drugs (me-too status)	Terbiderm Tablet by Atco

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	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 both Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.
2.	3.2.S.4.3	Submit analytical method verification report of both drug substance performed by drug product manufacturer.
3.	3.2.P.2.1.2	Excipients against which you analyze the compatibility of API is not same to the excipients mentioned in section composition table of section 3.2.P.1.
4.	3.2.P.2.2.1	• Justify how the conclusion for Comparative Dissolution Profile (CDP) is made and the test product is declared comparable to innovator product without determining similarity factor "f2" and discussing its results. • Justify how you have performed the pharmaceutical equivalence and comparative dissolution profiling of applied strength of 125mg tablet against the comparator product of higher strength i.e. terbiderm forte tablet.
5.	3.2.P.5.3	Justify for keeping the run time 5 minutes while performing the verification studies of assay of drug product, when the USP monograph of risperidone tablet recommends 30 minutes run time.
6.	3.2.P.6	Submit COA of reference standard actually used in the analysis of drug product in section 3.2.P.6.
7.	3.2.P.8.3	• Provide a scientific rationale for using a 20 µl injection volume while performing the assay of the drug product, despite the USP monograph for Terbinafine tablets recommending a 5 µl injection volume in the chromatography system for assay. • Justify submitting the same raw data sheets for dissolution testing for both strengths of the applied tablet.
8.	3.2.R.1.1	• Justify the use of 281.31 mg/tablet and 140.64 mg/tablet of terbinafine base in the manufacturing of trial batches for the 250 mg and 125 mg terbinafine tablets, respectively.

		• Explain along with calculation that how can 337.57 mg of Terbinafine HCl is equivalent to 250 mg of Terbinafine base, since you have mentioned the same quantity of active ingredient in composition table of executed BMR. • Similarly, Explain along with calculation that how can 168.77 mg of Terbinafine HCl is equivalent to 125 mg of Terbinafine base , since you have mentioned the same quantity of active ingredient in composition table of BMR.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

690.	Name, address of Applicant / Marketing Authorization Holder	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan
	Name, address of Manufacturing site.	M/s Winbrains Research Laboratories. Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 22431 dated 12-09-2023
	Details of fee submitted	Rs.30,000/- dated 10-07-2023
	The proposed proprietary name / brand name	Terbiwen 125mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Uncoated Tablet Contains: Terbinafine as HCl…125mg
	Pharmacotherapeutic Group of (API)	Antifungal
	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
	For generic drugs (me-too status)	Terbiderm Tablet by Atco

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	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 both Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.
2.	3.2.S.4.3	Submit analytical method verification report of both drug substance performed by drug product manufacturer.
3.	3.2.P.2.1.2	Excipients against which you analyze the compatibility of API is not same to the excipients mentioned in section composition table of section 3.2.P.1.
4.	3.2.P.2.2.1	• Justify how the conclusion for Comparative Dissolution Profile (CDP) is made and the test product is declared comparable to innovator product without determining similarity factor "f2" and discussing its results. • Justify how you have performed the pharmaceutical equivalence and comparative dissolution profiling of applied strength of 125mg tablet against the comparator product of higher strength i.e. terbiderm forte tablet.
5.	3.2.P.5.3	Justify for keeping the run time 5 minutes while performing the verification studies of assay of drug product, when the USP monograph of risperidone tablet recommends 30 minutes run time.
6.	3.2.P.6	Submit COA of reference standard actually used in the analysis of drug product in section 3.2.P.6.

7.	3.2.P.8.3	• Provide a scientific rationale for using a 20 µl injection volume while performing the assay of the drug product, despite the USP monograph for Terbinafine tablets recommending a 5 µl injection volume in the chromatography system for assay. • Justify submitting the same raw data sheets for dissolution testing for both strengths of the applied tablet.
8.	3.2.R.1.1	• Justify the use of 281.31 mg/tablet and 140.64 mg/tablet of terbinafine base in the manufacturing of trial batches for the 250 mg and 125 mg terbinafine tablets, respectively. • Explain along with calculation that how can 337.57 mg of Terbinafine HCl is equivalent to 250 mg of Terbinafine base, since you have mentioned the same quantity of active ingredient in composition table of executed BMR. • Similarly, Explain along with calculation that how can 168.77 mg of Terbinafine HCl is equivalent to 125 mg of Terbinafine base , since you have mentioned the same quantity of active ingredient in composition table of BMR.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

691.	Name, address of Applicant / Marketing Authorization Holder	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No 22453 dated 12-09-2023
	Details of fee submitted	Rs.30,000/- dated 07-07-2023
	The proposed proprietary name / brand name	**Rispo 2mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Risperidone…2mg
	Pharmacotherapeutic Group of (API)	Other antipsychotics
	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	MHRA Approved
	For generic drugs (me-too status)	Neo-Risp Tablet by Wilshire

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	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 both Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.
2.	3.2.S.4.3	Submit analytical method verification report of both drug substance performed by drug product manufacturer.
3.	3.2.S.7	Submit readable copy of stability data sheets of drug substance.
4.	3.2.P.2.2.1	Justify how the conclusion for Comparative Dissolution Profile (CDP) is made and the test product is declared comparable to innovator product without determining similarity factor “f2” and discussing its results.

5.	3.2.P.5.3	Justify for keeping the run time 5 minutes while performing the verification studies of assay of drug product, when the USP monograph of risperidone tablet recommends 30 minutes run time.
6.	3.2.P.6	Submit COA of reference standard actually used in the analysis of drug product in section 3.2.P.6.
7.	3.2.P.8.2	Explain how the main peak retention time was observed at approximately 2.1 minutes during HPLC analysis for both dissolution and assay tests, despite utilizing different chromatographic conditions, since the USP recommends different chromatography systems for both of these tests.
8.	3.2.R.1.1	Justify the use of 2.4 mg of risperidone active ingredient per tablet in the manufacturing of trial batches, and provide the complete calculation for the dispensed weight of the active ingredient.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

692.	Name, address of Applicant / Marketing Authorization Holder	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 22452 dated 12-09-2023
	Details of fee submitted	Rs.30,000/- dated 07-07-2023
	The proposed proprietary name / brand name	**Rispo 4mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Risperidone…4mg
	Pharmacotherapeutic Group of (API)	Other antipsychotics
	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	MHRA Approved
	For generic drugs (me-too status)	Neo-Risp Tablet by Wilshire

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	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 both Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.
2.	3.2.S.4.3	Submit analytical method verification report of both drug substance performed by drug product manufacturer.
3.	3.2.S.7	Submit readable copy of stability data sheets of drug substance.
4.	3.2.P.2.2.1	Justify how the conclusion for Comparative Dissolution Profile (CDP) is made and the test product is declared comparable to innovator product without determining similarity factor “f2” and discussing its results.
5.	3.2.P.5.3	Justify for keeping the run time 5 minutes while performing the verification studies of assay of drug product, when the USP monograph of risperidone tablet recommends 30 minutes run time.
6.	3.2.P.6	Submit COA of reference standard actually used in the analysis of drug product in section 3.2.P.6.

7.	3.2.P.8.2	Explain how the main peak retention time was observed at approximately 2.1 minutes during HPLC analysis for both dissolution and assay tests, despite utilizing different chromatographic conditions, since the USP recommends different chromatography systems for both of these tests.
8.	3.2.R.1.1	Justify the use of 2.4 mg of risperidone active ingredient per tablet in the manufacturing of trial batches, and provide the complete calculation for the dispensed weight of the active ingredient.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

693.	Name, address of Applicant / Marketing Authorization Holder	M/s Meditech Pharmaceuticals. Plot No. 83-A, 83-B, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Name, address of Manufacturing site.	M/s Meditech Pharmaceuticals. Plot No. 83-A, 83-B, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No 23476 dated 22-09-2023
	Details of fee submitted	Rs.30,000/- dated 02-08-2023
	The proposed proprietary name / brand name	**Fexomed 30mg/5ml Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Fexofenadine HCl…30mg
	Pharmacotherapeutic Group of (API)	Other antipsychotics
	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	MHRA Approved
	For generic drugs (me-too status)	Neo-Risp Tablet by Wilshire

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	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 drug product manufacturer.
2.	3.2.S.4.3	Submit analytical method verification report of both drug substance performed by drug product manufacturer.
3.	3.2.P.2	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.
4.	3.2.P.2.2.1	Justify for not performing the test for determination of pH, microbial content test and deliverable volume test while establishing the pharmaceutical equivalence against the comparator product.
5.	3.2.P.5.1	Justify for not including the test for determination of pH, microbial content test and deliverable volume test in the finished product specification, since these tests are recommended by the USP in their general chapter *<2> ORAL DRUG PRODUCTS—PRODUCT QUALITY TESTS.*
6.	3.2.P.5.2	Submit detailed analytical procedure used for routine testing of the Drug product.
7.	3.2.P.5.3	Submit analytical method validation report of both drug product in the relevant section.
8.	3.2.P.5.4	Justify, how you have obtained a white color suspension after adding yellow color in the formulation of applied product.

9.	3.2.P.6	Submit COA of reference standard actually used in the analysis of drug product in section 3.2.P.6.
10.	3.2.P.8.3	• A scientific justification is required for achieving consistent retention times up to three decimal places (e.g., 3.550 minutes) across all chromatograms in the stability study. • Submit documents for the procurement of API including copy of commercial invoice attested by AD (I&E) DRAP. Provide details that which lot number of drug substance has been used in manufacturing of each batch of drug product. Also provide documents confirming evidence of import of each lot of drug substance used in manufacturing of these batches of drug product. • Provide Reference of previous approval of applications with stability study data of the firm (if any). • Compliance Record of HPLC software 21CFR & audit trail reports on product testing. • Submit valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin.
11.	3.2.R.1.1	Provide Batch Manufacturing Record (BMR) of all stability batches.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Previously Deferred Cases of Form-5F (Local Manufacturing):

694.	Name, address of Applicant / Marketing Authorization Holder	M/s Pharm Evo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi
	Name, address of Manufacturing site.	M/s Pharm Evo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No 16992 dated 07-07-2023
	Details of fee submitted	Rs.30,000/- dated 17-05-2023
	The proposed proprietary name / brand name	**Thewril 4mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Thiocolchicoside…4mg
	Pharmacotherapeutic Group of (API)	Muscle Relaxant
	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	MIOREL 4 mg/2 ml solution for injection (IM) ampoule ANSM France approved.
	For generic drugs (me-too status)	Thioget 4mg Capsule of M/s. Getz Pharma (Reg.no.086076)

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.1-3.2.S.4.2	Submit specification and detailed analytical procedure of drug substance used by drug product manufacturer.

2.	3.2.S.4.3	Submit analytical method verification report of drug substance performed by drug product manufacturer.
3.	3.2.P.2.2.1	Please submit the documented evidence which reveal the specification of innovator/reference product, since you have mentioned the specification of innovator product in the pharmaceutical equivalence report.
4.	3.2.P.5.2	Please clarify the sampling time point of dissolution method with reference to release pattern of applied formulation. Further, the time point against which you have set the acceptance criteria i.e. 45 minutes is not included in the sampling time points mentioned in the dissolution procedure, clarification is required in this regard.
5.	3.2.P.5.3	The assay method used to determine pharmaceutical equivalence differs from the method described in Section 3.2.P.5.2., as the validated method is based on a gradient elution system. Please justify the discrepancy observed between the assay methods in these two sections.
6.	3.2.P.8	• In reviewing the chromatograms provided in the CDP report and those attached to the stability report, a notable discrepancy in the retention times of the main peak has been observed. Specifically, the CDP report indicates that the main peak elutes around 2.4 to 2.8 minutes, whereas the stability report shows the main peak eluting around 15 to 16 minutes. Scientific justification is required regarding the significant difference in retention times, despite utilizing the same dissolution method. • You have used different procedure for assay of the applied formulation and for the *Content Uniformity* test, but you have not establish the correction factor which has to be applied to the results of *Content Uniformity* test as recommended in the general chapter of pharmacopeia, then scientifically justify the results *Content Uniformity* test obtained during the stability study of the drug product. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired.

Decision of 340th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply of Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit specification and detailed analytical procedure of drug substance used by drug product manufacturer.	Firm submitted the specification and analytical procedure of drug substance used by drug product manufacturer.
2.	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Firm submitted the analytical verification report of drug substance performed by drug product manufacturer.
3.	Please submit the documented evidence which reveal the specification of innovator/reference product, since you have mentioned the specification of innovator product in the pharmaceutical equivalence report.	Firm claimed that reference product and teste product has been tested in accordance with general chapter of pharmacopeia and found within specification. Additionally, appearance and average weight specification is adopted from innovator/reference product, so we mentioned innovator specification.
4.	Please clarify the sampling time point of dissolution method with reference to release pattern of applied formulation. Further, the time point against which you have set the acceptance criteria i.e. 45 minutes is not included in the sampling time points mentioned in the dissolution procedure, clarification is required in this regard.	Firm clarified that sampling point of test product is 45 minutes, but there were typographical error in procedure related to sampling time point.
5.	The assay method used to determine pharmaceutical equivalence differs from the method described in Section 3.2.P.5.2., as the	Firm submitted the assay procedure based on isocratic system with the clarification that they shifted from

	validated method is based on a gradient elution system. Please justify the discrepancy observed between the assay methods in these two sections.	gradient system to isocratic elution system in order to minimize the run time.
6.	In reviewing the chromatograms provided in the CDP report and those attached to the stability report, a notable discrepancy in the retention times of the main peak has been observed. Specifically, the CDP report indicates that the main peak elutes around 2.4 to 2.8 minutes, whereas the stability report shows the main peak eluting around 15 to 16 minutes. Scientific justification is required regarding the significant difference in retention times, despite utilizing the same dissolution method.	Firm in their reply again claimed that due to change of system from gradients to isocratic, difference in the retention times of the main peak has been observed. However, the dissolution procedure given in section 3.2.P.5.2 of the submitted dossier revealed that quantification of released percentage of drug has been evaluated via isocratic elution system.
7.	You have used different procedure for assay of the applied formulation and for the *Content Uniformity* test, but you have not establish the correction factor which has to be applied to the results of *Content Uniformity* test as recommended in the general chapter of pharmacopeia, then scientifically justify the results *Content Uniformity* test obtained during the stability study of the drug product.	Firm claimed that correction is not applicable as per USP pharmacopeia because correction factor is to be applied only if F is not less than 1.03 nor greater or not less than 0.90 or not greater than 0.97. If F is between 0.97 to 1.030 no correction factor F is required. Our product content uniformity (correction factor) F is 0.983, Hence no correction factor is required.
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired.	Submitted

Decision: Approved. Registration letter will be issued upon submitting the dissolution method applied for conducting the stability studies of drug product along with the supporting documents which includes performance report of dissolution test , raw data sheets and chromatograms.

695.	Name, address of Applicant / Marketing Authorization Holder	M/s Scilife Pharma Pvt Ltd. Plot no. FD-57/58-A2, Korangi Creek Industrial Park, Karachi
	Name, address of Manufacturing site.	M/s Scilife Pharma Pvt Ltd. Plot no. FD-57/58-A2, Korangi Creek Industrial Park, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No 17842 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 17-05-2023
	The proposed proprietary name / brand name	**Sciria CR 165mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Tablet Contains: Pregabalin…165mg
	Pharmacotherapeutic Group of (API)	Antiepileptic
	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	LYRICA CR Extended Release, USFDA Approved.
	For generic drugs (me-too status)	NA

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.4	Assay results of drug substance specified by the drug product manufacturer is as basis and on anhydrous basis while the USP monograph of pregabalin mentioned the limits of assay on dried basis, provide the results of assay according to the recommendation of USP monograph.
2.	3.2.S.7	Specification of drug substance mentioned in the COA, given in section 3.2.S.4.1 and recommended by USP monograph of pregabalin is different from the specification on which stability of drug substance has been performed, clarification is required in this regard.
3.	3.2.P.2.2.1	Justify for not including the dissolution data of time point 4hr and 9hr in the CDP report since the innovator literature recommends to include these time points in the dissolution analysis of drug product.
4.	3.2.P.5.1	• Provide reference used for adjusting the acceptance criteria of percentage moisture content of drug product. • Innovator review literature recommends dissolution data at time point 9hrs also to ensure quality control from 55% to complete release, considering the recommendation of innovator you have not included the 9hr in the dissolution specification of applied drug product, so justification is required in this regard.
5.	3.2.P.8	• Provide scientific rational regarding the sudden downward trend observed after the zero month in the percentage moisture content of drug product, since in one of the trial batches its drop from 5.79% to 0.79% within one month. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired. • Documents for the procurement of API with approval from DRAP (in case of import).

Decision of 340th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Assay results of drug substance specified by the drug product manufacturer is as basis and on anhydrous basis while the USP monograph of pregabalin mentioned the limits of assay on dried basis, provide the results of assay according to the recommendation of USP monograph.	Firm submitted the batch analysis report of drug substance in which the results of assay has been mentioned in accordance with USP monograph of pregabalin.
2.	Specification of drug substance mentioned in the COA, given in section 3.2.S.4.1 and recommended by USP monograph of pregabalin is different from the specification on which stability of drug substance has been performed, clarification is required in this regard.	Firm replied that "We would like to inform the Agency that Pregabalin API batches PG120001, PG120002 and PG120003 were initially kept for stability studies as per inhouse Specification and Method of Analysis as Pregabalin monograph was not yet published in any pharmacopeia in 2012. Later on, monograph of Pregabalin was published in year 2016. Accordingly, API Specification and Method of Analysis for Assay and Related substance was revised in-line with the Ph.Eur. monograph. Hence, initial control sample and 48 months stability interval sample of these API batches

		were analyzed as per revised specification and batches meeting Ph.Eur. Specification. Further, Pregabalin API got official in USP monograph (USP 40-NF_August 01, 2017). However, stability study of these API batches was completed. Hence, initial control sample and stability sample of last interval i.e. 72 months were checked as per USP specification. Accordingly, stability data are attached. Later on, CTX has initiated the accelerated and long-term stability study for API batches PG183002, PG183003 and PG183004 as per Pregabalin USP Specification and Method of Analysis. Kindly find attached 06 months accelerated and 60 months long term stability data of above batches as per USP Specification and Method of Analysis. Conclusion: Based on the above justification, it is concluded that stability study data of Pregabalin API batches PG120001, PG120002 and PG120003 (from the initial and 72 months as provided on page # 2 of stability study) were in-line with the USP specification and Method of Analysis as recommended in USP monograph. Additionally, accelerated and long-term stability data in-line with the Pregabalin USP specification is also attached.
3.	Justify for not including the dissolution data of time point 4hr and 9hr in the CDP report since the innovator literature recommends to include these time points in the dissolution analysis of drug product.	Firm replied that "In response to the query for not including the 4-hour and 9-hour time points in the Comparative Dissolution Profile (CDP) for Pregabalin CR 82.5mg (Test Product) compared to Pregabalin extended release Tablet 82.5 mg (Reference Product) respectively, we would like to clarify the following: The dissolution profile was conducted in accordance with WHO TRS 1003 (2017), Appendix 1: "Recommendations for Conducting and Assessing Comparative Dissolution Profiles." The time points selected for the dissolution profile were at 1, 2, 3, 5, 8, 12, 16, and 24 hours. These time points were chosen based on the guidance provided by the WHO, and as such, the 4-hour and 9-hour time points were not included in the original study. Both the test and reference products were subjected to dissolution testing under identical conditions in three different media, and the drug release profiles were found to be similar and acceptable. The F2 similarity factor for all three media was calculated to be greater than 50, indicating comparable dissolution behavior. However, we have theoretically calculated the drug release at the 4-hour and 9-hour time points using a non-linear polynomial regression model (second order). The predicted release values were determined" However, the reference WHO guidelines stated that "For extended-release FPPs the time-points should be set to cover the entire duration of expected release, e.g. in addition to earlier timepoints: samples at 1, 2, 3, 5 and 8 hours should be collected for a 12-hour release and additional test intervals would be necessary for longer duration of release". It is clear from the guidelines that it does not bound the manufacturer to

		perform the CDP on the stated sampling time rather it is an example quoted to explain the procedure.
4.	Provide reference used for adjusting the acceptance criteria of percentage moisture content of drug product.	Firm replied that Our product is manufactured using direct compression process, and we have developed an inhouse testing method. Based on the formulation, excipient quantities, loss on drying specifications, and their impact on the product, we initially established an acceptance criterion for the moisture content, which must not exceed 10.00%. However, in fact the stability results of moisture content obtained under different environmental conditions e.g., accelerated and real time which are less than 7% and no signs of degradation, discoloration, hardness changes or changes in the disintegration/dissolution profile so the limit of moisture content has been reduced to "Not more than 7%" that will be followed for all future batches testing and reporting.
5.	Innovator review literature recommends dissolution data at time point 9hrs also to ensure quality control from 55% to complete release, considering the recommendation of innovator you have not included the 9hr in the dissolution specification of applied drug product, so justification is required in this regard.	Firm replied In the initial submission, the dissolution time points of 1, 4, and 24 hours were selected based on the innovator's specification, as reflected in the literature. The 9-hour time point was not included, as it was not part of the specification submitted to the DRAP. However, after reviewing the additional literature and considering the regulatory recommendation, we have revised our dissolution specification to include the 9-hour time point, with a limit of not less than (NLT) 55%. We have also conducted testing on the current stability batches of the drug product, and the results have been provided for your review. This revision ensures alignment with both quality control expectations and innovator specifications.
6.	Provide scientific rational regarding the sudden downward trend observed after the zero month in the percentage moisture content of drug product, since in one of the trial batches its drop from 5.79% to 0.79% within one month.	Firm responds the requisite query.
7.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired.	Submitted
8.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted

Decision: Approved.

696.	Name, address of Applicant / Marketing Authorization Holder	M/s Scilife Pharma Pvt Ltd. Plot no. FD-57/58-A2, Korangi Creek Industrial Park, Karachi
	Name, address of Manufacturing site.	M/s Scilife Pharma Pvt Ltd. Plot no. FD-57/58-A2, Korangi Creek Industrial Park, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No 17843 dated 14-07-2023
	Details of fee submitted	Rs.75,000/- dated 17-05-2023
	The proposed proprietary name / brand name	Sciria CR 330mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Extended Release Tablet Contains: Pregabalin…330mg
	Pharmacotherapeutic Group of (API)	Antiepileptic
	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	LYRICA CR Extended Release, USFDA Approved.
	For generic drugs (me-too status)	NA

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.4	Assay results of drug substance specified by the drug product manufacturer is as basis and on anhydrous basis while the USP monograph of pregabalin mentioned the limits of assay on dried basis, provide the results of assay according to the recommendation of USP monograph.
2.	3.2.S.7	Specification of drug substance mentioned in the COA, given in section 3.2.S.4.1 and recommended by USP monograph of pregabalin is different from the specification on which stability of drug substance has been performed, clarification is required in this regard.
3.	3.2.P.2.2.1	Justify for not including the dissolution data of time point 4hr and 9hr in the CDP report since the innovator literature recommends to include these time points in the dissolution analysis of drug product.
4.	3.2.P.5.1	• Provide reference used for adjusting the acceptance criteria of percentage moisture content of drug product. • Innovator review literature recommends dissolution data at time point 9hrs also to ensure quality control from 55% to complete release, considering the recommendation of innovator you have not included the 9hr in the dissolution specification of applied drug product, so justification is required in this regard.
5.	3.2.P.8	• Provide scientific rational regarding the sudden downward trend observed after the zero month in the percentage moisture content of drug product, since in one of the trial batches its drop from 5.79% to 0.79% within one month. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired. • Documents for the procurement of API with approval from DRAP (in case of import).

Decision of 340th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Assay results of drug substance specified by the drug product manufacturer is as basis and on anhydrous basis while the USP monograph of pregabalin mentioned the limits of assay on dried basis, provide the results of assay	Firm submitted the batch analysis report of drug substance in which the results of assay has been mentioned in accordance with USP monograph of pregabalin.

	according to the recommendation of USP monograph.	
2.	Specification of drug substance mentioned in the COA, given in section 3.2.S.4.1 and recommended by USP monograph of pregabalin is different from the specification on which stability of drug substance has been performed, clarification is required in this regard.	Firm replied that "We would like to inform the Agency that Pregabalin API batches PG120001, PG120002 and PG120003 were initially kept for stability studies as per inhouse Specification and Method of Analysis as Pregabalin monograph was not yet published in any pharmacopeia in 2012. Later on, monograph of Pregabalin was published in year 2016. Accordingly, API Specification and Method of Analysis for Assay and Related substance was revised in-line with the Ph.Eur. monograph. Hence, initial control sample and 48 months stability interval sample of these API batches were analyzed as per revised specification and batches meeting Ph.Eur. Specification. Further, Pregabalin API got official in USP monograph (USP 40-NF_August 01, 2017). However, stability study of these API batches was completed. Hence, initial control sample and stability sample of last interval i.e. 72 months were checked as per USP specification. Accordingly, stability data are attached. Later on, CTX has initiated the accelerated and long-term stability study for API batches PG183002, PG183003 and PG183004 as per Pregabalin USP Specification and Method of Analysis. Kindly find attached 06 months accelerated and 60 months long term stability data of above batches as per USP Specification and Method of Analysis. Conclusion: Based on the above justification, it is concluded that stability study data of Pregabalin API batches PG120001, PG120002 and PG120003 (from the initial and 72 months as provided on page # 2 of stability study) were in-line with the USP specification and Method of Analysis as recommended in USP monograph. Additionally, accelerated and long-term stability data in-line with the Pregabalin USP specification is also attached.
3.	Justify for not including the dissolution data of time point 4hr and 9hr in the CDP report since the innovator literature recommends to include these time points in the dissolution analysis of drug product.	Firm replied that "In response to the query for not including the 4-hour and 9-hour time points in the Comparative Dissolution Profile (CDP) for Pregabalin CR 82.5mg (Test Product) compared to Pregabalin extended release Tablet 82.5 mg (Reference Product) respectively, we would like to clarify the following: The dissolution profile was conducted in accordance with WHO TRS 1003 (2017), Appendix 1: "Recommendations for Conducting and Assessing Comparative Dissolution Profiles." The time points selected for the dissolution profile were at 1, 2, 3, 5, 8, 12, 16, and 24 hours. These time points were chosen based on the guidance provided by the WHO, and as such, the 4-hour and 9-hour time points were not included in the original study. Both the test and reference products were subjected to dissolution testing under identical conditions in three different media, and the drug release profiles were found to be similar and acceptable. The F2 similarity factor for all three media was calculated to be greater than 50, indicating

		comparable dissolution behavior. However, we have theoretically calculated the drug release at the 4-hour and 9-hour time points using a non-linear polynomial regression model (second order). The predicted release values were determined" However, the reference WHO guidelines stated that "For extended-release FPPs the time-points should be set to cover the entire duration of expected release, e.g. in addition to earlier timepoints: samples at 1, 2, 3, 5 and 8 hours should be collected for a 12-hour release and additional test intervals would be necessary for longer duration of release". It is clear from the guidelines that it does not bound the manufacturer to perform the CDP on the stated sampling time rather it is an example quoted to explain the procedure.
4.	Provide reference used for adjusting the acceptance criteria of percentage moisture content of drug product.	Firm replied that Our product is manufactured using direct compression process, and we have developed an inhouse testing method. Based on the formulation, excipient quantities, loss on drying specifications, and their impact on the product, we initially established an acceptance criterion for the moisture content, which must not exceed 10.00%. However, in fact the stability results of moisture content obtained under different environmental conditions e.g., accelerated and real time which are less than 7% and no signs of degradation, discoloration, hardness changes or changes in the disintegration/dissolution profile so the limit of moisture content has been reduced to "Not more than 7%" that will be followed for all future batches testing and reporting.
5.	Innovator review literature recommends dissolution data at time point 9hrs also to ensure quality control from 55% to complete release, considering the recommendation of innovator you have not included the 9hr in the dissolution specification of applied drug product, so justification is required in this regard.	Firm replied "In the initial submission, the dissolution time points of 1, 4, and 24 hours were selected based on the innovator's specification, as reflected in the literature. The 9-hour time point was not included, as it was not part of the specification submitted to the DRAP. However, after reviewing the additional literature and considering the regulatory recommendation, we have revised our dissolution specification to include the 9-hour time point, with a limit of not less than (NLT) 55%. We have also conducted testing on the current stability batches of the drug product, and the results have been provided for your review. This revision ensures alignment with both quality control expectations and innovator specifications".
6.	Provide scientific rational regarding the sudden downward trend observed after the zero month in the percentage moisture content of drug product, since in one of the trial batches its drop from 5.79% to 0.79% within one month.	Firm responds the requisite query.
7.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired.	Submitted

8.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted

Decision: Approved.

697.	Name, address of Applicant / Marketing Authorization Holder	M/s. Saffron Pharmaceuticals (Pvt.) Limited 19-km, Sheikhupura Road, Faisalabad
	Name, address of Manufacturing site.	M/s. Saffron Pharmaceuticals (Pvt.) Limited 19-km, Sheikhupura Road, Faisalabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 10833 : dated 02-05-2023
	Details of fee submitted	PKR 30,000/- : vide slip no.355926665049 dated 15-03-2023
	The proposed proprietary name / brand name	Lignocaine 1% Injection (3.5ml) IM
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Lidocaine Hydrochloride….10mg
	Pharmacotherapeutic Group of (API)	Local Anesthetic
	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	Lidocaine HCl 1% w/v Solution for Injection (MHRA Approved) 2ml,5ml,10ml,20ml
	For generic drugs (me-too status)	Anacaine 1% Injection of M/s. Akson (Reg.no. 052412) 2ml

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	1.5.8-15.9	Submit evidence of international approved reference of applied volume i.e. 3.5ml, since the submitted international reference and Me-Too evidence both are available in the volume size of 2ml,5ml,10ml or 20ml.
2.	3.2.S.4.1	• Submit specification of drug substance used for analysis by the drug product manufacturer. • Justify for not using sterile API for the manufacturing of injectable drug product, since the specification did not mention the test of sterility and Bacterial Endotoxin Test.
3.	3.2.S.4.2	Submit detailed analytical procedure used for analysis of drug substance by drug product manufacturer.
4.	3.2.S.4.3	Submit analytical method verification report of drug substance performed by drug product manufacturer.
5.	3.2.P.1	Justify the formulation without any excipient as submitted in section 3.2.P.1 of module 3

Decision of 339th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response of the Firm

S.no.	Observations/Deficiencies/ Short-comings	Reply of the Firm
1.	Submit evidence of international approved reference of applied volume i.e. 3.5ml, since the submitted international reference and Me-Too evidence both are available in the volume size of 2ml,5ml,10ml or 20ml.	Firm claimed that innovator product of rocephin injection 1gm IM injection (Ceftriaxone sodium) used with the diluent of 3.5ml, SmPc of rocephin injection is attached an evidence. Further, firm that claimed they will use this applied product as a diluent for their registered product Sonnet 1gm IM Injection.

2.	Submit specification of drug substance used for analysis by the drug product manufacturer.	Firm submitted the specification of drug substance.
3.	Justify for not using sterile API for the manufacturing of injectable drug product, since the specification did not include the test of sterility and Bacterial Endotoxin Test.	Firm in their reply explained the sterilization procedure of drug product instead of replying the relevant query.
4.	Submit detailed analytical procedure used for analysis of drug substance by drug product manufacturer.	Submitted
5.	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Submitted
6.	Justify the formulation without any excipient as submitted in section 3.2.P.1 of module 3	Firm claimed that there is no excipient used as it will be used as solvent with Ceftriaxone sodium 1gm IM injection. The firm has imported Lidocaine hydrochloride powder as an active pharmaceutical ingredient (API) for use in their formulation. To manufacture the liquid injection formulation from the powder, a solvent and pH adjuster are necessary. Therefore, further clarification from the firm regarding these components is required.

Decision of 340th meeting:
Deferred for clarification regarding the development of applied liquid injectable formulation without any excipient, since you have claimed in the drug substance part that the imported API is the Lidocaine hydrochloride powder. So, how the liquid formulation being developed from the powder API without adding any excipient.

Response of the Firm:
Firm submitted the amended formulation containing water for injection and active ingredient Lidocaine HCl (Powder) along with pH adjuster i.e. 1M NaOH. Furthermore, firm submitted the BMR of trial batches which evident that said formulation has been used to manufactured the liquid injectable.

Decision: Approved.

698.	Name, address of Applicant / Marketing Authorization Holder	M/s BJ Pharmaceuticals.18 Km, Mandialli Stop, Lahore-Sheikhupura Road, Lahore
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals.18 Km, Mandialli Stop, Lahore-Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No 18743 dated 25-07-2023
	Details of fee submitted	Rs.30,000/- dated 08-07-2023
	The proposed proprietary name / brand name	Bemol Forte 450/35 mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Paracetamol…450mg Orphenadrine Citrate…35mg
	Pharmacotherapeutic Group of (API)	Analgesic, Antipyretic and muscle relaxant.
	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	Norgesic Tablets, TGA approved.
	For generic drugs (me-too status)	Pauco Tablets by M/s Dew-max Pharma Rawat, Reg. No. 103597

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	1.5.9	The innovator product approved by TGA Australia, Norgesic Tablet, is uncoated, whereas your application is for a film-coated tablet. How can the innovator product be used as a reference for the applied formulation, when you mentioned in section 3.2.P.1 that the applied formulation is film coated tablet.
2.	3.2.S.4.3 Paracetamol	Submit analytical method verification report of drug substance performed by drug product manufacturer.
3.	3.2.S.4.4 Paracetamol	Justify for not including the Sulphated Ash test in the batch analysis report of drug substance by drug product manufacturer.
4.	3.2.S.4.3 Orphenadrine Citrate	Submit analytical method verification report of drug substance performed by drug product manufacturer.
5.	3.2.P.5.1	Justify for not including the content uniformity test in the specification of finished product. Further the time limit of dissolution test is also not mentioned in the acceptance criteria.
6.	3.2.P.5.2	Please provide a reference for the dissolution medium chosen for both active substances, as the most commonly recommended dissolution medium for paracetamol is pH 5.8, while you have selected a neutral pH for both APIs. Additionally, justify why water was not chosen as the dissolution medium, given that the final pH of your selected medium is neutral.
7.	3.2.P.5.4	Adapt the acceptance criteria of dissolution test in term of Q value along with time limit in which the pre-defined percentage release of both actives should be achieved.
8.	3.2.P.8.3	• Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. • Documents for the procurement of API with approval from DRAP (in case of import).
9.	3.2.R.1.1	Justify the dispensed quantity of ceftaroline fosamil injection with respect to the potency of active.

Decision of 340th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response of the Firm

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	The innovator product approved by TGA Australia, Norgesic Tablet, is uncoated, whereas your application is for a film-coated tablet. How can the innovator product be used as a reference for the applied formulation, when you mentioned in section 3.2.P.1 that the applied formulation is film coated tablet.	Firm replied that "We decided to use Norgesic Tablet as reference but it is uncoated and we want to apply for film coated tablet, therefore we change the reference tablet as Sinaxamol Tablet by AGP Pharma Karachi. Unfortunately, we previously written Norgesic in required documents mistakenly and forgot change it to Sinaxamol Tablet which is film coated tablet and we use as reference". However, the query is relevant to the approval status of applied film coated formulation in approved RRA,which is still not confirmed.
2.	<u>Paracetamol</u> Submit analytical method verification report of drug substance performed by drug product manufacturer.	Submitted
3.	Justify for not including the Sulphated Ash test in the batch analysis report of drug substance by drug product manufacturer.	Firm submitted the batch analysis report of drug substance performed by drug product manufacturer, in which result of Sulphated Ash test is also included.
4.	<u>Orphenadrine Citrate</u>	Submitted

	Submit analytical method verification report of drug substance performed by drug product manufacturer.	
5.	Justify for not including the content uniformity test in the specification of finished product. Further the time limit of dissolution test is also not mentioned in the acceptance criteria.	Firm replied that "We performed content uniformity test but mistakenly not added in specification, we added and attach specifications with the answer".
6.	Please provide a reference for the dissolution medium chosen for both active substances, as the most commonly recommended dissolution medium for paracetamol is pH 5.8, while you have selected a neutral pH for both APIs. Additionally, justify why water was not chosen as the dissolution medium, given that the final pH of your selected medium is neutral.	Firm replied that "We choose dissolution medium as water but mistakenly mention pH 7.0 buffer, we write correctly and SAP attach with the answer".
7.	Adapt the acceptance criteria of dissolution test in term of Q value along with time limit in which the pre-defined percentage release of both actives should be achieved.	Firm replied that Added Q limits with dissolution limits in the specification and attach with the answer.
8.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted invoice document of API Orphenadrine Citrate which is not endorsed/attested by the DRAP.
9.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Firm submitted the GMP certificate of both API Manufacturer.

Decision: Deferred for following points:

a. **Confirmation of approval status of applied formulation i.e. film coated tablet of Paracetamol…450mg /Orphenadrine Citrate…35mg combination in the approved reference regulatory agencies. Furthermore.**
b. **Confirmation of manufacturing status as suspended by QA&LT Division.**

699.	Name, address of Applicant / Marketing Authorization Holder	M/s BJ Pharmaceuticals.18 Km, Mandialli Stop, Lahore-Sheikhupura Road, Lahore
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals.18 Km, Mandialli Stop, Lahore-Sheikhupura Road, Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No 18744 dated 25-07-2023
	Details of fee submitted	Rs.30,000/- dated 08-07-2023
	The proposed proprietary name / brand name	Bemol Duo Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Paracetamol…500mg Ibuprofen…150mg
	Pharmacotherapeutic Group of (API)	Musculoskeletal system, anti-inflammatory and antirheumatic products, non-steroids, propionic acid derivatives. Ibuprofen combinations ATC Code: M01AE51
	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	TGA Australia approved formulation
	For generic drugs (me-too status)	NA

Evaluation by PEC-XV:

Differential fee for new molecule is need to be submitted by the Firm.

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.3 Paracetamol	Submit analytical method verification report of drug substance performed by drug product manufacturer.
2.	3.2.S.4.4 Paracetamol	Justify for not including the Sulphated Ash test in the batch analysis report of drug substance by drug product manufacturer.
3.	3.2.S.4.3 Ibuprofen	Submit analytical method verification report of drug substance performed by drug product manufacturer.
4.	3.2.P.5.1	Justify for not including the content uniformity test in the specification of finished product.
5.	3.2.P.5.2	• Provide reference of dissolution medium choose for the dissolution of both active substances. • Assay method given in section 3.2.P.5.2 indicate that method of simultaneous quantification of both active substance has developed while the verification report revealed that both active substance was quantified separately using two different UV wavelength, clarification is required in this regard. • Scientifically rationalize the initial amount of crushed powder of tablet taken for making final dilution of sample solution in both strength because its neither represent the total weight per tablet nor it's the claimed amount of both actives used in both formulations.
6.	3.2.P.5.4	Adapt the acceptance criteria of dissolution test in term of Q value along with time limit in which the pre-defined percentage release of both actives should be achieved.

Decision of 340th meeting of Registration Board:

Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response
1.	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Submitted
2.	Justify for not including the Sulphated Ash test in the batch analysis report of drug substance by drug product manufacturer.	Firm replied that they performed Sulphated ash test but mistakenly not added in the analysis report, revised batch analysis report is attached.
3.	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Submitted
4.	Justify for not including the content uniformity test in the specification of finished product.	Firm replied that they performed content uniformity test but mistakenly not added in the analysis report, revised batch analysis report is attached
5.	Provide reference of dissolution medium choose for the dissolution of both active substances.	Firm replied that they choose dissolution medium from ibuprofen suspension and tablet USP Monograph Vol-I and its pH 7.2 but mistakenly we write pH 7.0 in SAP, we write correctly and revised SAP is attached. However, the revised analytical testing method attached along with reply again specified that pH 7.0 is the dissolution medium for the dissolution testing of drug product.
6.	Assay method given in section 3.2.P.5.2 indicate that method of simultaneous quantification of both active substance has developed while the	Firm replied that in assay method we quantify both the actives at two different wavelengths but

	verification report revealed that both active substance was quantified separately using two different UV wavelength, clarification is required in this regard.	mistakenly instrumental conditions not mention in the procedure. However the revised assay method submitted along with reply did not reflect that both actives will be quantified separately nor mentioned the two wavelength in the assay method.
7.	Scientifically rationalize the initial amount of crushed powder of tablet taken for making final dilution of sample solution in both strength because its neither represent the total weight per tablet nor it's the claimed amount of both actives used in both formulations	Firm replied that we understand and we will follow accordingly. However, firm has to rationalize the initial amount of sample taken for making final dilution of sample solution in both strength.
8.	Adapt the acceptance criteria of dissolution test in term of Q value along with time limit in which the pre-defined percentage release of both actives should be achieved.	Firm replied that added Q limits with dissolution limit in the specification and attach with answer. However, the revised specification table did not mentioned the acceptance limit in terms of Q-value.

Decision: Deferred for submission of following shortcomings:

- **Confirmation of manufacturing status as suspended by QA&LT Division.**
- **Submit dissolution method of drug product that has actually been used for the quality analysis of drug product.**
- **Submit assay method of drug product with clearly outline the chromatographic conditions, which has been adopted for the quantification of both actives.**
- **Scientifically rationalize the initial amount of crushed powder of tablet taken for making final dilution of sample solution, because its neither represent the total weight per tablet nor it's the claimed amount of both actives used in both formulations.**
- **Adapt the acceptance criteria of dissolution test in term of Q value along with time limit in which the pre-defined percentage release of both actives should be achieved.**

700.	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)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No 18845 dated 26-07-2023
	Details of fee submitted	Rs.30,000/- dated 13-07-2023
	The proposed proprietary name / brand name	Linagliptin 5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Linagliptin…5mg
	Pharmacotherapeutic Group of (API)	Dipeptidyl peptidase-4 (DPP-4) inhibitor (Treatment for type 2 Diabetes Mellitus)
	Reference to Finished product specifications	Innovators specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Tradjenta 5mg film coated tablets USFDA Approved.
	For generic drugs (me-too status)	Linvesta 5mg Tablet by M/s Wilshire Laboratories (Reg#110608)

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.2	• Justify for using different assay method for analysis of drug substance by drug product manufacturer from that specified by the drug substance manufacturer, specifically with reference to mobile phase, diluting solution and concentration of sample and standard solution. • Justify for not including the enantiomeric purity test in the specification of drug substance, since the innovator product recommend to include the test in the specification of drug substance.
2.	3.2.P.5.1	• How can the target weight of coated tablet be kept 123.6mg, when the composition table given in section 3.2.P.1 shows that the final weight of tablet is 204.68mg per tablet. • Adapt the acceptance limit of dissolution in term of Q, since the innovator product approved in USFDA specify the limit with Q value i.e. (Q) at 30 minutes.
3.	3.2.P.5.2	Justify for keeping the media volume 500ml in the dissolution condition of finished product when the innovator product keep the media volume 900ml in their dissolution conditions.
4.	3.2.P.8	• Justify for not performing the uniformity of dosage unit test while performing the stability of drug product. • According to the raw data sheets of stability studies mobile phase of assay procedure was change at each time point, further, neither the ratio of mobile phase is similar to the ratio given in section 3.2.P.5.2, justification is required in this regard. • Please clarify the retention time of main peak eluted while performing the assay of drug product since it is fluctuated between 5.4 minutes to 7.7. minutes. • Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired. • Documents for the procurement of API with approval from DRAP (in case of import).

Decision of 340th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Justify for using different assay method for analysis of drug substance by drug product manufacturer from that specified by the drug substance manufacturer, specifically with reference to mobile phase, diluting solution and concentration of sample and standard solution.	Firm claimed that they used the same testing method for drug substance provided by drug substance manufacturer. However, firm has not provided any evidence which supports their reply.
2.	Justify for not including the enantiomeric purity test in the specification of drug substance, since the innovator product recommend to include the test in the specification of drug substance.	Firm submitted a declaration by drug substance manufacturer in which they stated that "the isomer impurities of Linagliptin, and based on the process validation of three batches of test results and stability study results, it is known that isomer impurities were not detected, so they were not included in the specification.
3.	How can the target weight of coated tablet be kept 123.6mg, when the composition table given in section 3.2.P.1 shows that the final weight of tablet is 204.68mg per tablet.	Firm replied that the target weight is 123.5mg/tablet and same in specification. The difference in weight given in section 3.2.P.1 is a typographical error.

4.	Adapt the acceptance limit of dissolution in term of Q, since the innovator product approved in USFDA specify the limit with Q value i.e. (Q) at 30 minutes.	Firm replied that they have changed the specification with dissolution limits NLT 85% (80%Q) of the labelled amount of Linagliptin is dissolved after 30 minutes.
5.	Justify for keeping the media volume 500ml in the dissolution condition of finished product when the innovator product keep the media volume 900ml in their dissolution conditions.	Firm claimed that they follow USFDA dissolution database, which referred to FDA's Dissolution Guidance, 2018 for Linagliptin tablet. The said guidance document recommends that *500 mL of medium is commonly used and is an appropriate volume of medium for a highly soluble, rapidly dissolving drug substance. The 500 mL dissolution medium should be an appropriate volume to provide sink conditions for dissolution of the high soluble drug.* However, the innovator review literature revealed the following dissolution condition for linagliptin tablet: USP Apparatus *I (Basket)* Speed 50 (rpm) Medium 0.1N HCl Volume 900 (mL) 37 °C ± 0.5 °C Acceptance criteria, Q= at 30 min
6.	Justify for not performing the uniformity of dosage unit test while performing the stability of drug product.	Firm refers the WHO guidelines, which recommends dissolution, disintegration, water content and hardness/friability for tablet dosage form. However, general chapter of USP *<2> ORAL DRUG PRODUCTS—PRODUCT QUALITY TESTS* recommends that *Uniformity of dosage units must be demonstrated by either content uniformity or weight variation* for tablet dosage form.
7.	According to the raw data sheets of stability studies mobile phase of assay procedure was change at each time point, further, neither the ratio of mobile phase is similar to the ratio given in section 3.2.P.5.2, justification is required in this regard.	Firm replied that analyst used the same method as provided in linagliptin 5mg tablet, the raw data is checked for mobile phase preparation and other parameters and found according to tablet testing method, may any change be due to error during raw data writing. However, firm has not submitted any document in support of their reply.
8.	Please clarify the retention time of main peak eluted while performing the assay of drug product since it is fluctuated between 5.4 minutes to 7.7. minutes.	The change in retention time is due to testing on different HPLC but within the test the retention time remained same and no effect on testing results.
9.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired.	Submitted
10.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted

Decision: Deferred for submission of following shortcomings:

- **Submit assay method of drug substance that has been used by the drug product manufacturer for the quality analysis of drug substance.**
- **Justify for not performing the uniformity of dosage unit test while performing the stability of drug product. Since, the general chapter of USP *<2> ORAL DRUG PRODUCTS—PRODUCT QUALITY***

***TESTS* recommends that *Uniformity of dosage units must be demonstrated by either content uniformity or weight variation* for tablet dosage form.**

- **According to the raw data sheets of stability studies mobile phase of assay procedure was change at each time point, further, neither the ratio of mobile phase is similar to the ratio given in section 3.2.P.5.2, justification is required in this regard along with supporting documents.**

701.	Name, address of Applicant / Marketing Authorization Holder	M/s Fortune Pharmaceuticals Private Limited Karachi
	Name, address of Manufacturing site.	M/s Fortune Pharmaceutical Private Limited Plot K/201 S.I.T.E. (SHW) Phase II, 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. 12392 dated 21/05/2022
	Details of fee submitted	PKR 30,000/-: dated 27/04/2022
	The proposed proprietary name / brand name	F -OMEZOL 20mg Gastro-resistance Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Omeprazole 22.5% Enteric coated pellets E.q to to Omeprazole 20mg
	Pharmaceutical form of applied drug	A Green cap with grey body size "3" hard Gelatin filled capsule having white pallets.
	Pharmacotherapeutic Group of (API)	Drugs for acid-related disorders, Proton pump inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size	1×14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved Omeprazole 20mg Gastro – resistant capsule MHRA
	For generic drugs (me-too status)	LOSEC CAPSUL 20 mg BARRETT HODGSON PAKISTAN (PVT) LTD
	GMP status of the Finished product manufacturer	New license granted on 21/02/2021 Tablet, Capsule (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	SAAKH PHARMA. Address: Plot # C -7/1, North West Industrial Zone, Karachi
	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 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 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (OME-EC – 22.5-001-19, OME-EC – 22.5-008-19, OME -EC – 22.5-009-19)
	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 LOSECCAPSULE 20 mg Capsule by BARRETT HODGSON PAKISTAN (PVT) LTD. performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is LOSEC CAPSULE 20 mg by BARRETT HODGSON PAKISTAN (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 verification studies have submitted including linearity, range, accuracy, precision, specificty.

STABILITY STUDY DATA	
Manufacturer of API	SAAKH PHARMA. Address: Plot # C -7/1, North West Industrial Zone,
API Lot No.	22GT2 2002
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, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	FE-001	FE-002	FE-003
Batch Size	1400 capsule	1400 capsule	1400 capsule
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	02-04-2021	02-04-2021	02-04-2021
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. Because of new DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP Certificate No. 83/2020-DRAP(K) dated 23-06-2022
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Local purchase from M/s. Saakh Pharma,Karachi
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	HPLC software 21CFR not Installed
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr.no.	Observations/Shortcomings	Reply of the Form
1.	Justify how you claim USP specification for drug substance, when the submitted analytical method is not in accordance with USP neither similar to the assay method of drug substance manufacturer. Further, the assay method given in section 3.2. S. 4.2 is different from the method which is validated in section 3.2.S.4.3, clarification is required in this regard.	Firm submitted the specification of drug substance by drug substance manufacturer which is also not incompliance of USP monograph.
2.	Clarification is required regarding the assay results of stability data of drug substance, either the quantity is of dried basis of omeprazole magnesium or the labelled amount of omeprazole, since the COA of drug substance claim the content of active on dried basis.	Firm submitted the stability data sheet of drug substance in which assay results are specified on dried basis, while in USP monograph the content of active should be quantify on the basis of labelled amount of omeprazole. Further the dissolution result of acidic stage has not been included in the stability data sheet of the drug substance.
3.	Provide complete method of dissolution testing along with details of HPLC parameters used during the dissolution testing of drug product in line with USP.	Firm has not submitted the reply in response of this query.
4.	Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.	Firm has not submitted the analytical verification report of drug product.
5.	Performance of comparative dissolution profile is not in accordance with guidelines approved in 293rd meeting of Registration Board with reference to following points:	Firm submitted the revised Comparative dissolution profile data in which all 12 units of both test product and reference shows below 65% release in pH 6.8 medium till 45 minutes while the dissolution results

	✓ For f2 calculations a minimum of three time points (excluding point zero) must be used; mentioned the time point which were considered for the calculation of f2 value. ✓ A maximum of one time-point should be considered after 85% dissolution of the innovator / reference product has been reached; but as per the submitted documents you have used all time point until 30minutes, which are all below 85%. Clarify how you have calculated the f2 without considering the time point after 85% drug release.	of stability data reveals that more than 90% drug release at pH 6.8 medium within 30 minutes.
6.	Clarify, why you have not mentioned the results of dissolution test in acidic medium in the stability data of drug product. Further, the specification of dissolution test did not mention the time limit in which NLT 75% (Q) should be achieved.	Firm has submitted the revised stability data in which results of assay of esomeprazole has been mentioned instead of omeprazole.

Decision of 322nd meeting of Registration Board:

Deferred for submission of following:

- Justify how you claim USP specification for drug substance, when the submitted analytical method is not in accordance with USP neither similar to the assay method of drug substance manufacturer. Further, the assay method given in section 3.2. S. 4.2 is different from the method which is validated in section 3.2.S.4.3, clarification is required in this regard.
- Stability data sheet of drug substance including the results of dissolution test of acidic stage.
- Provide complete method of dissolution testing along with details of HPLC parameters used during the dissolution testing of drug product in line with USP.
- Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.
- Justify the dissolution results of stability data in which more than 90% drug release at pH 6.8 medium within 30 minutes, while the revised Comparative dissolution profile data evident that both test product and reference product release below 65% in pH 6.8 medium till 45 minutes.
- Revised stability data of drug product specify the results of assay of esomeprazole, clarification is required in this regard.

Response of the Firm:

Sr.no.	Decision of 322nd meeting	Response of the Firm
1.	Justify how you claim USP specification for drug substance, when the submitted analytical method is not in accordance with USP neither similar to the assay method of drug substance manufacturer. Further, the assay method given in section 3.2. S. 4.2 is different from the method which is validated in section 3.2.S.4.3, clarification is required in this regard.	In the reply firm has only submitted the copy of USP monograph of omeprazole without any clarification and verification studies.
2.	Stability data sheet of drug substance including the results of dissolution test of acidic stage.	The firm submitted stability data for the drug substance covering only 6 months, which includes the results of the dissolution test for the acidic stage.
3.	Provide complete method of dissolution testing along with details of HPLC parameters used during the dissolution testing of drug product in line with USP.	Submitted

4.	Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.	Firm submitted the analytical verification report which is not in accordance with USP Monograph of "*Omeprazole Delayed-Release Capsules".*
5.	Justify the dissolution results of stability data in which more than 90% drug release at pH 6.8 medium within 30 minutes, while the revised Comparative dissolution profile data evident that both test product and reference product release below 65% in pH 6.8 medium till 45 minutes.	Firm submitted the CDP report of omeprazole delayed release capsule showing that more than 80% drug release at acidic pH, while the release pattern at pH 6.8 reflects that less than 80% drug release within 30 minutes, since the USP monograph of omeprazole delayed release recommends that NLT 75%(Q) of drug release within 30 minutes.
6.	Revised stability data of drug product specify the results of assay of esomeprazole, clarification is required in this regard.	Firm submitted the stability data of drug product without the results of dissolution test performed at acidic stage

Decision of 340th meeting of Registration Board:

Deferred for submission of following shortcomings:

- Justify how you claim USP specification for drug substance, when the submitted analytical method is not in accordance with USP neither similar to the assay method of drug substance manufacturer. Further, the assay method given in section 3.2. S. 4.2 is different from the method which is validated in section 3.2.S.4.3, clarification is required in this regard.
- Submit stability data of drug substance including all the test of reference specification till the claimed re-test date.
- Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.
- Provide a scientific justification for the release pattern of the drug product at acidic pH as evident from the submitted CDP report, where more than 80% of the drug is released, despite the formulation consisting of enteric-coated pellets.
- Submit the stability data of drug product including all the test mentioned in the finished product specification.

Response of the Firm:

Sr.no.	Decision of 340th meeting	Response of the Firm
1.	Justify how you claim USP specification for drug substance, when the submitted analytical method is not in accordance with USP neither similar to the assay method of drug substance manufacturer. Further, the assay method given in section 3.2. S. 4.2 is different from the method which is validated in section 3.2.S.4.3, clarification is required in this regard.	Firm replied that as we previously not further reviewed our documents that's the main reason we submitted API Specification and testing method (Omeprazole) instead of Omeprazole Delayed Release 2 Capsule, so we have revised our Specification and Testing Method as per USP Specification. However, the API of applied formulation is delayed release pellets while firm submitted the analytical procedure of finished product in their reply.
2.	Submit stability data of drug substance including all the test of reference specification till the claimed re-test date.	Submitted
3.	Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.	Submitted
4.	Provide a scientific justification for the release pattern of the drug product at acidic pH as evident from the submitted CDP report, where more than 80% of the drug is released, despite the formulation consisting of enteric-coated pellets.	Firm in their reply state that "*As we previously not further reviewed our documents that's the main reason we submitted in-correct file, now we are submitting correct file as per WHO Dissolution profiling".*

	5.	Submit the stability data of drug product including all the test mentioned in the finished product specification.	Submitted

Decision: Approved. Firm shall submit specifications and analytical procedure of drug substance used by the drug product manufacturer, before issuance of registration letter.

702.	Name, address of Applicant / Marketing Authorization Holder	M/s Fortune Pharmaceuticals Private Limited Karachi
	Name, address of Manufacturing site.	M/s Fortune Pharmaceutical Private Limited Plot K/201 S.I.T.E. (SHW) Phase II, 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. 12393 dated 21/05/2022
	Details of fee submitted	PKR 30,000/-: dated 27/04/2022
	The proposed proprietary name / brand name	**F -OMEZOL 40mg Gastro-resistance Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Omeprazole 22.5% Enteric coated pellets E.q to to Omeprazole 40mg
	Pharmaceutical form of applied drug	A Green cap with grey body size “3” hard Gelatin filled capsule having white pallets.
	Pharmacotherapeutic Group of (API)	Drugs for acid-related disorders, Proton pump inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size	1×14’s
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved Omeprazole 40mg Gastro – resistant capsule MHRA
	For generic drugs (me-too status)	LOSEC CAPSUL 40 mg BARRETT HODGSON PAKISTAN (PVT) LTD
	GMP status of the Finished product manufacturer	New license granted on 21/02/2021 Tablet, Capsule (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	SAAKH PHARMA. Address: Plot # C -7/1, North West Industrial Zone,
	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 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 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (OME-EC – 22.5-001-19, OME-EC – 22.5-008-19, OME -EC – 22.5-009-19)
	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 LOSEC CAPSULE 40 mg Capsule by BARRETT HODGSON PAKISTAN (PVT) LTD. performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is LOSEC CAPSULE 40 mg by BARRETT HODGSON PAKISTAN (PVT) LTD in all three physiological mediums. 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, specificty.

STABILITY STUDY DATA	
Manufacturer of API	SAAKH PHARMA. Address: Plot # C -7/1, North West Industrial Zone,
API Lot No.	22GT2 2002
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, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)

Batch No.	FE-001	FE-002	FE-003
Batch Size	1400 capsule	1400 capsule	1400 capsule
Manufacturing Date	04-2021	04-2021	04-2021
Date of Initiation	02-04-2021	02-04-2021	02-04-2021
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. Because of new DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP Certificate No. 83/2020-DRAP(K) dated 23-06-2022
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Local purchase from M/s. Saakh Pharma, Karachi
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	HPLC software 21CFR not Installed
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks of Evaluator:

Sr.no.	Observations/Shortcomings	Reply of the Form
1.	Justify how you claim USP specification for drug substance, when the submitted analytical method is not in accordance with USP neither similar to the assay method of drug substance manufacturer. Further, the assay method given in section 3.2. S. 4.2 is different from the method which is validated in section 3.2.S.4.3, clarification is required in this regard.	Firm submitted the specification of drug substance by drug substance manufacturer which is also not incompliance of USP monograph.
2.	Clarification is required regarding the assay results of stability data of drug substance, either the quantity is of dried basis of omeprazole magnesium or the labelled amount of omeprazole, since the COA of drug substance claim the content of active on dried basis.	Firm submitted the stability data sheet of drug substance in which assay results are specified on dried basis, while in USP monograph the content of active should be quantify on the basis of labelled amount of omeprazole. Further the dissolution result of acidic stage has not been included in the stability data sheet of the drug substance.
3.	Provide complete method of dissolution testing along with details of HPLC parameters used during the dissolution testing of drug product in line with USP.	Firm has not submitted the reply in response of this query.
4.	Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.	Firm has not submitted the analytical verification report of drug product.
5.	Performance of comparative dissolution profile is not in accordance with guidelines	Firm submitted the revised Comparative dissolution profile data in which all 12 units of both test product and reference shows below 65% release in pH 6.8

	approved in 293rd meeting of Registration Board with reference to following points: ✓ For f2 calculations a minimum of three time points (excluding point zero) must be used; mentioned the time point which were considered for the calculation of f2 value. ✓ A maximum of one time-point should be considered after 85% dissolution of the innovator / reference product has been reached; but as per the submitted documents you have used all time point until 30minutes, which are all below 85%. Clarify how you have calculated the f2 without considering the time point after 85% drug release.	medium till 45 minutes while the dissolution results of stability data reveals that more than 90% drug release at pH 6.8 medium within 30 minutes.
6.	Clarify, why you have not mentioned the results of dissolution test in acidic medium in the stability data of drug product. Further, the specification of dissolution test did not mention the time limit in which NLT 75% (Q) should be achieved.	Firm has submitted the revised stability data in which results of assay of esomeprazole has been mentioned instead of omeprazole.

Decision of 322nd meeting of Registration Board:

Deferred for submission of following:

- Justify how you claim USP specification for drug substance, when the submitted analytical method is not in accordance with USP neither similar to the assay method of drug substance manufacturer. Further, the assay method given in section 3.2. S. 4.2 is different from the method which is validated in section 3.2.S.4.3, clarification is required in this regard.
- Stability data sheet of drug substance including the results of dissolution test of acidic stage.
- Provide complete method of dissolution testing along with details of HPLC parameters used during the dissolution testing of drug product in line with USP.
- Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.
- Justify the dissolution results of stability data in which more than 90% drug release at pH 6.8 medium within 30 minutes, while the revised Comparative dissolution profile data evident that both test product and reference product release below 65% in pH 6.8 medium till 45 minutes.
- Revised stability data of drug product specify the results of assay of esomeprazole, clarification is required in this regard.

Response of the Firm

Sr.no.	Decision of 322nd meeting	Response of the Firm
1.	Justify how you claim USP specification for drug substance, when the submitted analytical method is not in accordance with USP neither similar to the assay method of drug substance manufacturer. Further, the assay method given in section 3.2. S. 4.2 is different from the method which is validated in section 3.2.S.4.3, clarification is required in this regard.	In the reply firm has only submitted the copy of USP monograph of omeprazole without any clarification and verification studies.
2.	Stability data sheet of drug substance including the results of dissolution test of acidic stage.	The firm submitted stability data for the drug substance covering only 6 months, which includes the results of the dissolution test for the acidic stage.
3.	Provide complete method of dissolution testing along with details of HPLC	Submitted

	parameters used during the dissolution testing of drug product in line with USP.	
4.	Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.	Firm submitted the analytical verification report which is not in accordance with USP Monograph of "*Omeprazole Delayed-Release Capsules".*
5.	Justify the dissolution results of stability data in which more than 90% drug release at pH 6.8 medium within 30 minutes, while the revised Comparative dissolution profile data evident that both test product and reference product release below 65% in pH 6.8 medium till 45 minutes.	Firm submitted the CDP report of omeprazole delayed release capsule showing that more than 80% drug release at acidic pH, while the release pattern at pH 6.8 reflects that less than 80% drug release within 30 minutes, since the USP monograph of omeprazole delayed release recommends that NLT 75%(Q) of drug release within 30 minutes.
6.	Revised stability data of drug product specify the results of assay of esomeprazole, clarification is required in this regard.	Firm submitted the stability data of drug product without the results of dissolution test performed at acidic stage

Decision of 340th meeting of Registration Board:

Deferred for submission of following shortcomings:

- Justify how you claim USP specification for drug substance, when the submitted analytical method is not in accordance with USP neither similar to the assay method of drug substance manufacturer. Further, the assay method given in section 3.2. S. 4.2 is different from the method which is validated in section 3.2.S.4.3, clarification is required in this regard.
- Submit stability data of drug substance including all the test of reference specification till the claimed re-test date.
- Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.
- Provide a scientific justification for the release pattern of the drug product at acidic pH as evident from the submitted CDP report, where more than 80% of the drug is released, despite the formulation consisting of enteric-coated pellets.
- Submit the stability data of drug product including all the test mentioned in the finished product specification.

Sr.no.	Decision of 340th meeting	Response of the Firm
1.	Justify how you claim USP specification for drug substance, when the submitted analytical method is not in accordance with USP neither similar to the assay method of drug substance manufacturer. Further, the assay method given in section 3.2. S. 4.2 is different from the method which is validated in section 3.2.S.4.3, clarification is required in this regard.	Firm replied that as we previously not further reviewed our documents that's the main reason we submitted API Specification and testing method (Omeprazole) instead of Omeprazole Delayed Release 2 Capsule, so we have revised our Specification and Testing Method as per USP Specification. However, the API of applied formulation is delayed release pellets while firm submitted the analytical procedure of finished product in their reply.
2.	Submit stability data of drug substance including all the test of reference specification till the claimed re-test date.	Submitted
3.	Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.	Submitted. However, the same analytical verification report has been submitted for both 20mg and 40mg capsule.
4.	Provide a scientific justification for the release pattern of the drug product at acidic pH as evident from the submitted CDP report, where more than 80% of the drug is released, despite the formulation consisting of enteric-coated pellets.	Firm in their reply state that "*As we previously not further reviewed our documents that's the main reason we submitted in-correct file, now we are submitting correct file as per WHO Dissolution profiling".*

	5.	Submit the stability data of drug product including all the test mentioned in the finished product specification.	Submitted

Decision: Approved. Firm shall submit specifications and analytical procedure of drug substance used by the drug product manufacturer, before issuance of registration letter.

703.	Name, address of Applicant / Marketing Authorization Holder	M/s Fortune Pharmaceuticals Private Limited Karachi
	Name, address of Manufacturing site.	M/s Fortune Pharmaceutical Private Limited Plot K/201 S.I.T.E. (SHW) Phase II, 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. 12391 dated 21/05/2022
	Details of fee submitted	PKR 30,000/-: dated 27/04/2022
	The proposed proprietary name / brand name	F -EZOLE 40mg Gastro resistant Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Esomeperazole Magnisium Trihydrate E.q to to Esomeperazole 40mg
	Pharmaceutical form of applied drug	A dark blue cap with blue body size "3" hard Gelatin filled capsule having white pallets.
	Pharmacotherapeutic Group of (API)	Drugs for acid-related disorders, Proton pump inhibitors
	Reference to Finished product specifications	USP
	Proposed Pack size	1×14's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	NEXIUM 40mg Capsule USFDA. Esomeprazole 40mg Gastro – resistant capsule MHRA
	For generic drugs (me-too status)	ACIREG CAPSUL 40 mg BARRETT HODGSON PAKISTAN (PVT) LTD
	GMP status of the Finished product manufacturer	New license granted on 21/02/2021 Tablet, Capsule (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	SAAKH PHARMA. Address: Plot # C -7/1, North West Industrial Zone,Karachi
	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 Esomeprazole Mg 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 36 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (ESO-EC – 22.5-001-19, ESO-EC – 22.5-002-19, ESO-EC – 22.5-003-19)
	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 ACIREG CAPSULE 40 mg Capsule by BARRETT HODGSON PAKISTAN (PVT) LTD. performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is ACIREG CAPSULE 40 mg by BARRETT HODGSON PAKISTAN (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 verification studies have submitted including linearity, range, accuracy, precision, specificty.

STABILITY STUDY DATA	
Manufacturer of API	SAAKH PHARMA. Address: Plot # C -7/1, North West Industrial Zone,
API Lot No.	21GT1 2003
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, 2, 4, 6 (Months)

	Real Time: 0, 3, 6 (Months)		
Batch No.	FE-001	FE-002	FE-003
Batch Size	1400 capsule	1400 capsule	1400 capsule
Manufacturing Date	03-2021	03-2021	03-2021
Date of Initiation	02-03-2021	02-03-2021	02-03-2021
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 not submitted any document. Because of new DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP Certificate No. 83/2020-DRAP(K) dated 23-06-2022
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Local purchase from M/s. Saakh Pharma, Karachi
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	HPLC software 21CFR not Installed
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr.no.	Observations/Shortcomings	Reply of the Form
1.	Justify how you claim USP specification for drug substance, when the submitted analytical method is not in accordance with USP neither similar to the assay method of drug substance manufacturer. Further, the assay method given in section 3.2. S. 4.2 is different from the method which is validated in section 3.2.S.4.3, clarification is required in this regard.	Firm submitted the specification of drug substance by drug substance manufacturer which is also not incompliance of USP monograph with reference to the assay results.
2.	Provide COA of primary / secondary reference standard including source and lot number used for testing of drug substance.	Firm submitted the COA of working standard of Esomeprazole, while the USP recommends Omeprazole RS for the assay testing of Esomeprazole delayed release capsule.
3.	Clarification is required regarding the assay results of stability data of drug substance, either the quantity is of dried basis of omeprazole magnesium or the labelled amount of omeprazole, since the COA of drug substance claim the content of active on dried basis.	Firm submitted the stability data sheet of drug substance in which assay results are specified on anhydrous basis, while in USP monograph the content of active should be quantify on the basis of labelled amount of Esomeprazole. Further the dissolution result of acidic stage has not been included in the stability data sheet of the drug substance.
4.	Provide complete method of dissolution testing along with details of HPLC parameters used during the dissolution testing of drug product in line with USP.	Firm has submitted the reply in response of this query.
5.	Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.	Firm has not submitted the analytical verification report of drug product neither the drug substance.

6.	Performance of comparative dissolution profile is not in accordance with guidelines approved in 293rd meeting of Registration Board with reference to following points: ✓ For f2 calculations a minimum of three time points (excluding point zero) must be used; mentioned the time point which were considered for the calculation of f2 value. ✓ A maximum of one time-point should be considered after 85% dissolution of the innovator / reference product has been reached; but as per the submitted documents you have used all time point until 30minutes, which are all below 85%. Clarify how you have calculated the f2 without considering the time point after 85% drug release.	Firm submitted the revised Comparative dissolution profile data in which all 12 units of both test product and reference shows below 65% release in pH 6.8 medium till 45 minutes while the dissolution results of stability data reveals that more than 90% drug release at pH 6.8 medium within 30 minutes.
7.	Clarify, why you have not mentioned the results of dissolution test in acidic medium in the stability data of drug product. Further, the specification of dissolution test did not mention the time limit in which NLT 75% (Q) should be achieved.	Firm has submitted the revised stability data in which more than 90% drug release at buffer stage within 30 minutes.
8.	Raw data sheets of dissolution testing and assay testing have not been attached in section 3.2. P.8., provide raw data sheet to analyse the result of dissolution and assay. Firm has submitted the raw data sheets and chromatograms of dissolution and assay testing, which evident that the assay was not performed in comply with USP specification in term of sample and standard solution conc and the total run time which is consist of 25 minutes' gradient elution program. Further, the chromatogram of standard evident that the esomeprazole has been used as a standard, while USP monograph recommends omeprazole RS for the Esomeprazole capsule.	
9.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted

Decision: Deferred for submission of following:

- Justify how you claim USP specification for drug substance, when the submitted analytical method is not in accordance with USP neither similar to the assay method of drug substance manufacturer. Further, the assay method given in section 3.2. S. 4.2 is different from the method which is validated in section 3.2.S.4.3, clarification is required in this regard.
- Scientific justification for use of Esomeprazole as reference standard in analytical procedures instead of Omeprazole RS as specified by USP monograph.
- Stability data sheet of drug substance including the results of dissolution test of acidic stage.
- Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.
- Justify the dissolution results of stability data in which more than 90% drug release at pH 6.8 medium within 30 minutes, while the revised Comparative dissolution profile data evident that both test product and reference product release below 65% in pH 6.8 medium till 45 minutes.
- Scientific justification for using assay method different from that specified in USP monograph in term of gradient program, total run time and reference standard.
- Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

Sr.no.	Decision of 322nd meeting	Response of the Firm
1.	Justify how you claim USP specification for drug substance, when the submitted analytical method is not in accordance with USP neither similar to the assay method of drug substance manufacturer. Further, the assay method given in section	In the reply firm has only submitted the copy of USP monograph of omeprazole without any clarification and verification studies.

	3.2. S. 4.2 is different from the method which is validated in section 3.2.S.4.3, clarification is required in this regard.	
2.	Scientific justification for use of Esomeprazole as reference standard in analytical procedures instead of Omeprazole RS as specified by USP monograph.	There was a typographical mistake we have used Omeprazole RS as specified by USP monograph.
3.	Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.	Firm submitted the analytical verification of drug product in which again esomeprazole reference standard has been used instead of omeprazole reference standard as recommended by USP.
4.	Stability data sheet of drug substance including the results of dissolution test of acidic stage.	The firm submitted stability data for the drug substance covering only 6 months, which includes the results of the dissolution test for the acidic stage.
5.	Provide complete method of dissolution testing along with details of HPLC parameters used during the dissolution testing of drug product in line with USP.	Submitted
6.	Justify the dissolution results of stability data in which more than 90% drug release at pH 6.8 medium within 30 minutes, while the revised Comparative dissolution profile data evident that both test product and reference product release below 65% in pH 6.8 medium till 45 minutes.	Firm submitted the CDP report of omeprazole delayed release capsule showing that more than 80% drug release at acidic pH, while the release pattern at pH 6.8 reflects that less than 80% drug release within 30 minutes, since the USP monograph of omeprazole delayed release recommends that NLT 75%(Q) of drug release within 30 minutes.
7.	Revised stability data of drug product specify the results of assay of esomeprazole, clarification is required in this regard.	Firm submitted the stability data of drug product without the results of dissolution test performed at acidic stage

Decision of 340th meeting of Registration Board:

Deferred for submission of following shortcomings:

- Justify how you claim USP specification for drug substance, when the submitted analytical method is not in accordance with USP neither similar to the assay method of drug substance manufacturer. Further, the assay method given in section 3.2. S. 4.2 is different from the method which is validated in section 3.2.S.4.3, clarification is required in this regard.
- Submit stability data of drug substance including all the test of reference specification till the claimed re-test date.
- Scientific justification for use of Esomeprazole as reference standard in verification of analytical procedures instead of Omeprazole RS as specified by USP monograph.
- Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.
- Provide a scientific justification for the release pattern of the drug product at acidic pH as evident from the submitted CDP report, where more than 80% of the drug is released, despite the formulation consisting of enteric-coated pellets.
- Submit the stability data of drug product including all the test mentioned in the finished product specification.

Response of the Firm:

Sr.no.	Decision of 340th meeting	Response of the Firm
1.	Justify how you claim USP specification for drug substance, when the submitted analytical method is not in accordance with USP neither similar to the assay method of drug substance manufacturer. Further, the assay method given in section 3.2. S. 4.2 is different from the method which is validated in section 3.2.S.4.3, clarification is required in this regard.	Firm replied that as we previously not further reviewed our documents that's the main reason we submitted API Specification and testing method (Omeprazole) instead of Omeprazole Delayed Release 2 Capsule, so we have revised our Specification and Testing Method as per USP Specification. However, the API of applied formulation is delayed release pellets while firm submitted the

		analytical procedure of finished product in their reply.
2.	Submit stability data of drug substance including all the test of reference specification till the claimed re-test date.	Firm submit the stability data of drug substance, in which one of the tests is Gastric resistant with the acceptance criteria of NLT 90%, which seems that it is the dissolution test performed at acid resistant stage. However, the limits of dissolution test performed at acid resistant stage should be NMT 10% for delayed release pellets.
3.	Scientific justification for use of Esomeprazole as reference standard in verification of analytical procedures instead of Omeprazole RS as specified by USP monograph.	Firm replied that, it was Human error / typographical error instead of Omeprazole we typed Esomeprazole.
4.	Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.	Submitted
5.	Provide a scientific justification for the release pattern of the drug product at acidic pH as evident from the submitted CDP report, where more than 80% of the drug is released, despite the formulation consisting of enteric-coated pellets.	Firm in their reply state that "*As we previously not further reviewed our documents that's the main reason we submitted in-correct file, now we are submitting correct file as per WHO Dissolution profiling".*
6.	Submit the stability data of drug product including all the test mentioned in the finished product specification.	Firm submitted the stability data of drug product in which the results of dissolution test performed at acid resistant stage has not been included.

Decision: Deferred for the submission of following shortcomings:

- **Submit specification and analytical procedure of drug substance that has been used by the drug product manufacturer for the quality analysis of drug substance.**
- **Clarification is required regarding the mentioned acceptance limit of gastric resistant stage i.e. NLT 90% in the stability data sheets of drug substance, since the limits of dissolution test performed at acid resistant stage for delayed release pellets should be NMT 10%.**
- **Submit the stability data of drug product including all the test mentioned in the finished product specification.**

704.	Name, address of Applicant / Marketing Authorization Holder	M/s Fortune Pharmaceuticals Private Limited Karachi
	Name, address of Manufacturing site.	M/s Fortune Pharmaceutical Private Limited Plot K/201 S.I.T.E. (SHW) Phase II, 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.12972 dated 27/05/2022
	Details of fee submitted	PKR 30,000/-: dated 27/04/2022
	The proposed proprietary name / brand name	Fungazole 150mg Capsule
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule contains: Fluconazole...150mg
	Pharmaceutical form of applied drug	A dark blue cap with blue body size "3" hard Gelatin filled capsule having white pallets.

	Pharmacotherapeutic Group of (API)	Antifungal
	Reference to Finished product specifications	BP
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	MHRA approved
	For generic drugs (me-too status)	Zolanix 150mg capsule of M/s. Glaxo smithkline,Karachi
	GMP status of the Finished product manufacturer	New license granted on 21/02/2021 Tablet (General & General Antibiotic) section approved.
	Name and address of API manufacturer.	Hema Pharmaceuticals Plot no.6201/A&B Opp. Ewac Alloys Ltd. GIDC Ankleshwar,Gujrat,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 Fluconazole 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 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (12PDFC001,12PDFC002,12PDFC003)
	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 comparator product that is Flozex capsule of M/S. Martin Dow Pharmaceuticals Pvt. Ltd,Karachi Batch no. 225 expiry date 03-2023. performing quality tests (Identification, Assay, Dissolution, Uniformity of dosage form). CDP has been performed against the same brand that is Flozex capsule of M/S. Martin Dow Pharmaceuticals Pvt. Ltd,Karachi Batch no. 225

		expiry date 03-2023.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 verification studies have submitted including linearity, range, accuracy, precision, specificty.

STABILITY STUDY DATA

Manufacturer of API	Hema Pharmaceuticals Plot no.6201/A&B Opp. Ewac Alloys Ltd. GIDC Ankleshwar,Gujrat,India		
API Lot No.	Not mentioned		
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, 2, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	FL-001	FL-002	FL-003
Batch Size	1500 capsule	1500 capsule	1500 capsule
Manufacturing Date	10-2021	10-2021	10-2021
Date of Initiation	25-10-2021	25-10-2021	25-10-2021
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. Because of new DML
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	GMP Certificate No. S-GMP/2062028 dated 12-06-2020 valid till 11/06/2022
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Consignment slip and DHL courier slip has been attached only
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	HPLC software 21CFR not Installed
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted

Remarks OF Evaluator:

Sr.no.	Observations/Shortcomings	Reply of the Form
1.	Clarify the specification of drug product since the JP monograph of fluconazole capsule is not applicable for 150mg strength. Revise your specification along with the requisite fee.	Firm submitted the revised specification of drug product which is neither in comply of BP monograph nor in compliance of JP.
2.	The validation of analytical procedure has been performed using assay method (HPLC) with flow rate 1.0ml/min, column temperature 35°C, UV detector set at 261nm	Not submitted

	and mobile phase sodium acetate: methanol: acetonitrile while USP recommended flow rate 0.5ml/min, column temperature 40°C, UV detector 260nm and mobile phase Acetonitrile and water (20:80). Justify, how have comply USP specification by keeping the chromatographic condition different from USP monograph of fluconazole.	
3.	Clarify, how you have performed accuracy parameter in the verification studies of drug substance that, despite spiking the sample 25%,50%,75%,100%,125% and 150%, the amount of fluconazole has not been changed in all these spiked sample.	Not submitted any reply of this query
4.	Identification test specified on the COA of working standard of fluconazole attached in section 3.2.S.5 stated that IR absorption spectrum of test solution should be concordant with that of clotrimazole working standard, clarification is required in this regard. Further, the COA reflect that batch qualified against Indian pharmacopeia reference standard, justify how you can standardize the drug substance that comply with USP specification to the working standard that qualified against Indian pharmacopeia.	.Not submitted any reply of this query
5.	Scientific justification is required for using 3mg overage of active substance as evident from the composition given in section 3.2. P.1.	Firm has not submitted any reply.
6.	Clarify, that the dissolution method given in section 3.2.P.5.2 is different from the method via which dissolution has been performed in section 3.2.P.2.2.1 for comparative dissolution profile of drug product.	Firm submitted the revised Comparative dissolution profile in which the dissolution were not in accordance with BP monograph.
7.	• Justify selection of dissolution parameters i.e. USP apparatus-II paddle with 50rpm, water as dissolution medium and acceptance criteria NLT 75% of the labeled amount of the claim content, since JP monograph of fluconazole capsule is recommending the dissolution testing for 50mg and 100mg fluconazole capsule strength. • Justify the variation in dissolution parameters in different section of dossier, acceptance limit specified in section 3.2.P.5.2 is NLT 75% in 45 minutes while the dissolution specifications mentioned on batch analysis report is NLT 80%.	Firm has not submitted any justification regarding these queries.
8.	Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.	Not submitted.
9.	Justify the weight of sample between 33-34mg, while as per the analytical method given in section 3.2.P.5.2 the weight of	Not submitted

	content equivalent to 50mg of fluconazole should be taken initially for preparation of final dilution of sample solution.	
10.	Provide COA of primary / secondary reference standard including source and lot number used for testing of drug product.	Not submitted
11.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Not submitted

Decision of 322nd meeting: Deferred for submission of following:

- Clarify the specification of drug product since the JP monograph of fluconazole capsule is not applicable for 150mg strength. Revise your specification along with the requisite fee.
- The validation of analytical procedure has been performed using assay method (HPLC) with flow rate 1.0ml/min, column temperature 35°C, UV detector set at 261nm and mobile phase sodium acetate: methanol: acetonitrile while USP recommended flow rate 0.5ml/min, column temperature 40°C, UV detector 260nm and mobile phase Acetonitrile and water (20:80). Justify, how have comply USP specification by keeping the chromatographic condition different from USP monograph of fluconazole.
- Clarify, how you have performed accuracy parameter in the verification studies of drug substance that, despite spiking the sample 25%,50%,75%,100%,125% and 150%, the amount of fluconazole has not been changed in all these spiked sample.
- Identification test specified on the COA of working standard of fluconazole attached in section 3.2.S.5 stated that IR absorption spectrum of test solution should be concordant with that of clotrimazole working standard, clarification is required in this regard. Further, the COA reflect that batch qualified against Indian pharmacopeia reference standard, justify how you can standardize the drug substance that comply with USP specification to the working standard that qualified against Indian pharmacopeia.
- Justify, for adopting the dissolution parameter specified in JP monograph, since the JP monograph recommends the acceptance limits for 50mg and 100g fluconazole strength.
- Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.
- Provide COA of primary / secondary reference standard including source and lot number used for testing of drug product.
- Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

Response of the Firm:

Sr.no.	Decision of 322nd meeting of Registration Board	Response of the Firm
1.	Clarify the specification of drug product since the JP monograph of fluconazole capsule is not applicable for 150mg strength. Revise your specification along with the requisite fee.	Firm submitted the copy of monograph of fluconazole drug substance instead of replying about the specification of drug product.
2.	The validation of analytical procedure has been performed using assay method (HPLC) with flow rate 1.0ml/min, column temperature 35°C, UV detector set at 261nm and mobile phase sodium acetate: methanol: acetonitrile while USP recommended flow rate 0.5ml/min, column temperature 40°C, UV detector 260nm and mobile phase Acetonitrile and water (20:80). Justify, how have comply USP specification by keeping the chromatographic condition different from USP monograph of fluconazole.	Not submitted the reply of this query.
3.	Clarify, how you have performed accuracy parameter in the verification studies of drug substance that, despite	Not submitted the reply of this query.

	spiking the sample 25%,50%,75%,100%,125% and 150%, the amount of fluconazole has not been changed in all these spiked sample.	
4.	Identification test specified on the COA of working standard of fluconazole attached in section 3.2.S.5 stated that IR absorption spectrum of test solution should be concordant with that of clotrimazole working standard, clarification is required in this regard. Further, the COA reflect that batch qualified against Indian pharmacopeia reference standard, justify how you can standardize the drug substance that comply with USP specification to the working standard that qualified against Indian pharmacopeia.	Submitted the COA of working standard of fluconazole.
5.	Justify, for adopting the dissolution parameter specified in JP monograph, since the JP monograph recommends the acceptance limits for 50mg and 100g fluconazole strength.	Not submitted the reply of this query.
6.	Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.	Firm submitted the verification report.
7.	Provide COA of primary / secondary reference standard including source and lot number used for testing of drug product.	Not submitted the reply of this query.
8.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Firm replied that, they has not installed the 21CFR compliance HPLC system.

Decision of 340th meeting:

Deferred for submission of following:

- Clarify the specification of drug product since the JP monograph of fluconazole capsule is not applicable for 150mg strength. Revise your specification along with the requisite fee.
- The validation of analytical procedure has been performed using assay method (HPLC) with flow rate 1.0ml/min, column temperature 35°C, UV detector set at 261nm and mobile phase sodium acetate: methanol: acetonitrile while USP recommended flow rate 0.5ml/min, column temperature 40°C, UV detector 260nm and mobile phase Acetonitrile and water (20:80). Justify, how have comply USP specification by keeping the chromatographic condition different from USP monograph of fluconazole.
- Clarify, how you have performed accuracy parameter in the verification studies of drug substance that, despite spiking the sample 25%,50%,75%,100%,125% and 150%, the amount of fluconazole has not been changed in all these spiked sample.
- Justify, for adopting the dissolution parameter specified in JP monograph, since the JP monograph recommends the acceptance limits for 50mg and 100g fluconazole strength.
- Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.
- Provide COA of primary / secondary reference standard including source and lot number used for testing of drug product.

Response of the Firm:

Sr.no.	Decision of 340th meeting	Response of the Firm
1.	Clarify the specification of drug product since the JP monograph of fluconazole	Firm replied that "Fluconazole Capsule 150mg strength is available in BP Monograph, so we have

	capsule is not applicable for 150mg strength. Revise your specification along with the requisite fee.	revised the Specification on BP Monograph and details is enclosed."
2.	The validation of analytical procedure has been performed using assay method (HPLC) with flow rate 1.0ml/min, column temperature 35°C, UV detector set at 261nm and mobile phase sodium acetate: methanol: acetonitrile while USP recommended flow rate 0.5ml/min, column temperature 40°C, UV detector 260nm and mobile phase Acetonitrile and water (20:80). Justify, how have comply USP specification by keeping the chromatographic condition different from USP monograph of fluconazole.	Firm submit the analytical verification report of drug substance without including the results of accuracy parameter.
3.	Clarify, how you have performed accuracy parameter in the verification studies of drug substance that, despite spiking the sample 25%,50%,75%,100%,125% and 150%, the amount of fluconazole has not been changed in all these spiked sample.	Firm replied that, it was human error/typographical mistake has done, so we had validated the analytical procedure is as per USP Monograph, details is enclosed. However, results of accuracy parameters were not included in the submitted analytical verification report.
4.	Justify, for adopting the dissolution parameter specified in JP monograph, since the JP monograph recommends the acceptance limits for 50mg and 100mg fluconazole strength.	Firm replied that Fluconazole Capsule 150mg strength is available in BP Monograph, so we have revised the Specification on BP Monograph and details is enclosed. However, the assay procedure outlined by the applicant in their reply is not in accordance with BP monograph of fluconazole capsule.
5.	Provide complete analytical method verification studies of drug product including the specificity and repeatability parameter along with raw data sheets and chromatogram.	Submitted. However, the assay procedure outlined by the applicant in their reply is not in accordance with BP monograph of fluconazole capsule.
6.	Provide COA of primary / secondary reference standard including source and lot number used for testing of drug product.	Submitted the COA of reference standard bearing the validity date june,2021.

Decision: Deferred for submission of following shortcomings:

- **Submit analytical verification report of drug substance performed by drug product manufacturer including all three parameters of analytical verification studies.**
- **Submit assay method of drug product in accordance with BP monograph of Fluconazole Capsule and accordingly submit the performance report in-line with revised assay method performed at next time point of stability study.**
- **Provide COA of primary / secondary reference standard including source and lot number used for testing of drug product.**

705.	Name, address of Applicant / Marketing Authorization Holder	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Name, address of Manufacturing site.	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No 20067 dated 15-08-2023
	Details of fee submitted	Rs.30,000/- dated 10-07-2023
	The proposed proprietary name / brand name	Gebrex 90mg Tablet

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Etoricoxib…90mg
	Pharmacotherapeutic Group of (API)	NSAID
	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	MHRA Approved formulation
	For generic drugs (me-too status)	Starcox 90mg Tablets, Manufacturer: Getz Pharma (Pvt) Limited

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.4	Justify for not including the test of sulphated ash in the batch analysis report of drug substance performed by drug product manufacturer, since the sulphated ash test is the part of COA of API by the drug substance manufacturer.
2.	3.2.S.7	• The stability data for the drug substance indicates that the moisture content test was used to measure the water content in the API. However, the batch analysis report shows that the API manufacturer used a loss on drying (LOD) test to assess the water content in the drug substance. Please clarify the discrepancy regarding the method used for determining the water content in the drug substance. • Justify for not including the test of identification while performing the stability study of drug substance by drug substance manufacturer.
3.	3.2.P.2.2.1	A scientific justification is required for the observed high percentage of drug release in media with pH 1.2 and 4.5, considering that Etoricoxib is classified as a BCS Class II compound.
4.	3.2.P.5.2	Sample solution preparation is initiated by taking powder of tablet equivalent to120mg of Etoricoxib how can the method be implemented on the tablet of strength of 90mg.
5.	3.2.P.8.3	• Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. • Documents for the procurement of API with approval from DRAP (in case of import).
6.	2.3.R.1.1	Provide Batch Manufacturing Record (BMR) of three stability batches.

Decision of 340th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Justify for not including the test of sulphated ash in the batch analysis report of drug substance performed by drug product manufacturer, since the sulphated ash test is the part of COA of API by the drug substance manufacturer.	Firm replied that "We add the sulphated ash test in certificate of analysis (COA) by drug product manufacturer. Moreover, certificate of analysis (COA) by drug product manufacturer is attached as
2.	The stability data for the drug substance indicates that the moisture content test was used to measure the water content in the API. However, the batch analysis report shows that the API manufacturer used a loss on drying (LOD) test to assess the water content in the drug substance. Please clarify the discrepancy regarding the method used for determining the water content in the drug substance.	Firm replied that moisture content or water of API is measured by Loss on Drying (LOD). Moreover, this similarity is also shown in certificate of analysis (COA) by drug product manufacturer.
3.	Justify for not including the test of identification while performing the stability study of drug substance by drug substance manufacturer.	Firm replied that Identification of drug substance will not change during the stability studies thus, this test was not included.

4.	A scientific justification is required for the observed high percentage of drug release in media with pH 1.2 and 4.5, considering that Etoricoxib is classified as a BCS Class II compound.	Firm replied that "As from literature and chemistry review of innovator's drug which shows highly solubility in all different medias, our formulation also showed same profile like that of innovator's. So, that's why we found high solubility in all three medias".
5.	Sample solution preparation is initiated by taking powder of tablet equivalent to120mg of Etoricoxib how can the method be implemented on the tablet of strength of 90mg.	Firm submitted the Revised product testing method (PTM) for 90mg strength of Etoricoxib tablet.
6.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
7.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted
8.	Provide Batch Manufacturing Record (BMR) of three stability batches.	Submitted

Decision: Approved.

706.	Name, address of Applicant / Marketing Authorization Holder	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Name, address of Manufacturing site.	M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 20068 dated 15-08-2023
	Details of fee submitted	Rs.30,000/- dated 10-07-2023
	The proposed proprietary name / brand name	Gebrex 120mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Etoricoxib…120mg
	Pharmacotherapeutic Group of (API)	NSAID
	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	MHRA Approved formulation
	For generic drugs (me-too status)	Starcox 120mg Tablets, Manufacturer: Getz Pharma (Pvt) Limited

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.4	Justify for not including the test of sulphated ash in the batch analysis report of drug substance performed by drug product manufacturer, since the sulphated ash test is the part of COA of API by the drug substance manufacturer.
2.	3.2.S.7	• The stability data for the drug substance indicates that the moisture content test was used to measure the water content in the API. However, the batch analysis report shows that the API manufacturer used a loss on drying (LOD) test to assess the water content in the drug substance. Please clarify the discrepancy regarding the method used for determining the water content in the drug substance. • Justify for not including the test of identification while performing the stability study of drug substance by drug substance manufacturer.

3.	3.2.P.2.2.1	A scientific justification is required for the observed high percentage of drug release in media with pH 1.2 and 4.5, considering that Etoricoxib is classified as a BCS Class II compound.
4.	3.2.P.5.2	Sample solution preparation is initiated by taking powder of tablet equivalent to120mg of Etoricoxib how can the method be implemented on the tablet of strength of 90mg.
5.	3.2.P.8.3	• Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. • Documents for the procurement of API with approval from DRAP (in case of import).
6.	2.3.R.1.1	Provide Batch Manufacturing Record (BMR) of three stability batches.

Decision of 340th meeting :
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Justify for not including the test of sulphated ash in the batch analysis report of drug substance performed by drug product manufacturer, since the sulphated ash test is the part of COA of API by the drug substance manufacturer.	Firm replied that "We add the sulphated ash test in certificate of analysis (COA) by drug product manufacturer. Moreover, certificate of analysis (COA) by drug product manufacturer is attached as
2.	The stability data for the drug substance indicates that the moisture content test was used to measure the water content in the API. However, the batch analysis report shows that the API manufacturer used a loss on drying (LOD) test to assess the water content in the drug substance. Please clarify the discrepancy regarding the method used for determining the water content in the drug substance.	Firm replied that moisture content or water of API is measured by Loss on Drying (LOD). Moreover, this similarity is also shown in certificate of analysis (COA) by drug product manufacturer.
3.	Justify for not including the test of identification while performing the stability study of drug substance by drug substance manufacturer.	Firm replied that Identification of drug substance will not change during the stability studies thus, this test was not included.
4.	A scientific justification is required for the observed high percentage of drug release in media with pH 1.2 and 4.5, considering that Etoricoxib is classified as a BCS Class II compound.	Firm replied that "As from literature and chemistry review of innovator's drug which shows highly solubility in all different medias, our formulation also showed same profile like that of innovator's. So, that's why we found high solubility in all three medias".
5.	Sample solution preparation is initiated by taking powder of tablet equivalent to120mg of Etoricoxib how can the method be implemented on the tablet of strength of 90mg.	Firm submitted the Revised product testing method (PTM) for 90mg strength of Etoricoxib tablet.
6.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Submitted
7.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted
8.	Provide Batch Manufacturing Record (BMR) of three stability batches.	Submitted

Decision: Approved.

707.	Name, address of Applicant / Marketing Authorization Holder	M/s Surge Laboratories Pvt Ltd. 10 km, Faisalabad Road, Bikhi, District Sheikhupura
	Name, address of Manufacturing site.	M/s Surge Laboratories Pvt Ltd. 10 km, Faisalabad Road, Bikhi, District Sheikhupura
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 21072 dated 25-08-2023
	Details of fee submitted	Rs 30,000/- dated 18-07-2023
	The proposed proprietary name / brand name	Atraxum 10mg/5ml IV Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Ampoule Contains: Cisatracurium Besylate Eq. to Cisatracurium…10mg
	Pharmacotherapeutic Group of (API)	Neuromuscular blocking agent
	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	MHRA Approved formulation
	For generic drugs (me-too status)	Cis-Curon Injection of M/s. Brookes Pharma (Pvt.) Ltd. (Reg.no.088248)

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	3.2.S.4.1	Justify for not including the microbial analysis test and Bacterial endotoxin test in the specification of drug substance when the drug substance manufacturer done microbiological analysis of drug substance.	Firm replied that they follow the monograph of USP to test drug substance. However, the drug substance will be used in the manufacturing of injectable dosage form therefore we have revised drug substance specification with incorporation of additional test of microbial limit and bacterial endotoxin for QC release.
2.	3.2.P.8.3	During the stability study of the drug product, the area of the main peak was approximately 7,249,413.16, whereas during the verification procedure, the area of the main peak was around 2,300. Please clarify the significant discrepancy in peak areas, despite using the same assay method in both instances.	Firm replied that the difference in values of main peak area is due to the reason that method verification was performed on Agilent brand HPLC and stability studies were performed on Perkin Elmer HPLC. Different brand of HPLC have different recorder settings and different software's to convert signal into area response with different units of measurement like Mv,mAU.

Decision of 340th meeting of Registration Board:

Deferred for clarification regarding the following point:

- Additionally, in your response, you mentioned that the verification studies of the drug product were conducted using an Agilent HPLC, while the assay testing for the stability studies was performed using a Perkin Elmer HPLC. However, the chromatograms from certain time points during the stability studies indicate that an Agilent HPLC was used.
- Furthermore, the audit trail report of stability study submitted with the registration dossier also shows that the assay was only performed on an Agilent HPLC, which differs your earlier statement that stability testing was conducted on a Perkin Elmer HPLC. Clarification is required on this matter.

Response of the Firm:

Sr.no.	Decision of 340th meeting	Response of the Firm
1.	Additionally, in your response, you mentioned that the verification studies of the drug product were conducted using an Agilent HPLC, while the assay testing for the stability studies was performed using a Perkin Elmer HPLC. However, the chromatograms from certain	We correct our justification, initial studies were conducted on Agilent HPLC, 03-month stability studies were conducted on Perkin Elmer HPLC and 06-month stability studies were conducted on Agilent HPLC. Reference to query letter received dated 25 September 2024, your good self-asked in sec 3.2.P.8.3, with

<table>
<tr><td></td><td>time points during the stability studies indicate that an Agilent HPLC was used.</td><td>respect to the difference in area of main peaks observed despite using the same assay method, please find below the observed Areas at different intervals of stability studies performed on different brands of HPLC.
<table>
<tr><td>Stability studies Interval</td><td>HPLC Brand</td><td>Area of Main Peak Observed</td></tr>
<tr><td>Initial(Zero Time Point)</td><td>Agilent</td><td>2353.53mAU</td></tr>
<tr><td>3rd month</td><td>Perkin Elmer</td><td>7249413.16mV</td></tr>
<tr><td>6th Month</td><td>Agilent</td><td>2340.78mAU</td></tr>
</table>
Respective chromatograms are enclosed for reference. Peak responses obtained at initial and 6month stability studies are approximately similar representing the product stability and HPLC system reproducibility. Significant difference in area at 03 month studies is due to the change in brand of HPLC.</td></tr>
<tr><td>2.</td><td>Furthermore, the audit trail report of stability study submitted with the registration dossier also shows that the assay was only performed on an Agilent HPLC, which differs your earlier statement that stability testing was conducted on a Perkin Elmer HPLC. Clarification is required on this matter.</td><td>Complete audit trail report of both HPLC systems (Agilent Brand and Perkin Elmer Brand) are enclosed for your reference.</td></tr>
</table>

Decision: Approved.

708.	Name, address of Applicant / Marketing Authorization Holder	M/s. Bio-Next Pharmaceuticals Plot no. 50, Street no. S-10, RCCI Industrial Estate Rawat Islamabad
	Name, address of Manufacturing site.	M/s. Bio-Lab (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.
	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 Panel inspection of M/s Biolabs Pvt Limited Plot No. 145 Industrial triangle Kahuta Road Islamabad dated 08.07.2021, 15.07.2021, 30.07.2021 and 03.08.2021 recommends renewal of DML and indicates Dry Powder Injection (General).
	Evidence of approval of manufacturing facility	Firm has submitted copy of grant of additional section letter of M/s. Bio-Labs (Pvt.) Ltd. Dated 27th September,2021, in which firm has grant additional section Dry Vial Injection (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.28381: dated 06-10-2022
	Details of fee submitted	PKR 75,000/-: 26-09-2022
	The proposed proprietary name / brand name	PantoNext 40mg Injection
	Strength / concentration of drug of Active	Each Vial contains:

	Pharmaceutical ingredient (API) per unit	Pantoprazole sodium equivalent to Pantoprazole…40mg
	Pharmaceutical form of applied drug	Lyophilized Dry Powder Injection
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Reference to Finished product specifications	BP
	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)	NEEGE 40mg Injection of M/s Sami Pharma (Reg # 057832)
	Name and address of API 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. 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 40ºC ± 2ºC / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30ºC ± 2ºC / 65% ± 5% RH for 9 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. Zopent 40mg Injection of Nabi Qasim 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	M/s Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.	

API Lot No.	2109901		
Description of Pack (Container closure system)	Tubular Type-I glass vial filled with almost white colored sterile powder		
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.	PNT 21-001	PNT 21-002	PNT 21-003
Batch Size	1633 vials	1633 vials	1633 vials
Manufacturing Date	11-21	11-21	11-21
Date of Initiation	04-11-2021	04-11-2021	04-11-2021
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)	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 for M/s Vision pharma pvt Ltd, Lahore issued by DRAP Lahore. It is valid till 10-02-2022.
3.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of invoice for the purchase of pantoprazole sodium sterile powder (570gM, Batch # 2109901) from M/s vision pharma vide invoice # 600091 dated 04-10-2021.
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	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:

S.no.	Observations/Deficiencies/ Short-comings
1.	• Justification of addition of mannitol as an excipient in the preparation of lyophilized dry powder injectable. • Justify the quantity of EDTA used in the formulation with reference to the quantity mentioned in the document of innovator product.
2.	Submit analytical method verification report of drug substance performed by drug product manufacturer in section 3.2.S.4.3.
3.	The assay limit specified by drug substance manufacturer is 36% to 40% w/w while you have defined the assay limit as 34% to 40%. Justify how drug product manufacturer can change the assay limits.
4.	Analytical procedure used for the analysis of drug substance by drug product manufacturer is different from the analytical method specified by drug substance manufacturer, justification is required in this regard.
5.	Justify for performing the stability study on drug substance packaged in glass vial, while the container closure described in section 3.2.S.6 is aluminium tin.

6.	Submit stability data of drug substance packaged in aluminum tin as per the described container closure in section 3.2.S.6 performed both at accelerated and long term condition till the claimed re-test period
7.	• Justify the declared potency of pantoprazole working standard 89% with reference to submitted COA of reference standard. • Expiry date of primary reference standard was 20-07-2021 and the retest date mentioned on the submitted COA of working standard is 19-01-2021, while the stability initiation date of trial batches was 04-11-2021, clarification is required how the submitted expired COA of reference standard is used for the analysis of stability trial batches.
8.	Submit updated stability data of drug product, since you have only submitted the real time stability data of 6 months.
9.	Submit complete calculation of dispensed quantity of active per vial specifically with reference to the adjustment of salt factor.

Decision of 331st meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Applied formulation has been approved on Form 5F from the same manufacturer i.e., M/s. Bio-Lab (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad. in its 340th meeting as per following details:
Applicant name: M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Balochistan
Brand name: Prazovant 40mg Injection
Manufacturer: M/s. Bio-Lab (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad

Decision: Approved.

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."

709.	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 (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	Firm submitted the analytical procedure instead of pharmaceutical equivalence report including the test

		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.	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 of 329th meeting of Registration Board:
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.

Response of the Firm:
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.

Firm submitted the revised dissolution acceptance criteria in line with innovator product along with revised CDP report but did not submit the 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.
Firm did not submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Decision of 336th meeting of Registration Board:
Deferred for submission of following:

- Submit performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.
- Submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Response of the Firm:

- Submit performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

Firm submitted the comparative dissolution profile data of drug product along with the reference product Nebil 2.5mg Tablet of M/s. Getz Pharma, but the case was deferred for submission of performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

- Submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Firm submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Decision of 339th meeting of Registration Board:
The Registration Board deferred the application as last chance to submit the reply for the shortcomings already communicated. their submitted responses were still deemed unsatisfactory after evaluation.

Response of the Firm:
Firm in their reply submitted the comparative dissolution profile data of drug product instead of performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria in-line with innovator product i.e. NLT Q within 30 minutes.

Decision: Registration Board while considering the fact that firm has not submitted satisfactory response to the previous decision, decied to give last opportunity to firm for submission of dissolution test performance as per the acceptance criteria of innovator drug product.

710.	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.n	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 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".	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.

		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 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	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.

		have taken the potency of drug substance without HCl on as is basis.	

Decision of 329th meeting of Registration Board:
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.

Response of the Firm:
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.
Firm submitted the revised dissolution acceptance criteria in line with innovator product along with revised CDP report but did not submit the 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.
Firm did not submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Decision of 336th meeting of Registration Board:
Deferred for submission of following:

- Submit performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.
- Submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Response of the Firm:

- Submit performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

Firm submitted the comparative dissolution profile data of drug product along with the reference product Nebil 2.5mg Tablet of M/s. Getz Pharma, but the case was deferred for submission of performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

- Submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Firm submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Decision of 339th meeting of Registration Board:
The Registration Board deferred the application as last chance to submit the reply for the shortcomings already communicated. their submitted responses were still deemed unsatisfactory after evaluation.

Response of the Firm:
Firm in their reply submitted the comparative dissolution profile data of drug product instead of performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria in-line with innovator product i.e. NLT Q within 30 minutes.

Decision: Registration Board while considering the fact that firm has not submitted satisfactory response to the previous decision, decied to give last opportunity to firm for submission of dissolution test performance as per the acceptance criteria of innovator drug product. Registration Board further advised PEC to communicate the instant decision to firm via letter.

711.	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 (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.	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 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 of 329th meeting of Registration Board:

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.

Response of the Firm:

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.

Firm submitted the revised dissolution acceptance criteria in line with innovator product along with revised CDP report but did not submit the 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.

Firm did not submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Decision of 336th meeting of Registration Board:

Deferred for submission of following:

- Submit performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.
- Submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Response of the Firm:

- Submit performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

Firm submitted the comparative dissolution profile data of drug product along with the reference product Nebil 2.5mg Tablet of M/s. Getz Pharma, but the case was deferred for submission of performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria.

- Submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Firm submit pharmaceutical equivalence report including all the quality test as per the revised specification of finished product.

Decision of 339th meeting of Registration Board:

The Registration Board deferred the application as last chance to submit the reply for the shortcomings already communicated. their submitted responses were still deemed unsatisfactory after evaluation.

Response of the Firm:
Firm in their reply submitted the comparative dissolution profile data of drug product instead of performance report of dissolution testing of stability batches in accordance with the revised acceptance criteria in-line with innovator product i.e. NLT Q within 30 minutes.

Decision: Registration Board while considering the fact that firm has not submitted satisfactory response to the previous decision, decied to give last opportunity to firm for submission of dissolution test performance as per the acceptance criteria of innovator drug product.

712.	Name, address of Applicant / Marketing Authorization Holder	M/s. FAAS Pharmaceuticals (Pvt.) Ltd. Plot No. F/748-I, S.I.T.E., Karachi.
	Name, address of Manufacturing site.	M/s. FAAS Pharmaceuticals (Pvt.) Ltd. Plot No. F/748-I, S.I.T.E., Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.39373 dated : 29-12-2022
	Details of fee submitted	PKR 30,000/- : vide slip no.48397659956 dated 20-10-2022
	The proposed proprietary name / brand name	SEROFAAS 12.5mg CR Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Enteric film coated controlled release tablet contains: Paroxetine (as Hydrochloride Hemihydrate)….12.5mg
	Pharmacotherapeutic Group of (API)	Selective Serotonin Reuptake Inhibitors
	Reference to Finished product specifications	USP specification

Evaluation by PEC (XV):

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.5	Submit valid GMP certificate of applicant since the submitted GMP was expired back in 2020.
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 drug product manufacturer.
3.	3.2.S.4.3	Submit analytical method verification report of drug substance performed by drug product manufacturer.
4.	3.2.S.5	Submit COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.
5.	3.2.P.5.3	Performance of system suitability is not in accordance with USP monograph of *"Paroxetine Extended-Release Tablets",* since you have not used the recommended system suitability solution as evident from the submitted verification report, clarification is required in this regard.
6.	3.2.P.5.4	Provide quantitative results of average weight per tablet and test of uniformity of dosage unit in the batch analysis report of drug product instead of vague statement such as "*within limits" or "complies*".
7.	3.2.P.6	Submit COA of reference standard actually used in the analysis of drug product in section 3.2.P.6.
8.	3.2.P.8.2	• Provide quantitative results of average weight per tablet and test of uniformity of dosage unit in the stability data sheets of drug product instead of vague statement such as "*within limits" or "complies*". Further, the submitted raw data sheets did not evident the performance of said test.

		• Import invoice of drug substance for confirmation of API lot no. which is actually used in the preparation of stability batches. • Submit Loan letter from the loan taken manufacturer, along with DRAP attested commercial invoice, since the submitted invoice has not been attested by DRAP. • Submit HPLC chromatograms of assay test, content uniformity test and acid stage test of dissolution, since you have only the UV chromatograms of buffer stage of dissolution.
9.	3.2.R.1.1	Provide Batch Manufacturing Record (BMR) of all stability batches.

Decision of 336th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit valid GMP certificate of applicant since the submitted GMP was expired back in 2020.	Submitted
2.	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.	Submitted
3.	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Submitted
4.	Submit COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.	Submitted
5.	Performance of system suitability is not in accordance with USP monograph of *"Paroxetine Extended-Release Tablets",* since you have not used the recommended system suitability solution as evident from the submitted verification report, clarification is required in this regard.	Firm submitted the system suitability report, in which only the results of replicates of working standard solution were considered to calculate the RSD value. While, the assay procedure given in the USP monograph of "*Paroxetine Extended-Release Tablets"* recommends that two samples are run in system suitability study includes *Standard solution* and *System suitability solution* and accordingly following parameters will have analyzed to conclude the system suitability report. [NOTE—The relative retention times for paroxetine related compound B and paroxetine are 0.9 and 1.0, respectively.] Suitability requirements Resolution: NLT 1.5 between paroxetine related compound B and paroxetine, *System suitability solution* Tailing factor: NMT 2.0 for paroxetine, *System suitability* *solution* Relative standard deviation: NMT 2.0% for paroxetine, *Standard solution*
6.	Provide quantitative results of average weight per tablet and test of uniformity of dosage unit	Submitted the revised batch analysis report of drug product.

	in the batch analysis report of drug product instead of vague statement such as "*within limits" or "complies*".	
7.	Submit COA of reference standard actually used in the analysis of drug product in section 3.2.P.6.	Submitted
8.	Provide quantitative results of average weight per tablet and test of uniformity of dosage unit in the stability data sheets of drug product instead of vague statement such as "*within limits" or "complies*". Further, the submitted raw data sheets did not evident the performance of said test.	Firm has not submitted the raw data sheets of content uniformity test.
9.	Import invoice of drug substance for confirmation of API lot no. which is actually used in the preparation of stability batches.	Submitted
10	Submit Loan letter from the loan taken manufacturer, along with DRAP attested commercial invoice, since the submitted invoice has not been attested by DRAP.	Submitted
11	Submit HPLC chromatograms of assay test, content uniformity test and acid stage test of dissolution, since you have only the UV chromatograms of buffer stage of dissolution.	Firm has again only submitted raw data sheets of and UV chromatograms of dissolution test performed at buffer stage.
12	Provide Batch Manufacturing Record (BMR) of all stability batches.	Submitted.

Decision: Deferred for submission of following shortcomings:

- **Justify for not performing the system suitability parameter in accordance with the USP monograph of "Paroxetine Extended-Release Tablets" during the assay verification study of the drug product.**
- **Provide quantitative results of average weight per tablet and test of uniformity of dosage unit in the stability data sheets of drug product instead of vague statement such as "*within limits" or "complies*".**
- **Submit HPLC chromatograms of assay test, content uniformity test and acid stage test of dissolution, since you have only the UV chromatograms of buffer stage of dissolution.**

713.	Name, address of Applicant / Marketing Authorization Holder	M/s. FAAS Pharmaceuticals (Pvt.) Ltd. Plot No. F/748-I, S.I.T.E., Karachi.
	Name, address of Manufacturing site.	M/s. FAAS Pharmaceuticals (Pvt.) Ltd. Plot No. F/748-I, S.I.T.E., Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No.39374 dated : 29-12-2022
	Details of fee submitted	PKR 30,000/- : vide slip no. 38329361038 dated 20-10-2022
	The proposed proprietary name / brand name	SEROFAAS 25mg CR Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Enteric film coated controlled release tablet contains: Paroxetine (as Hydrochloride Hemihydrate)….25mg
	Pharmacotherapeutic Group of (API)	Selective Serotonin Reuptake Inhibitors
	Reference to Finished product specifications	USP specification

Evaluation by PEC (XV):

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.5	Submit valid GMP certificate of applicant since the submitted GMP was expired back in 2020.
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 drug product manufacturer.
3.	3.2.S.4.3	Submit analytical method verification report of drug substance performed by drug product manufacturer.
4.	3.2.S.5	Submit COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.
5.	3.2.P.5.3	Performance of system suitability is not in accordance with USP monograph of *"Paroxetine Extended-Release Tablets",* since you have not used the recommended system suitability solution as evident from the submitted verification report, clarification is required in this regard.
6.	3.2.P.5.4	Provide quantitative results of average weight per tablet and test of uniformity of dosage unit in the batch analysis report of drug product instead of vague statement such as "*within limits" or "complies*".
7.	3.2.P.6	Submit COA of reference standard actually used in the analysis of drug product in section 3.2.P.6.
8.	3.2.P.8.2	• Provide quantitative results of average weight per tablet and test of uniformity of dosage unit in the stability data sheets of drug product instead of vague statement such as "*within limits" or "complies*". Further, the submitted raw data sheets did not evident the performance of said test. • Import invoice of drug substance for confirmation of API lot no. which is actually used in the preparation of stability batches. • Submit Loan letter from the loan taken manufacturer, along with DRAP attested commercial invoice, since the submitted invoice has not been attested by DRAP. • Submit HPLC chromatograms of assay test, content uniformity test and acid stage test of dissolution, since you have only the UV chromatograms of buffer stage of dissolution.
9.	3.2.R.1.1	Provide Batch Manufacturing Record (BMR) of all stability batches.

Decision of 336th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response of the Firm

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit valid GMP certificate of applicant since the submitted GMP was expired back in 2020.	Submitted
2.	Submit copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by drug product manufacturer.	Submitted
3.	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Submitted
4.	Submit COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.	Submitted

5.	Performance of system suitability is not in accordance with USP monograph of *"Paroxetine Extended-Release Tablets",* since you have not used the recommended system suitability solution as evident from the submitted verification report, clarification is required in this regard.	Firm submitted the system suitability report, in which only the results of replicates of working standard solution were considered to calculate the RSD value. While, the assay procedure given in the USP monograph of "*Paroxetine Extended-Release Tablets"* recommends that two samples are run in system suitability study includes *Standard solution* and *System suitability solution* and accordingly following parameters will analyzed to conclude the system suitability report. [NOTE—The relative retention times for paroxetine related compound B and paroxetine are 0.9 and 1.0, respectively.] Suitability requirements Resolution: NLT 1.5 between paroxetine related compound B and paroxetine, *System suitability solution* Tailing factor: NMT 2.0 for paroxetine, *System suitability* *solution* Relative standard deviation: NMT 2.0% for paroxetine, *Standard solution*
6.	Provide quantitative results of average weight per tablet and test of uniformity of dosage unit in the batch analysis report of drug product instead of vague statement such as "*within limits" or "complies*".	Submitted the revised batch analysis report of drug product.
7.	Submit COA of reference standard actually used in the analysis of drug product in section 3.2.P.6.	Submitted
8.	Provide quantitative results of average weight per tablet and test of uniformity of dosage unit in the stability data sheets of drug product instead of vague statement such as "*within limits" or "complies*". Further, the submitted raw data sheets did not evident the performance of said test.	Firm has not submitted the raw data sheets of content uniformity test.
9.	Import invoice of drug substance for confirmation of API lot no. which is actually used in the preparation of stability batches.	Submitted
10	Submit Loan letter from the loan taken manufacturer, along with DRAP attested commercial invoice, since the submitted invoice has not been attested by DRAP.	Submitted
11	Submit HPLC chromatograms of assay test, content uniformity test and acid stage test of dissolution, since you have only the UV chromatograms of buffer stage of dissolution.	Firm has again only submitted raw data sheets of and UV chromatograms of dissolution test performed at buffer stage.
12	Provide Batch Manufacturing Record (BMR) of all stability batches.	Submitted.

Decision: Deferred for submission of HPLC chromatograms of assay test, content uniformity test and acid stage test of dissolution, since firm has only submitted UV spectrums of buffer stage of dissolution.

714.	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan

	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 21074 dated 25-08-2023
	Details of fee submitted	Rs 30,000/- dated 23-06-2023
	The proposed proprietary name / brand name	Paloron 0.25mg/5ml Solution for Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Palonosetron Hcl Eq. to Palonosetron…0.25mg
	Pharmacotherapeutic Group of (API)	Serotonin (5HT3) Antagonist ,Antiemetic,antinauseatic
	Reference to Finished product specifications	Innovators Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA approved formulation
	For generic drugs (me-too status)	Paloxi by Himmel (Import)

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.3	Submit analytical method verification report of drug substance performed by drug product manufacturer.
2.	3.2.S.4.4	Justify for not including the sterility test in the specification of drug substance when the USP monograph recommend the test and the COA claimed that API is for injection.
3.	3.2.S.7	Justify for not including the Microbiological examination, Bacterial Endotoxin test and sterility test in the stability study of drug substance.
4.	3.2.P.1	How you adjust the pH of final solution as you have neither used hydrochloric acid solution nor sodium hydroxide solution, since the innovator product mentioned both of these excipient in their composition.
5.	3.2.P.5.3	Please clarify the target concentration that is considered while validation study of analytical procedure comparing the final concentration of standard solution given in section 3.2.P.5.2.

Decision of 340th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Firm submitted analytical method verification report of drug substance performed by drug product manufacturer.
2.	Justify for not including the sterility test in the specification of drug substance when the USP monograph recommend the test and the COA claimed that API is for injection.	The USP monograph for Palonosetron Hydrochloride became official on January 1, 2023. Prior to this, the active pharmaceutical ingredient was manufactured in May 2022, and subsequent testing by the drug substance & drug product manufacturer occurred at that time, sterility testing was not part of routine raw material testing procedures. However, drug product manufacturer updated their method which is attached as Annex-II
3.	Justify for not including the Microbiological examination, Bacterial Endotoxin test and sterility test in the stability study of drug substance.	Revised stability data attached .

4.	How you adjust the pH of final solution as you have neither used hydrochloric acid solution nor sodium hydroxide solution, since the innovator product mentioned both of these excipient in their composition.	Firm replied that Paloron Injection 0.075mg/1.5ml & 0.25mg/5ml has been developed as per Innovator, ALOXI Injection FDA. The developed product (Paloron Injection 0.075mg/1.5ml & 0.25mg/5ml) and the innovator product (ALOXI Injection 0.075mg/1.5ml & 0.25mg/5ml) both contain same excipients. Innovator have neither used HCl nor NaOH solution for pH adjustment. Reference is attached. However it is clearly written the chemistry review literature of innovator product Aloxi Injection, that hydrochloric acid solution or sodium hydroxide solution are used for adjustment to pH 5.
5.	Please clarify the target concentration that is considered while validation study of analytical procedure comparing the final concentration of standard solution given in section 3.2.P.5.2.	Firm replied that "we have submitted the method validation protocol and report with the necessary corrections to address the concentration discrepancies, as outlined in our finalized Standard Operating Procedure (SOP). The updated validation protocol, report, and SOP are attached.

Decision: Approved. Registration letter will be issued upon submission of clarification regading the achievement of desired pH of bulk solution without use use of any external agent i.e., hydrochloric acid solution or sodium hydroxide solution since the innovator drug product has declared use either of them for pH adjustment of bulk solution.

715.	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 21075 dated 25-08-2023
	Details of fee submitted	Rs 75,000/- dated 05-07-2023
	The proposed proprietary name / brand name	Paloron 0.075mg/1.5ml Solution for Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Palonosetron Hcl Eq. to Palonosetron…0.075mg
	Pharmacotherapeutic Group of (API)	Serotonin (5HT3) Antagonist ,Antiemetic,antinauseatic
	Reference to Finished product specifications	Innovators Specification
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Not confirmed
	For generic drugs (me-too status)	NA

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	1.5.9	Provide the evidence of reference product approved in reference regulatory agencies in the applied strength.
2.	3.2.S.4.3	Submit analytical method verification report of drug substance performed by drug product manufacturer.
3.	3.2.S.4.4	Justify for not including the sterility test in the specification of drug substance when the USP monograph recommend the test and the COA claimed that API is for injection.
4.	3.2.S.7	Justify for not including the Microbiological examination, Bacterial Endotoxin test and sterility test in the stability study of drug substance.

5.	3.2.P.1	How you adjust the pH of final solution as you have neither used hydrochloric acid solution nor sodium hydroxide solution, since the innovator product mentioned both of these excipient in their composition.
6.	3.2.P.5.3	Please clarify the target concentration that is considered while validation study of analytical procedure comparing the final concentration of standard solution given in section 3.2.P.5.2.

Decision of 340th of meeting:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response of the firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Firm submitted analytical method verification report of drug substance performed by drug product manufacturer.
2.	Justify for not including the sterility test in the specification of drug substance when the USP monograph recommend the test and the COA claimed that API is for injection.	The USP monograph for Palonosetron Hydrochloride became official on January 1, 2023. Prior to this, the active pharmaceutical ingredient was manufactured in May 2022, and subsequent testing by the drug substance & drug product manufacturer occurred at that time, sterility testing was not part of routine raw material testing procedures. However, drug product manufacturer updated their method which is attached as Annex-II
3.	Justify for not including the Microbiological examination, Bacterial Endotoxin test and sterility test in the stability study of drug substance.	Revised stability data attached .
4.	How you adjust the pH of final solution as you have neither used hydrochloric acid solution nor sodium hydroxide solution, since the innovator product mentioned both of these excipient in their composition.	Firm replied that Paloron Injection 0.075mg/1.5ml & 0.25mg/5ml has been developed as per Innovator, ALOXI Injection FDA. The developed product (Paloron Injection 0.075mg/1.5ml & 0.25mg/5ml) and the innovator product (ALOXI Injection 0.075mg/1.5ml & 0.25mg/5ml) both contain same excipients. Innovator have neither used HCl nor NaOH solution for pH adjustment. Reference is attached. However it is clearly written the chemistry review literature of innovator product Aloxi Injection, that hydrochloric acid solution or sodium hydroxide solution are used for adjustment to pH 5.
5.	Please clarify the target concentration that is considered while validation study of analytical procedure comparing the final concentration of standard solution given in section 3.2.P.5.2.	Firm replied that "we have submitted the method validation protocol and report with the necessary corrections to address the concentration discrepancies, as outlined in our finalized Standard Operating Procedure (SOP). The updated validation protocol, report, and SOP are attached.

Decision: Approved. Registration letter will be issued upon submission of clarification regading the achievement of desired pH of bulk solution without use use of any external agent i.e., hydrochloric acid solution or sodium hydroxide solution since the innovator drug product has declared use either of them for pH adjustment of bulk solution.

716.	Name, address of Applicant / Marketing Authorization Holder	M/s Weather Folds Pharmaceuticals.Plot # 69, Phase-II, Industrial Estate, Hattar
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No 19391 dated 04-08-2023
	Details of fee submitted	Rs.30,000/- dated 10-07-2023
	The proposed proprietary name / brand name	Ofloxx 200mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ofloxacin…200mg
	Pharmacotherapeutic Group of (API)	Fluoroquinolones
	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	Ofloxacin 200mg tablets approved by MHRA
	For generic drugs (me-too status)	Myobid 200mg Tablet Reg. No. 44643 Mfg.by M/s. Panacea Pharma

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.1-3.2.S.4.2	Submit specification and detailed analytical procedure of drug substance used by drug product manufacturer.
2.	3.2.S.4.3	Submit analytical method verification report of drug substance performed by drug product manufacturer.
3.	3.2.P.1	Clarification is required either the applied product is enteric coated or a film coated formulation, since the composition table specified the list of excipients used for enteric coating.
4.	3.2.P.2.2.1	Justify how the conclusion for Comparative Dissolution Profile (CDP) is made and the test product is declared comparable to innovator product without determining similarity factor "f2" and discussing its results.
5.	3.2.P.5.2	Submit detailed analytical procedure of drug product that is actually used for the analysis of applied product instead of submitting the copy of USP monograph of OFLOXACIN Tablet.
6.	3.2.P.5.3	Submit the complete analytical method verification report instead of only submitting the summary table of verification parameters.
7.	3.2.P.8	Form 7 indicates that 50 kg of ofloxacin, batch no. DC-002-18120021, was imported, whereas Form 6 states that only 2 kg of ofloxacin was imported from a drug substance manufacturer. Please clarify which procurement document should be considered in this case and confirm which batch of the active pharmaceutical ingredient (API) was actually used in the manufacturing of the trial batches for the applied product.

Decision of 340th meeting:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

Response of the Firm

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit specification and detailed analytical procedure of drug substance used by drug product manufacturer.	Firm submit the specification and analytical procedure of drug substance used by drug product manufacturer.
2.	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Submitted
3.	Clarification is required either the applied product is enteric coated or a film coated formulation, since the composition table specified the list of excipients used for enteric coating.	Firm clarified that the applied formulation if film coated and revised composition table is attached accordingly.

4.	Justify how the conclusion for Comparative Dissolution Profile (CDP) is made and the test product is declared comparable to innovator product without determining similarity factor "f2" and discussing its results.	Firm submit revised CDP reports performed against the product oflobid tablet 200mg.
5.	Submit detailed analytical procedure of drug product that is actually used for the analysis of applied product instead of submitting the copy of USP monograph of OFLOXACIN Tablet.	Submitted
6.	Submit the complete analytical method verification report instead of only submitting the summary table of verification parameters.	Submitted
7.	Form 7 indicates that 50 kg of ofloxacin, batch no. DC-002-18120021, was imported, whereas Form 6 states that only 2 kg of ofloxacin was imported from a drug substance manufacturer. Please clarify which procurement document should be considered in this case and confirm which batch of the active pharmaceutical ingredient (API) was actually used in the manufacturing of the trial batches for the applied product.	Firm submitted without DRAP attested commercial invoice (invoice no. OD190521 dated 22-12-2021, which evident that firm procured ofloxacin 2kg from M/s. Zhejiang East-Asia Pharmaceuticals co. Ltd. (Batch no. DC-002-1812001).Furthermore, firm submitted Form-6 attested by DRAP officer bearing Dy.no.0081/2022-DRAPCPS/329 dated 25-01-2022.

Decision: Approved.

717.	Name, address of Applicant / Marketing Authorization Holder	M/s. WnsFeild Pharmaceuticals Plot No.122, Block-A, Phase -V, Industrial Estate, Hattar
	Name, address of Manufacturing site.	M/s. WnsFeild Pharmaceuticals Plot No.122, Block-A, Phase -V, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15393 : dated 19-06-2023
	Details of fee submitted	PKR 30,000/- : vide slip no.79936521138 dated 20-03-2023
	The proposed proprietary name / brand name	Prefen 267mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated tablet contains: Pirfenidone……267mg
	Pharmacotherapeutic Group of (API)	Pyridones Immunosuppressant
	Reference to Finished product specifications	Manufacturer's Specification
	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

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	3.2.S.4.2	Submit detailed analytical procedure used for analysis of drug substance by drug product manufacturer.	Firm submitted the detailed analytical procedure used for analysis of drug substance by drug product manufacturer.

2.	3.2.S.4.3	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Firm submitted the same verification report for both drug substance and drug products.
3.	3.2.P.2.2.1	Submit complete data of comparative dissolution profile including the individual results of 12 units of both reference and test product of all three physiological media since you have only submitted the f2 value.	Firm submitted the summarised table of F2 calculation without submitting the complete data of comparative dissolution profile including the individual results of 12 units of both reference and test product in all three physiological media
4.	3.2.P.5.2	Submit complete and detailed analytical procedure used for analysis of drug product.	Submitted
5.	3.2.P.5.3	• Verification report revealed that the assay has been performed on HPLC while the procedure of assay given in section 3.2.P.5.3 revealed that the assay will performed on UV spectrophotometer, clarify the disparity observed regarding the method adopted for assay of drug product. • Justify for submitting same analytical method verification report for drug substance and drug product.	Without any clarification firm submitted the verification report which was the same report firm submitted in section 3.2.S.4.3 as a verification report for drug substance.
6.	3.2.R.1.1	Provide Batch Manufacturing Record (BMR) of all stability batches.	Submitted

Decision of 339th meeting of Registration Board:

Deferred for submission of following shortcomings:

- Submit analytical method verification report of drug substance performed by drug product manufacturer.
- Verification report revealed that the assay has been performed on HPLC while the procedure of assay given in section 3.2.P.5.3 revealed that the assay will performed on UV spectrophotometer, clarify the disparity observed regarding the method adopted for assay of drug product.
- Justify for submitting same analytical method verification report for drug substance and drug product.
- Submit complete data of comparative dissolution profile including the individual results of 12 units of both reference and test product of all three physiological media since you have only submitted the f2 value.

Response of the Firm:

Sr.no.	Shortcomings	Response of the Firm
1.	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Submitted
2.	Verification report revealed that the assay has been performed on HPLC while the procedure of assay given in section 3.2.P.5.3 revealed that the assay will performed on UV spectrophotometer, clarify the disparity observed regarding the method adopted for assay of drug product.	Firm clarified that assay of drug product has been performed on HPLC and dissolution of drug product is performed on UV.
3.	Justify for submitting same analytical method verification report for drug substance and drug product.	Firm submitted the analytical verification report of drug substance only.
4.	Submit complete data of comparative dissolution profile including the individual results of 12 units of both	submitted

	reference and test product of all three physiological media since you have only submitted the f2 value.	

Decision of 340th meeting of Registration Board:
Deferred for submission of analytical verification report of drug product.

Response of the Firm:
Firm submitted the analytical validation report of drug product.

Decision: Approved.

718.	Name, address of Applicant / Marketing Authorization Holder	M/s. WnsFeild Pharmaceuticals Plot No.122, Block-A, Phase -V, Industrial Estate, Hattar
	Name, address of Manufacturing site.	M/s. WnsFeild Pharmaceuticals Plot No.122, Block-A, Phase -V, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 15394 : dated 19-06-2023
	Details of fee submitted	PKR 30,000/- : vide slip no.60051552014 dated 20-03-2023
	The proposed proprietary name / brand name	Prefen 801mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated tablet contains: Pirfenidone……801mg
	Pharmacotherapeutic Group of (API)	Pyridones Immunosuppressant
	Reference to Finished product specifications	Manufacturer's Specification
	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

Evaluation by PEC-XV:

S.no.	Sections	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	3.2.S.4.2	Submit detailed analytical procedure used for analysis of drug substance by drug product manufacturer.	Firm submitted the detailed analytical procedure used for analysis of drug substance by drug product manufacturer.
2.	3.2.S.4.3	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Firm submitted the same verification report for both drug substance and drug products.
3.	3.2.P.2.2.1	Submit complete data of comparative dissolution profile including the individual results of 12 units of both reference and test product of all three physiological media since you have only submitted the f2 value.	Firm submitted the summarised table of F2 calculation without submitting the complete data of comparative dissolution profile including the individual results of 12 units of both reference and test product in all three physiological media
4.	3.2.P.5.2	Submit complete and detailed analytical procedure used for analysis of drug product.	Submitted
5.	3.2.P.5.3	• Verification report revealed that the assay has been performed on HPLC while the procedure of assay given in	Without any clarification firm submitted the verification report which was the same report

		section 3.2.P.5.3 revealed that the assay will performed on UV spectrophotometer, clarify the disparity observed regarding the method adopted for assay of drug product. • Justify for submitting same analytical method verification report for drug substance and drug product.	firm submitted in section 3.2.S.4.3 as a verification report for drug substance.
6.	3.2.R.1.1	Provide Batch Manufacturing Record (BMR) of all stability batches.	Submitted

Decision of 339th meeting of Registration Board:
Deferred for submission of following shortcomings:

- Submit analytical method verification report of drug substance performed by drug product manufacturer.
- Verification report revealed that the assay has been performed on HPLC while the procedure of assay given in section 3.2.P.5.3 revealed that the assay will performed on UV spectrophotometer, clarify the disparity observed regarding the method adopted for assay of drug product.
- Justify for submitting same analytical method verification report for drug substance and drug product.
- Submit complete data of comparative dissolution profile including the individual results of 12 units of both reference and test product of all three physiological media since you have only submitted the f2 value.

Response of the Firm:

Sr.no.	Shortcomings	Response of the Firm
1.	Submit analytical method verification report of drug substance performed by drug product manufacturer.	Submitted
2.	Verification report revealed that the assay has been performed on HPLC while the procedure of assay given in section 3.2.P.5.3 revealed that the assay will performed on UV spectrophotometer, clarify the disparity observed regarding the method adopted for assay of drug product.	Firm clarified that assay of drug product has been performed on HPLC and dissolution of drug product is performed on UV.
3.	Justify for submitting same analytical method verification report for drug substance and drug product.	Firm submitted the analytical verification report of drug substance only.
4.	Submit complete data of comparative dissolution profile including the individual results of 12 units of both reference and test product of all three physiological media since you have only submitted the f2 value.	submitted

Decision of 340th meeting of Registration Board:
Deferred for submission of analytical verification report of drug product.

Response of the Firm:
Firm submitted the analytical validation report of drug product.

Decision: Approved.

719.	Name, address of Applicant / Marketing Authorization Holder	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 6420: 07-03-2023
	Details of fee submitted	PKR 30,000/- : Deposit slip # 89820391
	The proposed proprietary name / brand name	Medopa 250mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Methyldopa……250mg
	Pharmacotherapeutic Group of (API)	Antihypertensive
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	METHYLDOPA TABLETS 250mg by Aspen Pharma Trading Limited of , MHRA Approved
	For generic drugs (me-too status)	Cara Dopa 250mg by M/s Caraway Pharma.
	Proposed Pack size	As per SRO

Evaluation by PEC (No[4]):

S.No	Section	Shortcomings
1.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be 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
3.	3.2.S.4.3	Detailed Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.
4.	3.2.P.2.2.1	In pharmaceutical Equivalence Manufacturer of Aldomet mentioned is Hilton while in CDP OBS pharma mentioned.
5.	3.2.P.5.3	• Submit complete analytical method validation parameter. • In precision concentration of sample is change from submitted analytical testing method • Assay method according to monograph is UV than how analytical method validation is performed by HPLC

Decision of 339th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

Response of the Firm:

S.No	Shortcomings	Response of the Firm
1.	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	Firm submitted the latest GMP inspection issue dated 19-04-2023.
2.	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
3.	Detailed Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	Firm submitted the analytical verification report of drug substance which they have performed on UV system. While the USP monograph of methyldopa recommend assay on HPLC system.
4.	In pharmaceutical Equivalence Manufacturer of Aldomet mentioned is Hilton while in CDP OBS pharma mentioned.	Firm replied that it is a typographical mistake. Aldomet tablet manufacturer is OBS Pharma, rectified pharmaceutical equivalence report has been submitted by the firm.

5.	• Submit complete analytical method validation parameter. • In precision concentration of sample is change from submitted analytical testing method • Assay method according to monograph is UV than how analytical method validation is performed by HPLC	Firm submitted the analytical method verification report which is not in accordance with USP monograph of Methyldopa tablet.

Decision of 340th meeting:
Deferred for submission of following:

- Justify for performing the assay verification studies of drug substance on UV system when the USP monograph of methyldopa recommend assay on HPLC system.
- Submit complete analytical method validation parameter in compliance of USP monograph of Methyldopa tablet.

Response of the Firm:

1. Justify for performing the assay verification studies of drug substance on UV system when the USP monograph of methyldopa recommend assay on HPLC system.

Firm submit assay verification studies of drug substance performed by drug product manufacturer.

2. Submit complete analytical method validation parameter in compliance of USP monograph of Methyldopa tablet

Firm submit the assay verification report of drug product which is not in compliance of USP monograph of Methyldopa tablet, since the wavelength mentioned in the report was 280nm while the USP recommends analytical wavelength: 520 nm for the assay of methyldopa tablet.

Decision: Approved. Firm shall submit drug product analytical method verification studies as per USP monograph of "Methyldopa tablets", before issuance of registration letter.

720.	Name, address of Applicant / Marketing Authorization Holder	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 7695: 17-03-2023
	Details of fee submitted	PKR 30,000/- : Deposit slip # 0385279769
	The proposed proprietary name / brand name	Amfold 5mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Amlodipine as Besylate…….5mg
	Pharmacotherapeutic Group of (API)	Calcium Channel Blockers
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	NORVASC 5mg Tablet of Pfizer Inc., USA (USFDA Approved).
	For generic drugs (me-too status)	Dispan 5mg Tablet of M/s Sante Pharma Reg# 081458
	Proposed Pack size	As per SRO

Evaluation by PEC (No[4]):

S.No	Section	Shortcomings
1.	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted./

2.	1.6.5 (a)	Two different drug substance manufacturer are submitted .Clarify drug substance of which source used.
	1.6.5(b)	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.
3.	3.2.S.4.1 3.2.S.4.2 3.2.S.5 3.2.S.7	Copies of the Drug substance specifications, detailed analytical procedures used for routine testing, COA of working standard and stability studies of Drug substance /Active Pharmaceutical Ingredient are from M/s Cadila Pharmaceuticals while submitted COA of drug substance is from M/s Prudence Pharmachem. Clarify which is actual source of drug substance and provide all the documents accordingly.
4.	3.2.S.4.3	Detailed 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.4.4	You have not performed uniformity of dosage unit by content uniformity. Justification shall be submitted.
6.	3.2.P.8	Reference of previous approval of applications with stability study data of the firm

Decision of 339th meeting of Registration Board:

Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

Response of the Firm:

S.No	Shortcomings	Response of the Firm
1.	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	Submitted
2.	Two different drug substance manufacturer are submitted .Clarify drug substance of which source used.	Firm clarified that they have used the API imported from M/s. Cadila Healthcare Limited in the manufacturing of trial batches. Further, firm submitted the procurement document Form-6 in which amlodipine besylate 3 kg was imported from M/s. Cadila Healthcare.
	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.	Firm submitted the GMP certification of COA of working standard and stability studies of Drug substance /Active Pharmaceutical Ingredient which was valid till 18/09/2021.
3.	Copies of the Drug substance specifications, detailed analytical procedures used for routine testing, COA of working standard and stability studies of Drug substance /Active Pharmaceutical Ingredient are from M/s Cadila Pharmaceuticals while submitted COA of drug substance is from M/s Prudence Pharmachem. Clarify which is actual source of drug substance and provide all the documents accordingly.	Firm submitted only the COA of API from M/s. cadila Pharmaceuticals, while the remaining documents of M/s. Cadila Healthcare which included Drug substance specifications, detailed analytical procedures used for routine testing, COA of working standard and stability studies of Drug substance /Active Pharmaceutical Ingredient has not submitted by the firm.
4.	Detailed Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	Firm submitted assay method verification report performed by drug product manufacturer.
5.	You have not performed uniformity of dosage unit by content uniformity. Justification shall be submitted.	Firm submitted the revised batch analysis report of drug product in which content uniformity test has been included however the acceptance limit against which the test has been performed is not in accordance with USP.
6.	Reference of previous approval of applications with stability study data of the firm	Submitted

Decision of 340th meeting:
Deferred for submission of following:

- Submit detailed analytical procedure, COA of drug substance, COA of working standard and stability studies of Drug substance /Active Pharmaceutical Ingredient from M/s. Cadila Healthcare, India.
- 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.
- Justify for not adopting the acceptance criteria of content uniformity test is accordance with USP.

Response of the Firm

Sr.no.	Decision of 340th	Response of the Firm
1.	Submit detailed analytical procedure, COA of drug substance, COA of working standard and stability studies of Drug substance /Active Pharmaceutical Ingredient from M/s. Cadila Healthcare, India.	Submitted all the requisite documents.
2.	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.	Not submitted
3.	Justify for not adopting the acceptance criteria of content uniformity test is accordance with USP.	Firm submitted the revised stability data specify the acceptance criteria of content uniformity test 85%-115%, while the USP recommends the acceptance criterion for CU test as "Maximum allowed acceptance value L1 = 15.0 unless otherwise specified."

Decision: Approved. Registration letter will be issued upon revision of acceptance criteria for content uniformity test in accordance with general chapter of USP <905> *Uniformity of dosage units.* Additionally, a performance report for the content uniformity test, conducted at the next stability study time point in line with the revised acceptance criteria, must be submitted.

721.	Name, address of Applicant / Marketing Authorization Holder	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Name, address of Manufacturing site.	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 7696: 17-03-2023
	Details of fee submitted	PKR 30,000/- : Deposit slip # 00276911474
	The proposed proprietary name / brand name	Amfold 10mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Amlodipine as Besylate…….10mg
	Pharmacotherapeutic Group of (API)	Calcium Channel Blockers
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	NORVASC 10mg Tablet of Pfizer Inc., USA (USFDA Approved).
	For generic drugs (me-too status)	Dispan 10mg Tablet of M/s Sante Pharma Reg# 081459
	Proposed Pack size	As per SRO

Evaluation by PEC (No4):

S.No	Section	Shortcomings
1	1.3.5	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.

2.	1.6.5 (a)	Two different drug substance manufacturer are submitted .Clarify drug substance of which source used.
	1.6.5(b)	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.
3.	3.2.S.4.1 3.2.S.4.2 3.2.S.5 3.2.S.7	Copies of the Drug substance specifications, detailed analytical procedures used for routine testing, COA of working standard and stability studies of Drug substance /Active Pharmaceutical Ingredient are from M/s Cadila Pharmaceuticals while submitted COA of drug substance is from M/s Prudence Pharmachem. Clarify which is actual source of drug substance and provide all the documents accordingly.
4.	3.2.S.4.3	Detailed 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.4.4	You have not performed uniformity of dosage unit by content uniformity. Justification shall be submitted.
6.	3.2.P.8	Reference of previous approval of applications with stability study data of the firm

Decision of 339th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

Response of the Firm:

S.No	Shortcomings	Response of the Firm
1.	GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years shall be submitted.	Submitted
2.	Two different drug substance manufacturer are submitted .Clarify drug substance of which source used.	Firm clarified that they have used the API imported from M/s. Cadila Healthcare Limited in the manufacturing of trial batches. Further, firm submitted the procurement document Form-6 in which amlodipine besylate 3 kg was imported from M/s. Cadila Healthcare.
	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.	Firm submitted the GMP certification of M/s. Cadila Healthcare Limited, India which was valid till 18/09/2021.
3.	Copies of the Drug substance specifications, detailed analytical procedures used for routine testing, COA of working standard and stability studies of Drug substance /Active Pharmaceutical Ingredient are from M/s Cadila Pharmaceuticals while submitted COA of drug substance is from M/s Prudence Pharmachem. Clarify which is actual source of drug substance and provide all the documents accordingly.	Firm submitted only the COA of API from M/s. cadila Pharmaceuticals, while the remaining documents of M/s. Cadila Healthcare which included Drug substance specifications, detailed analytical procedures used for routine testing, COA of working standard and stability studies of Drug substance /Active Pharmaceutical Ingredient has not submitted by the firm.
4.	Detailed Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted.	Firm submitted assay method verification report performed by drug product manufacturer.
5.	You have not performed uniformity of dosage unit by content uniformity. Justification shall be submitted.	Firm submitted the revised batch analysis report of drug product in which content uniformity test has been included however the acceptance limit against which the test has been performed is not in accordance with USP.
6.	Reference of previous approval of applications with stability study data of the firm	Submitted

Decision of 340th meeting:
Deferred for submission of following:

- Submit detailed analytical procedure, COA of drug substance, COA of working standard and stability studies of Drug substance /Active Pharmaceutical Ingredient from M/s. Cadila Healthcare, India.
- 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.
- Justify for not adopting the acceptance criteria of content uniformity test is accordance with USP.

Response of the Firm

Sr.no.	Decision of 340th	Response of the Firm
4.	Submit detailed analytical procedure, COA of drug substance, COA of working standard and stability studies of Drug substance /Active Pharmaceutical Ingredient from M/s. Cadila Healthcare, India.	Submitted all the requisite documents.
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.	Not submitted
6.	Justify for not adopting the acceptance criteria of content uniformity test is accordance with USP.	Firm submitted the revised stability data specify the acceptance criteria of content uniformity test 85%-115%, while the USP recommends the acceptance criterion for CU test as "Maximum allowed acceptance value L1 = 15.0 unless otherwise specified"

Decision: Approved. Registration letter will be issued upon revision of acceptance criteria for content uniformity test in accordance with general chapter of USP <905> *Uniformity of dosage units.* Additionally, a performance report for the content uniformity test, conducted at the next stability study time point in line with the revised acceptance criteria, must be submitted.

722.	Name, address of Applicant / Marketing Authorization Holder	M/s. Med Asia Pharmaceuticals (Pvt.) Ltd. Plot No. 7 Nowshera Industrial Estate (SIZ), Risalpur
	Name, address of Manufacturing site.	M/s. Med Asia Pharmaceuticals (Pvt.) Ltd. Plot No. 7 Nowshera Industrial Estate (SIZ), Risalpur
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	afresh license granted on 10/11/2021.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 11-11-2021 specifying Capsules (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 26128 dated 30-10-2023
	Details of fee submitted	PKR 30,000/- Dated 26-10-2023
	The proposed proprietary name / brand name	PTL Tablet 40mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Enteric coated tablet contains: Pantoprazole as sodium sequihydrate…40mg
	Pharmacotherapeutic Group of (API)	PPI (Proton Pump Inhibitor)

	Pharmaceutical form of applied drug	White to off white circular round enteric coated tablet
	Reference to Finished product specifications	USP
	Proposed Pack size	2 x 7's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Neege 40mg Tablet by M/s Searle Pakistan, Reg. No. 110185
	Name and address of API manufacturer.	M/s. Tagoor Laboratories Pvt. Limited, Survey 29 Tupakulagudem (village), Pochavaram Panchayat, Tallapudi (Mandal), West Godavari District Andra pardesh, 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, 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, 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 pharmaceutical equivalence of their product against the reference product Neege 40mg Tablet of M/s. Searle Pharma. Firm has submitted CDP results of their product against the reference product Neege 40mg Tablet of M/s. Searle Pharma. in 2 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	M/s. Tagoor Laboratories Pvt. Limited, Survey 29 Tupakulagudem (village), Pochavaram Panchayat, Tallapudi (Mandal), West Godavari District Andrapardesh, India.		
API Lot No.	NA		
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.	MA-PT-001	MA-PT-002	MA-PT-003
Batch Size	550 Tablets	550 Tablets	550 Tablets
Manufacturing Date	01-2023	01-2023	01-2023
Date of Initiation	25-01-2023	25-01-2023	25-01-2023
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)	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 copy of GMP Certificate no. WC-0494 issuing date 26-02-2021 and valid until three years from the date of issue.
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.	Firm has submitted analytical record for product testing.
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:

S.no.	Section	Observations/Deficiencies/ Short-comings
1.	3.2.S.4.1-3.2.S.4.2	Submit data 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."
2.	3.2.S.4.3	Submit data 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". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.

3.	3.2.S.5	Submit COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.
4.	3.2.S.7	COA of USP complied drug substance is submitted in section 3.2.S.4.4 while the stability data of EP complied drug substance has given in relevant section; clarification is required in this regard. Submit stability data of drug substance till the claimed re-test date, since you have submitted the long term data of only 24 months.
5.	3.2.P.1	Justify the formulation which is different in terms of qualitative composition from that of innovator product.
6.	3.2.P.2.2.1	Provision of details including batch number, expiry date and name of manufacturer of the innovator product along with pharmaceutical equivalence was performed.
7.	3.2.P.8	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired. Documents for the procurement of API with approval from DRAP (in case of import). Compliance Record of HPLC software 21CFR & audit trail reports on product testing
8.	2.3.R.1.1	Provide Batch Manufacturing Record (BMR) of three stability batches.

Decision of 333rd meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit data 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
2.	Submit data 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". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.	Not submitted
3.	Submit COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.	Not submitted
4.	COA of USP complied drug substance is submitted in section 3.2.S.4.4 while the stability data of EP complied drug substance has given in relevant section; clarification is required in this regard. Submit stability data of drug substance till the claimed re-test date, since you have submitted the long term data of only 24 months.	submitted
5.	Justify the formulation which is different in terms of qualitative composition from that of innovator product.	Not submitted
6.	Provision of details including batch number, expiry date and name of manufacturer of the innovator product along with pharmaceutical equivalence was performed.	Not submitted
7.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired. Documents for the procurement of API with approval from DRAP (in case of import). Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Not submitted
8.	Provide Batch Manufacturing Record (BMR) of three stability batches.	Submitted

Decision of 336th meeting of Registration Board:
Deferred for submission of following:

- Submit data 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."
- Submit data 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". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.
- Submit COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.
- Justify the formulation which is different in terms of qualitative composition from that of innovator product.
- Provision of details including batch number, expiry date and name of manufacturer of the innovator product along with pharmaceutical equivalence was performed.
- Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired.
- Documents for the procurement of API with approval from DRAP (in case of import).
- Compliance Record of HPLC software 21CFR & audit trail reports on product testing

Response of the Firm:
In their response to the aforementioned decision, the firm submitted only the procurement document for the API, stating that they had obtained the API on loan from M/s. Hicon Pharmaceuticals.

Decision: Deferred for submission of following:

- Submit data 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."
- Submit data 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". Further justify how the analysis of drug substance was conducted without performing verification studies of the analytical method of drug substance.
- Submit COA of reference standard actually used in the analysis of drug substance in section 3.2.S.5.
- Justify the formulation which is different in terms of qualitative composition from that of innovator product.
- Provision of details including batch number, expiry date and name of manufacturer of the innovator product along with pharmaceutical equivalence was performed.
- Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired.
- Compliance Record of HPLC software 21CFR & audit trail reports on product testing.

Response of the Firm:

Sr#	Shortcomings	Response
1	Submit data 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 and Manufacturer is required."	Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance/Active Pharmaceutical Ingredient by both Drug substance and Manufacturer has been submitted
2	Submit data 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". Further justify how the analysis of drug substance was conducted without performing verification	Analytical Method Verification studies had been carried out previously before the analysis of the drug substance but erroneously/with unconditional apology, not submitted earlier. It is hereby submitted.

	studies of the analytical method of drug substance.	
2	Submit COA of reference standard actually used in the analysis of the drug substance in section 3.2.S.5.	COA of USP reference standard has been submitted.
3	Justify the formulation which is different in terms of qualitative composition from that of innovator product.	The composition mentioned in the section 3.2.P.1 was added earlier by mistake and the firm seeks the unconditional pardon for that. The qualitative composition of the PTL tablets 40mg is same as that of the innovator product i-e; Protonix 40mg Tablet. For reference, link of the website is given under alongwith the relevant text in the description section and the qualitative composition of PTL 40mg tablets is correctly submitted again.
4	Provision of details including Batch number, expiry date and name of manufacturer of the innovator product along-with pharmaceutical equivalence was performed.	The Details of the Innovator Product taken for the Pharmaceutical Equivalence studies is as under; Innovator Product Name: Neege Tablet 40mg Batch no: 001H Mfg Date: 02-2022 Exp Date: 01-2025 ML No: 000072 DR No: 039504 Manufacturer:SAMI Pharmaceuticals (Pvt) Ltd. F-95, S.I.T.E., Karachi, Pakistan The detailed pharmaceutical equivalence study is here-by submitted.
5	Approval of API/DML/GMP certificate of API manufacturer issued by concerned Regulatory Authority of country of origin , since the submitted GMP certificate is expired.	Valid GMP certificate submitted.
6	Documemts for the procurement of API with approval from DRAP(in case of import).	It is most humbly prayed that the firm was un-aware of this rule that in case of Loan taken from any other manufacturer, for Research and Development purpose, approval from DRAP is mandatory. Appropriate measures shall be taken to ensure this may not happen in the future. We would appreciate your co-operation in moving forward despite this discrepancy. In ANNEXURE 7, all the documents of Purchase are again submitted.
7	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	We hereby inform you that our HPLC system does not comply with 21CFR regulations. Consequently, the firm is unable to submit a 21CFR compliance certificate, hence audit trail documentation for the system is not available.

Decision: Approved.

M/s Fleming Pharmaceutical. (New DML)

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 five (05) sections to M/s M/s Fleming Pharmaceutical.

1. Oral Dry Powder for suspension(Penicillin) 2. Capsule (Penicillin) 3. Tablet (Penicillin) 4. Dry Powder Injectable (Penicillin) 5. Dry Powder Injectable (Carbapenem)		
Dry Powder Injectable (Carbapenem)		
723.	Name, address of Applicant / Marketing Authorization Holder	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Name, address of Manufacturing site.	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 14-09-2021 specifying Dry powder injectable(Carbapenem) 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. 25740 dated 24-10-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 217358766635
	The proposed proprietary name / brand name	Flemaxin 250 mg Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Imipenem Monohydrate eq to Imipenem…… 250 mg Cilastatin Sodium eq to Cilastatin…….250 mg
	Pharmaceutical form of applied drug	Carbapenem antibiotics
	Pharmacotherapeutic Group of (API)	A white or light yellow powder filled in glass vial properly sealed and labelled and packed in white colored unit cardboard box.
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Primaxin Injection (USFDA Approved)
	For generic drugs (me-too status)	Cilapen 250 mg Injection of M/s Bosh pharmaceuticals Reg # 048490
	Name and address of API manufacturer.	Name: ACS DOBFAR S.p.A Address: Viale Addetta 2a/12-3/520067 Tribiano Milano-Italy.
	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'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 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 pharmaceutical equivalence of their product against the product Cilapen 250 mg Injection manufactured by Bosch pharmaceuticals (PVT) LTD by performing quality tests Description, pH, Bacterial Endotoxins, Particulate matters, Assay, and Sterility Test, Loss on drying.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Name: ACS DOBFAR S.p.A Address: Viale Addetta 2a/12-3/520067 Tribiano Milano-Italy.		
API Lot No.	0069E1		
Description of Pack (Container closure system)	FPP is packed in a white or light yellow powder filled in glass vial properly sealed and labelled and packed in white colored unit cardboard box.		
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.	T01	T02	T03
Batch Size	1190 Vials	1190 Vials	1190 Vials
Manufacturing Date	05-2022	05-2022	05-2022
Date of Initiation	21-05-2022	21-05-2022	21-05-2022

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.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Take API's Loan from M/s Stallion Pharmaceuticals Firm has submitted copy of Clearnce certificate # E-417242824518, dated; 17-03-2020 issued by DRAP (Lahore) specifying Invoice # 100809 dated: 10-03-2022 specifying. Imipenem and Cilastatin Sodium Batch # 0069E1 (M/s Stallion Pharmaceuticals.)
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, raw data sheets, COA and summary data sheets.
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 along with audit trail report for 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 and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming
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
2.	3.2.S.4.1	Copies of the Drug substance specifications by Drug substance manufacturer is required.
3.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer is required.
4.	3.2.S.5 & 3.2.P.2.6	Compatibility studies for the dry powder for injections shall be performed as per the instructions provided in individual label of the drug product
5.	3.2.P.6	COA of reference standard submitted for Cilastatin Sodium while USP monograph specified Cilastatin Ammonium as reference standard.

Decision of 333rd meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

Response of the Firm:

S.No	Shortcoming	Response of the Firm
1.	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	Firm submitted the certificate of GMP compliance manufacturer based on inspection conducted on 12/0 and valid for three years.
2.	Copies of the Drug substance specifications by Drug substance manufacturer is required.	Submitted.
3.	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer is required.	Submitted.

4.	Compatibility studies for the dry powder for injections shall be performed as per the instructions provided in individual label of the drug product	Firm submitted the compatibility studies of dry p against the diluent 0.9% NaCl.
5.	COA of reference standard submitted for Cilastatin Sodium while USP monograph specified Cilastatin Ammonium as reference standard.	Firm submitted the COA of reference standard of imip while the query is relevant to COA of reference stand Cilastatin.

Decision: Approved. Registration letter will be issued upon submission of COA of reference standard of Cilastatin Ammonium.

724.	Name, address of Applicant / Marketing Authorization Holder	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Name, address of Manufacturing site.	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 14-09-2021 specifying Dry powder injectable(Carbapenem) sections.
	Status of application	☐ New Drug Product (NDP) ☒ Generic Drug Product (GDP)
	Intended use of pharmaceutical product	☐ Domestic sale ☐ Export sale ☒0 Domestic and Export sales
	Dy. No. and date of submission	Dy No. 25741 dated 24-10-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 68456344007
	The proposed proprietary name / brand name	Flemaxin 500 mg Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Imipenem Monohydrate eq to Imipenem…… 500 mg Cilastatin Sodium eq to Cilastatin…….500 mg
	Pharmaceutical form of applied drug	Carbapenem antibiotics
	Pharmacotherapeutic Group of (API)	A white or light yellow powder filled in glass vial properly sealed and labelled and packed in white colored unit cardboard box.
	Reference to Finished product specifications	USP
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Primaxin Injection (USFDA Approved)
	For generic drugs (me-too status)	Cilapen 500 mg Injection of M/s Bosh pharmaceuticals Reg # 048491
	Name and address of API manufacturer.	Name: ACS DOBFAR S.p.A Address: Viale Addetta 2a/12-3/520067 Tribiano Milano-Italy.
	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'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 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 pharmaceutical equivalence of their product against the product Cilapen 500 mg Injection manufactured by Bosch pharmaceuticals (PVT) LTD by performing quality tests Description, pH, Bacterial Endotoxins, Particulate matters, Assay, and Sterility Test, Loss on drying.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Name: ACS DOBFAR S.p.A Address: Viale Addetta 2a/12-3/520067 Tribiano Milano-Italy.		
API Lot No.	0069E1		
Description of Pack (Container closure system)	FPP is packed in a white or light yellow powder filled in glass vial properly sealed and labelled and packed in white colored unit cardboard box.		
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.	T01	T02	T03
Batch Size	1190 Vials	1190 Vials	1190 Vials
Manufacturing Date	05-2022	05-2022	05-2022

Date of Initiation	21-05-2022	21-05-2022	21-05-2022
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.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Take API's Loan from M/s Stallion Pharmaceuticals Firm has submitted copy of Clearnce certificate # E-417242824518, dated; 17-03-2020 issued by DRAP (Lahore) specifying Invoice # 100809 dated: 10-03-2022 specifying. Imipenem and Cilastatin Sodium Batch # 0069E1 (M/s Stallion Pharmaceuticals.)
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, raw data sheets, COA and summary data sheets.
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 along with audit trail report for 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 and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming
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
2.	3.2.S.4.1	Copies of the Drug substance specifications by Drug substance manufacturer is required.
3.	3.2.S.4.2	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer is required.
4.	3.2.S.5 & 3.2.P.2.6	Compatibility studies for the dry powder for injections shall be performed as per the instructions provided in individual label of the drug product
5.	3.2.P.6	COA of reference standard submitted for Cilastatin Sodium while USP monograph specified Cilastatin Ammonium as reference standard.

Decision of 333rd meeting:
Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

Response of the Firm:

S.No	Shortcoming	Response of the Firm
1.	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	Firm submitted the certificate of GMP compliance manufacturer based on inspection conducted on 12/0 and valid for three years.
2.	Copies of the Drug substance specifications by Drug substance manufacturer is required.	Submitted.
3.	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug substance manufacturer is required.	Submitted.

4.	Compatibility studies for the dry powder for injections shall be performed as per the instructions provided in individual label of the drug product	Firm submitted the compatibility studies of dry p against the diluent 0.9% NaCl.
5.	COA of reference standard submitted for Cilastatin Sodium while USP monograph specified Cilastatin Ammonium as reference standard.	Firm submitted the COA of reference standard of imip while the query is relevant to COA of reference stand Cilastatin.

Decision: Approved. Registration letter will be issued upon submission of COA of reference standard of Cilastatin Ammonium.

725.	Name, address of Applicant / Marketing Authorization Holder	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Name, address of Manufacturing site.	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 14-09-2021 specifying Dry powder injectable(Carbapenem) 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. 20847 dated 28-08-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 477158197
	The proposed proprietary name / brand name	Flerta 1.0 g Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Ertapenem sodium eq to Ertapenem…….. 1.0g
	Pharmaceutical form of applied drug	Carbapenem antibiotics
	Pharmacotherapeutic Group of (API)	White to light yellow lyophilized powder.
	Reference to Finished product specifications	Innovator's
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Invanz 1.0 g Injection (USFDA Approved)
	For generic drugs (me-too status)	Ernem 1.0 g Injection of Genix Pharma.Reg # 081179
	Name and address of API manufacturer.	Savior lifetec corporation. TINAN SITE Block A/B, 11 DA-SHUEN 9TH ROAD, XINSHI DISTRICT. TAINAN CITY, TW-74145, TAIWAN.
	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'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 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 30°C ± 2°C / 65 ± 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 product Invanz 1.0 g injection manufactured by Merck sharp & Dohme chibret (Mirabel), France by performing quality tests Description, pH, Bacterial Endotoxins, Particulate matters, Assay, and Sterility Test, Loss on drying.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Name: ACS DOBFAR S.p.A Address: Viale Addetta 2a/12-3/520067 Tribiano Milano-Italy.		
API Lot No.	805028AA011		
Description of Pack (Container closure system)	FPP is packed in a white or light yellow powder filled in glass vial properly sealed and labelled and packed in white colored unit cardboard box.		
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.	T01	T02	T03
Batch Size	333 Vials	333 Vials	333 Vials
Manufacturing Date	10-2022	10-2022	10-2022
Date of Initiation	12-10-2022	12-10-2022	12-10-2022

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.	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy of Commercial invoice # s220721-002, dated; 21-07-2022 specifying. Ertapenem Sodium Batch # 805028AA011
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, raw data sheets, COA and summary data sheets.
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 along with audit trail report for 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 and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming
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
2.	2.3.A.1	Provide evidence of Atomic absorption spectrometer.
3.	3.2.S.4.4	Specification for assay by drug substance manufacturer is 77.0% -82.7% while in COA of drug substance specifications for assay are 77.0% -85%
4.	3.2.S.5	Submitted drug substance analytical procedure mandates use of Ertapenem Sodium as working standard whereas submitted COA is of Ertapenem sodium lyophilized powder for injection. justification shall be submitted for using Ertapenem sodium lyophilized powder as working standard instead of the pure Ertapenem sodium.
5.	3.2.S.7	Justification shall be submitted for conducting drug substance stability studies at refrigerating conditions.
6.	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.
7.	3.2.P.2.6	Compatibility studies for the dry powder for injections shall be performed as per the instructions provided in individual label of the drug product
8.	3.2.P.6	Justification shall be submitted for using Ertapenem sodium lyophilized powder as working standard instead of the pure Ertapenem sodium.
9.	3.2.P.8	Documents for the procurement of API with approval from DRAP.

Decision of 333rd meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

Response of the Firm:

S.No	Shortcoming	Response of the Firm
1.	Valid Drug Manufacturing License or Valid Good Manufacturing Practice (GMP) certificate of the Drug	Firm submitted the GMP certificate of API manufacturer Savior lifetec corporation. TINAN SITE

	Substance manufacturer issued by relevant regulatory authority of country of origin	Block A/B, 11 DA-SHUEN 9TH ROAD, XINSHI DISTRICT. TAINAN CITY, TW-74145, TAIWAN which was expired on 23-01-2024.
2.	Provide evidence of Atomic absorption spectrometer.	Firm submitted an invoice of purchasing Atomic Absorption Spectrophotometer dated 12-10-2021 along with installation qualification and calibration document.
3.	Specification for assay by drug substance manufacturer is 77.0% -82.7% while in COA of drug substance specifications for assay are 77.0% -85%	Firm replied that Justification from Drug Substance manufacturer given below: Due to the continuous improvement of lyophilization process, now the upper limit of the assay specification is revised to 85% whereas the lower limit is unchanged. The revision well reflects the product quality improvement. Updated specification for the drug substance is Attached
4.	Submitted drug substance analytical procedure mandates use of Ertapenem Sodium as working standard whereas submitted COA is of Ertapenem sodium lyophilized powder for injection. justification shall be submitted for using Ertapenem sodium lyophilized powder as working standard instead of the pure Ertapenem sodium.	Firm replied that Justification from Drug Substance manufacturer given below: Ertapenem sodium is unstable and must be stored at freezer. As Ertapenem sodium is more prone to degradation when exposed to an open environment, it is not a good option as working standard. In relative, Ertapenem sodium lyophilized powder (also named as Ertapenem for injection bulk) is more stable and so it is more appropriate to act as working standard.
5.	Justification shall be submitted for conducting drug substance stability studies at refrigerating conditions.	Firm replied that Justification from Drug Substance manufacturer given below: Savior performed the in-house study to find out a recommended condition for transport and storage for Ertapenem for Injection (Sterile Bulk). In the study, we observe the degradation impurities are temperature dependent and can be minimized by storage of the sterile bulk in a refrigerator (2~8°C). To assure the acceptance criteria/specification for the impurities meet for the finished product (vial) through the whole shelf life, we minimize the increase in impurity profile before vial filling, so we suggest Ertapenem for Injection (Sterile Bulk) storing at 2~8°C and conduct the stability studies at refrigerating condition.
6.	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.	Firm replied that Total filled weight of Ertapenem for injection is 1307. As material supplied as Ertapenem sodium factor of sodium is 1.046 after adjusting factor weight is 1046 Potency of Ertapenem sodium as is basis is 80.41% after adjusting this potency to 100% we will get total filled weight which include content of sodium and sodium bicarbonate declared in analysis of drug substance.
7.	Details of accompanying reconstitution diluent shall be submitted.	Firm replied that Flerta is supplied as sterile lyophilized powder for intravenous infusion after reconstitution with 0.9% sodium chloride 10 ml and transfer to 50 mL 0.9% Sodium Chloride Injection. Compatibility study of dry powder for injection is performed with 0.9% NACL and Report has been attached.
8.	Compatibility studies for the dry powder for injections shall be performed as per the instructions provided in individual label of the drug product	Firm replied that Flerta is supplied as sterile lyophilized powder for intravenous infusion after reconstitution

		with 0.9% sodium chloride 10 ml and transfer to 50 mL 0.9% Sodium Chloride Injection. Compatibility study of dry powder for injection is performed with 0.9% NACL and Report has been attached as ANNEX IV.
9.	Justification shall be submitted for using Ertapenem sodium lyophilized powder as working standard instead of the pure Ertapenem sodium.	Firm replied that Justification from Drug Substance manufacturer given below: Ertapenem sodium is unstable and must be stored at freezer. As Ertapenem sodium is more prone to degradation when exposed to an open environment, it is not a good option to be as working standard. In relative, Ertapenem sodium lyophilized powder (also named as Ertapenem for injection bulk) is more stable and so it is more appropriate to act as working standard.
10.	Documents for the procurement of API with approval from DRAP.	Submitted

Decision: Approved.

Oral Dry Powder for suspension(Penicillin)

726.	Name, address of Applicant / Marketing Authorization Holder	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Name, address of Manufacturing site.	M/s Fleming Pharmaceutical. 23- Km Lahore- Sheikhupura Road, Lahore.
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of grant of section dated 14-09-2021 specifying oral dry powder for suspension (Penicillin)
	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. 20848 dated 23-08-2023
	Details of fee submitted	Rs.30,000/- Deposit slip # 358853822803
	The proposed proprietary name / brand name	Flemicillin 125 mg/5mL Suspension
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5mL contains: Ampicillin Trihydrate eq to Ampicillin…… 125mg
	Pharmaceutical form of applied drug	Penicillin antibiotics
	Pharmacotherapeutic Group of (API)	White to off white well homogenized powder free from extraneous matter filled in ambered glass bottle sealed with pp cap, neatly labelled and packed in a unit carton with insertion of a leaflet, plastic measuring cup 20ml, and plastic spoon 5ml, on reconstitution with 40ml of water, off white suspension with sweet taste is availed.
	Reference to Finished product specifications	BP

	Proposed Pack size	60ml, 100ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Ampicillin 125 mg Suspension (MHRA Approved)
	For generic drugs (me-too status)	Ampistal Suspension of M/s Stallion pharmaceuticals (Reg # 077228).
	Name and address of API manufacturer.	Pharmagen Limited. Kot Nabi Bukshwala 34 Km- Ferozpur Road, Lahore, Pakistan.
	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'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 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 72 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 product Ampistal Suspension 125 mg manufactured by Stallion pharmaceutical (PVT) LTD by performing quality tests Description, Identification, pH, Microbial contamination, Deliverable volume, Assay,
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.
STABILITY STUDY DATA		

Manufacturer of API	M/s Pharmagen Limited Kot Nabi Bukshwala 34 Km- Ferozpur Road, Lahore, Pakistan.		
API Lot No.	00003/070/2021		
Description of Pack (Container closure system)	FPP is packed in ambered colored glass bottle, further packed in unit carton along with patient leaflet 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: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	T01	T02	T03
Batch Size	1666 bottles	1666 bottles	1666 bottles
Manufacturing Date	04-2022	04-2022	04-2022
Date of Initiation	22-04-2022	23-04-2022	25-04-2022
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.	Copy of GMP certificate No. 129/2020-DRAP (AD/1998630-530) issued by DRAP on the basis of evaluation conducted on 22-06-2022 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.	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data sheets.
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 along with audit trail report for 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 and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming
1.	1.6.5	Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer.
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 instead of drug product in accordance to BP monograph.
5.	3.2.S.7	Justification is required for not performing the identification test, pH and determination of optical rotation during the stability study of drug substance

6.	3.2.P.2.5	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.
7.	3.2.P.5.2	Concentrations of standard and sample solution as per BP monograph is 0.06mg/ml while your concentration for standard and sample are 0.6mg/ml. Clarify.
8.	3.2.P.5.3	Concentrations used for standard and sample are not as per BP monograph in analytical method verification. Clarification is required.
9.	3.2.P.6	• BP monograph specified use of anhydrous Ampicillin as reference standard while you have provided COA of Ampicillin Trihydrate as reference standard. Clarification is required. • Submit COA of reference standard Cefradine as per BP monograph.
10.	3.2.P.8	Purchase documents for Ampicillin trihydrate from Drug substance manufacturer.

Decision of 333rd meeting:
Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

Response of the Firm:

S.No	Shortcoming	Response of the Firm
1.	Valid Good Manufacturing Practice (GMP) certificate of the Drug Substance manufacturer.	Submitted
2.	Copies of the Drug substance specifications by Drug Product manufacturer is required.	Submitted in compliance of BP monograph of Ampicillin Trihydrate.
3.	Analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient by Drug Product manufacturer is required.	Submitted
4.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for drug substance(s) shall be submitted instead of drug product in accordance to BP monograph.	Submitted
5.	Justification is required for not performing the identification test, pH and determination of optical rotation during the stability study of drug substance	Stability summaries which include identification test, pH and optical rotation is attached
6.	Preservative effectiveness studies to be performed as per recommendations of pharmacopoeia) shall be provided.	Report of Preservative effectiveness study which is product specified is attached
7.	Concentrations of standard and sample solution as per BP monograph is 0.06mg/ml while your concentration for standard and sample are 0.6mg/ml. Clarify.	Firm replied that Dilution was prepared according to the concentration mentioned in BP monograph which is 0.06 mg/mL as 0.6 is much higher concentration as compared to 0.06 mg/mL and Peak area will also be much higher at 0.6 mg/mL. It was duly because of clerical error and we have attached
8.	Concentrations used for standard and sample are not as per BP monograph in analytical method verification. Clarification is required.	Firm replied that, as mentioned above dilution was prepared according to the concentration mentioned in BP monograph which is 0.06 mg/mL as 0.6 is much higher concentration as compared to 0.06 mg/mL and Peak area will also be much higher at 0.6 mg/mL. It was duly because of clerical error and we have attached revised copy of protocol and report for method verification

9.	• BP monograph specified use of anhydrous Ampicillin as reference standard while you have provided COA of Ampicillin Trihydrate as reference standard. Clarification is required. • Submit COA of reference standard Cefradine as per BP monograph.	Firm replied that Justification from drug substance manufacturer for Trihydrate are given below: For the preparation of lab working standard, sample is selected from the commercial batch of Ampicillin Trihydrate previously tested against lab working standard. The selected batch is B # 00002/096/2021 tested against USP Reference Standard, Catalog No. 1033000, Lot No. R084VO & CAS No. 69-53-4 after preparation. Detail of standardization is attached
10.	Purchase documents for Ampicillin trihydrate from Drug substance manufacturer.	Submitted

Decision: Approved.

727.	Name, address of Applicant / Marketing Authorization Holder	M/s Neutro Pharma (Pvt) Ltd. 9.5 KM, Sheikhupura Road, Lahore
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt) Ltd. 9.5 KM, Sheikhupura Road, Lahore
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted cGMP certificate dated:30-06-2022 on the basis of evaluation conducted on 14-04-2022 and valid for 3 years.
	Evidence of approval of manufacturing facility	Firm submitted copy of grant of additional section dated:22-06-2017 in which S.V..P (Blow fill & sealing in LDPE) section mentioned.
	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 27900 dated 03-10-2022
	Details of fee submitted	Rs.30,000/- Deposit slip # 0420453621
	The proposed proprietary name / brand name	Indrop D 300,000 IU LDPE Ampoule Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml Contains: Cholecalciferol……..300,000 IU
	Pharmaceutical form of applied drug	Light straw to yellow oily liquid free from extraneous matter filled in clear glass ampoule
	Pharmacotherapeutic Group of (API)	Vitamin D analogue
	Reference to Finished product specifications	BP
	Proposed Pack size	1 x 1ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	Xarenel by Italfarmaco of (AIFA Italy Approved)
	For generic drugs (me-too status)	
	Name and address of API manufacturer.	M/s Xinchang Dado West Road, Qixing street, Xinchang Country, Zhejang 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, 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 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 RH for 6 months. The real time stability data is conducted at 30˚C ± 2˚C / 65% ± 5%RH 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.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted pharmaceutical equivalence of their product against the Xareneol 300,000IU/ml of Italfarmaco by performing quality tests Description, Identification, average fill volume, sterility, Assay)
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA	
Manufacturer of API	M/s Xinchang Dado West Road, Qixing street, Xinchang Country, Zhejang Province, China.
API Lot No.	01210302VD
Description of Pack (Container closure system)	LDPE 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.	LDA_i T1-21	LDA_i T2-21	LDA_i T3-21
Batch Size	5 Litres	5 Litres	5 Litres
Manufacturing Date	08-2021	09-2021	09-2021
Date of Initiation	10-09-2021	24-09-2021	27-09-2021
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)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of DML# Zhejiang 20030221 issued by NMPA dated: 14-07-2022 and valid till 13-07-2027
3.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted copy Commercial Invoice # 122070 + 122073, dated; 25-03-2021 cleared by DRAP (Lahore) dated: 08-04-2021 specifying Cholecalciferol batch # 01210302VD
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, raw data sheets, COA and summary data sheets.
5.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	UV method is applied as per BP monograph.
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:

S.No	Section	Shortcoming	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	Submitted.
2.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer of drug substance(s) shall be submitted.	Analytical Method Verification of drug substance by drug product manufacturer is submitted.
3.	3.2.S.5	Submitted COA of working standard Complies with USP specification while drug substance specification Claimed Ph.EU. Clarification is required.	Mistakenly shared the working standard COA of different source, actual COA of working standard received from drug substance manufacturer is submitted.
4.	3.2.S.7.3	Submit drug substance stability studies of 3 batches.	Drug substance stability studies of 03 batches submitted.
5.	3.2.P.1	• Justify the applied formulation with BP	• We have used ethyl oleate as recommended in BP monograph,

		specifications while using medium chain triglycerides oil, since BP monograph specifies ethyloleate. • Justify the use of Butylated hydroxyanisole (BHA)	Trial manufacturing record is submitted please verify. • We observed the color change that is why practically developed and stabilized it using BHA as anti-oxidant, Compatibility studies are also performed and product is stable.
6.	3.2.P.2.2.1	How pharmaceutical equivalence of Indrop D 300,000 IU Glass Ampoule Injection and Indrop D 300,000 IU LDPE Ampoule Injection can be same. Clarification is required.	Already submitted are the pharmaceutical equivalence specifications that looks same now pharmaceutical equivalence report is submitted.
7.	3.2.P.5.1	Particulate matter testing not the part of specifications. Clarification is required.	Particulate matter testing is included in the finish product specifications.
8.	3.2.P.5.2	Submit complete method of sterility testing.	Complete sterility testing method is submitted.
9.	3.2.P.6	COA of primary / secondary reference standard including source and lot number shall be provided.	COA of primary/secondary reference standard including source & lot number is submitted.

Decision of 336th meeting of Registration Board:
Deferred for evidence of approval of applied formulation in same container closure in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.

Response of the Firm:
Firm in their reply submitted the same stability data which they earlier submitted along with the main dossier, performed at condition Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH. However, in their reply, firm changed the stability condition of data and submit the same stability data with condition mentioned on stability sheets are 30°C ± 2°C/35% RH ± 5% RH and 40°C ± 2°C/not more than (NMT) 25% RH.

Decision: Deferred for further deliberation regarding requirement of storage condition required for conducting stability studies considering the nature of applied formulation (oil base or aqueous based).

728.	Name, address of Applicant / Marketing Authorization Holder	M/s Genix Pharma Pvt Ltd. 44,45B, Korangi Creek Road, Karachi, 75190, Pakistan
	Name, address of Manufacturing site.	M/s Genix Pharma Pvt Ltd. 44,45B, Korangi Creek Road, Karachi, 75190, Pakistan
	Status of the applicant	☒Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	GMP status of the firm	Firm submitted cGMP certificate dated: 07-10-2021 on the basis of evaluation conducted on 15-06-2021 and valid for 2 years.
	Evidence of approval of manufacturing facility	Firm submitted copy of renewal of DML dated:20-11-2021 in which Dry Powder Injection (General) section mentioned.
	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 28939 dated 12-10-2022
	Details of fee submitted	Rs.30,000/- Deposit slip # 5040866617
	The proposed proprietary name / brand name	Colmixin 2 MIU Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Colistimethate Sodium…2MIU
	Pharmaceutical form of applied drug	Powder for Solution for Injection
	Pharmacotherapeutic Group of (API)	Antibacterial for systemic use, other antibacterial, polymyxins.
	Reference to Finished product specifications	USP
	Proposed Pack size	10ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	COLOMYCIN 2 million International Units (IU) Powder for Solution for Injection by Teva UK Limited of (MHRA Approved)
	For generic drugs (me-too status)	Nogotex injection 3MIU of M/s Nabiqasim Industries Reg# 110206
	Name and address of API manufacturer.	Livzon Group Fuzhous Fuxing Pharmaceutical Co, Ltd. Address: No.8 Nangang Road, Jiangyin industrial Concentration Zone, Fuzhou City, Fujian Province, P.R. China, 350309.
	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'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 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 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 pharmaceutical equivalence of their product against the Colomycin Injection 2 MIU of Teva UK limited performing quality tests Identification, Appearance, pH, Loss on drying , Free colistin, Assay.
	Analytical method validation/verification of product	Firm has submitted analytical method verification study reports for as drug product.

STABILITY STUDY DATA			
Manufacturer of API	Livzon Group Fuzhous Fuxing Pharmaceutical Co, Ltd. Address: No.8 Nangang Road, Jiangyin industrial Concentration Zone, Fuzhou City, Fujian Province, P.R. China, 350309.		
API Lot No.	CMS2106004		
Description of Pack (Container closure system)	10ml clear tubular glass vial Type-1		
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(B)-252-01	21SB(B)-253-02	21SB(B)-254-03
Batch Size	500 Vial	500 Vial	500 Vial
Manufacturing Date	11-2021	11-2021	11-2021
Date of Initiation	24-11-2021	24-11-2021	24-11-2021
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)	
2.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Written confirmation for active substance to EU #FJ00006 to M/s Livzon Group Fuzhous Fuxing Pharmaceutical Co, Ltd. Address: No.8 Nangang Road, Jiangyin industrial Concentration Zone, Fuzhou City, Fujian Province, P.R. China, 350309 Valid upto 21-09-2022.The certificate confirms that the manufacturing plant complies with requirement of Chinese Good Manufacturing practices.
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	Firm has submitted complete record of testing of all batches, raw data sheets, COA and summary data

	chromatograms, Raw data sheets, COA, summary data sheets etc.	sheets.
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)	Firm has submitted record of digital data logger for temperature and humidity monitoring of real time and accelerated stability chambers.

Evaluation by PEC:

S.No	Section	Shortcoming
1.	1.5.2	Label claim of Injection of Colistimethate sodium shall be updated according to approved pharmacopoeial specifications i.e mention equivalency of "Colistimetahte sodium (IU)" with "Colistin base activity" in miligrams with requisit fee.
2.	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
3.	3.2.S.4.2	Analytical procedure of Bioassay is not in accordance to with the USP General Chapter <81>
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) shall be submitted.
5.	3.2.S.5.4	As per USP monograph Test for free colistin not performed, Clarification is required
6.	3.2.P.2.6	Compatibility studies for the dry powder for injections shall be performed as per the instructions provided in individual label of the drug product
7.	3.2.P.5.4	Copies of complete analysis of three batches shall be provided.
8.	3.2.P.5.2	Analytical procedure of Bioassay is not in accordance to with the USP General Chapter <81> MICROBIAL ASSAYS Justify your sample preparation for assay in Analytical testing method with reference to USP monograph
9.	3.2.P.5.3	Analytical Method Verification studies performance is not in accordance to USP General Chapter <81> —MICROBIAL ASSAYS
10.	3.2.P.8	• Submit legible form of import documents • In submitted stability studies performance of microbial Assay is different than USP General Chapter <81> of MICROBIAL ASSAYS • Concentration of S_1-S_5 and U_3 are different than their own method

Previous Decision (M-336): Registration Board deferred the case for submission of reply to the above cited shortcomings and evaluation by PE&R Division.

Evaluation by PEC:

S.No	Section	Shortcoming	Reply
1.	1.5.2	Label claim of Injection of Colistimethate sodium shall be updated according to approved pharmacopoeial specifications i.e mention equivalency of "Colistimetahte sodium (IU)" with "Colistin base activity" in miligrams with requisit fee.	Revise label claim along with the requisite fees of Rs 30,000/- Having Deposit Slip # 22355197 attached as Annex-I Each Vial Contains: Colistin as colistimethate Sodium equivalent 2MIU.
2.	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	Copy of DML attached valid till 21-09-2025

3.	3.2.S.4.2	Analytical procedure of Bioassay is not in accordance to with the USP General Chapter <81>	➢ Our method of bioassay is according to USP Chapter 81 we can justify as: ➢ We have made dilutions of Standard and Sample According to USP 81, Stock solution concentration(1mg/ml) is same as USP monograph 81 ,plz see point number 6.3 and 6.4 in our Bioassay Method and table 2 in USP monograph 81. The successive solutions increase stepwise in Concentration in the ratio of 1:1.25 which is required by USP see dilution flow chart given in our bioassay method in point number 6.3 and 6.4. ➢ The median Concentration shows in USP chapter 81 for Colistimethate Sodium is 1 µg/Mlbut we make the 57.6 µg/mL because of Zone size which cannot readable on 1 µg/mL median concentration which we cannot estimate or read properly (*that It is acceptable to adjust the median concentration to optimize zone sizes if the data remain in the linear range).* Please see USP chapter 81 cylinder-Plate Method says (in Table 2 attached as Annex-III) ➢ We have made the dilution in the ratio of 1:1.25 and the data remain in the linear range. ➢ According to the USP 81 we have made sample and standard dilution according to USP and both concentrations are same. ➢ The size of zones diameter that was produce in Bioassay method, analytical method verification & Stability studies is according to USP Chapter 81which were between 11-19mm see attached USP 81 Heading Inocula *They are using medium 10 while USP Bioassay specifies Medium 9*
4.	3.2.S.4.3	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer drug substance(s) shall be submitted.	Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the drug product manufacturer drug substance(s) are attached.
5.	3.2.S.5.4	As per USP monograph Test for free colistin not performed, Clarification is required	We are using Colistimethate sodium sterile ready to fill material, according to USP monograph of Colistimethate for Injection, all tests including free colistin will be performed as per colistimethate sodium USP monograph. So, we performed free colistin test in finished product after filling of

			material. Revised COA having with free colistin test is attached
6.	3.2.P.2.6	Compatibility studies for the dry powder for injections shall be performed as per the instructions provided in individual label of the drug product	Compatibility study attached
7.	3.2.P.5.4	Copies of complete analysis of three batches shall be provided.	Complete analysis of three batches are attached
8.	3.2.P.5.2	Analytical procedure of Bioassay is not in accordance to with the USP General Chapter <81> MICROBIAL ASSAYS Justify your sample preparation for assay in Analytical testing method with reference to USP monograph	Please see the justification as mentioned in Section 3.2.S.4.2
9.	3.2.P.5.3	Analytical Method Verification studies performance is not in accordance to USP General Chapter <81> —MICROBIAL ASSAYS	Please see the justification as mentioned in Section 3.2.S.4.2
10.	3.2.P.8	• Submit legible form of import documents • In submitted stability studies performance of microbial Assay is different than USP General Chapter <81> of MICROBIAL ASSAYS • Concentration of S_1-S_5 and U_3 are different than their own method	• Import documents submitted. • Please see the justification as mentioned in Section 3.2. S.4. *In their method different concentrations are prepared for standard S_1-S_5 and sample U_3 while in performance different concentration are used.*

Decision of 339th meeting of Registration Board:
Deferred for clarification of using different concentration of standard *S1-S5 and sample U3* in analytical testing method and stability data.

Response of the Firm:
Firm submitted the verification report of drug product in which concentration of four standards and the conc. of median prepared for microbial assay was not in accordance with USP general chapter of <81> Antibiotics—Microbial assays.

Decision of 340th meeting:
Deferred to justify the significant difference in the median concentration adopted for the applied product compared to the concentration recommended in USP General Chapter <81> on Antibiotics—Microbial Assays. The median concentration used for the microbial assay of the applied product is 57.6 µg/ml, while USP <81> recommends a median concentration of 1 µg/ml for colistimethate analysis. Additionally, the detailed method outlined in section 3.2.P.5.2 specifies different concentrations for standards S1-S5 and sample U3, whereas the raw data sheet from the stability study shows that the concentrations of standards S1-S5 and sample U3 differ from those specified in the outlined method.

Response of the Firm:
In response of above query firm replied "The median Concentration shows in USP chapter 81 for Colistimethate Sodium is 1 µg/mL but we make the 57.6 µg/mL because of Zone size which cannot readable on 1 µg/mL median concentration which we cannot estimate or read properly plz see USP chapter 81 cylinder-Plate Method says (in Table 2 attached) that It is acceptable to adjust the median concentration to optimize zone sizes if the data remain in the linear range.(kindly see highlighted point in Attached reference)

- We have made the dilution in the ratio of 1:1.25 and the data remain in the linear range. The difference between the concentrations is 1:1.25 shows linearity and according to USP.

2. Concentration specifies for S1-S5 and sample U3 in method are same as in stability raw data sheet the detailed explanation is as below:

1mg of Colistimethate sodium contains 450 µg of colistin

1st We dissolve 10mg in 10ml WFI it makes 1mg /ml concentration (containing 450 µg Colistin)

↓

Take 5ml from stock solution and dissolve in 25ml buffer 6 it will make S5 concentration

450x5/25=90 µg of Colistin

↓

From S5 take 20ml and dissolve in 25ml of buffer 6 it will make S4 concentration

90x20/25=72 µg of Colistin

↓

From S4 take 20ml and dissolve in 25ml of buffer 6 it will make S3 concentration (Median Conc.)

72x20/25=57.6 µg of Colistin

↓

From S3 take 20ml and dissolve in 25ml of buffer 6 it will make S2 concentration

57.6x20/25=46.08 µg of Colistin

↓

From S2 take 20ml and dissolve in 25ml of buffer 6 it will make S1 concentration

46.08x20/25=36.86 µg of Colistin

We have made all the concentration same as in specifies in the methods all the concentrations from S1-S5 and sample U3 made in raw data sheet of stability study are made according to the method we have specified

Decision: Approved.

Previously Deferred Cases of Form-5F (Finished Import):

729.	Name, address of Applicant / Importer	M/s. Zhangjiakou Dongfang Pharmaceutical Pakistan Pvt. Ltd. D-2,2nd Floor, West Land Trade Centre, Plot No. C-5, Block 7/8, K C H S U, Shaheed-e-Millat Road Karachi
	Details of Drug Sale License of importer	License No: 0067 Address: D-2,2nd Floor, West Land Trade Centre, Plot No. C-5, Block 7/8, K C H S U, Shaheed-e-Millat Road Karachi. Address of Godown: D-2,2nd Floor, West Land Trade Centre, Plot No. C-5, Block 7/8, K C H S U, Shaheed-e-Millat Road Karachi. Validity: 09/10/2022 Status: Stock, Exhibit to sell, License to sell drugs as distributor by way of wholesale Renewal: Our license has been renewed and the details written above are for the renewed licenses.
	Name and address of marketing authorization holder (abroad)	M/s. Lunan Better Pharmaceutical Co. Ltd. No. 243 Yinqueshan Road, Linyi, Shandong, China
	Name, address of manufacturer(s)	Name of Manufacturer: M/s. Lunan Better Pharmaceutical Co. Ltd. Address: No. 243 Yinqueshan Road, Linyi, Shandong, China
	Name of exporting country	China

	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized CoPP certificate No: NO. SHANDONG 20210104 Dated 06-07-2021 issued by The Fifth Branch of Regional Inspection Shandong Food and Drug Administration valid till 26-06-2023. Firm has submitted GMP certificate no.HB20190552 of Manufacturer M/s. Lunan Better Pharmaceutical Co. Ltd. No. 243, Yinqueshan Road, Linyi, Shandong and the certificate remain valid until; 25-11-2023.
	Details of letter of authorization / sole agency agreement	Letter of Authorization submitted by the firm in which it is specifies that M/s.Lunan Better Pharmaceutical Co. Ltd. authorize to get registration of their product (Latanoprost Eye Drops) and authorized distributor for the product to make registration with DRAP and to sale, distribute, market & quote in any Government, semi-Government and Semi-Government and Autonomous Bodies & Private Sectors 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.no.23664 dated 22-08-2022
	Details of fee submitted	PKR 150,000/-: vide slip no. 51511233694 dated 15-08-2022.
	The proposed proprietary name / brand name	Latanoprost Eye Drops 2.5ml:0.125mg (0.005%)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2.5ml contains: Latanoprost……0.125mg
	Pharmaceutical form of applied drug	Ophthalmic solution
	Pharmacotherapeutic Group of (API)	Prostaglandin F2α Analogue (S01EE01)
	Reference to Finished product specifications	In-house
	Proposed Pack size	2.5ml of ophthalmic solution packed in 5ml LDPE eye drop bottle
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	USFDA Approved (XALATAN® (latanoprost ophthalmic solution) 0.005%, for topical ophthalmic use)
	For generic drugs (me-too status)	Xalatan Eye Drops of M/s. Pfizer Pakistan Pvt. Ltd., Karachi (Reg.no. 021125)
	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. Yonsung Fine Chemicals Co. Ltd. 207 Sujeong-Ro,Jangan-Myeon,Hwaseong-Si,Gyeonggi D0,18581,Republic of Korea.
	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 accelerated stability data is conducted at 5ºC ± 3ºC and the real time stability study is conducted at -20± 5ºC. 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	Firm has submitted Pharmaceutical Equivalence studies report against the innovator product XALATAN® (latanoprost ophthalmic solution) 0.005%, for topical ophthalmic use.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	2.5ml:0.125mg packaged in 5ml LDPE Medicinal Eye Drops bottle (containing bottle, inner stopper and bottle 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 25ºC ±2ºC / 60% ± 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:

S.no.	Section	Observations/Deficiencies/ Short-comings
1.	1.3.3	Submit valid, original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate issued by relevant regulatory authority of country of origin, since the submitted CoPP was expired on 06-06-2023.
2.	1.3.4	Submit valid Drug Sale License since the submitted DSL was expired on 09/10/2022.
3.	3.2.S.4.1-3.2.S.4.2	Provide specification and analytical procedure of drug substance used for analysis by drug product manufacturer.
4.	3.2.S.4.3	Provide analytical method validation report performed by drug product manufacturer.
5.	3.2.S.4.4	Provide batch analysis report of drug substance by the drug product manufacturer.
6.	3.2.P.2	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.
7.	3.2.P.8	How you have assess the extent of water loss from the semi-permeable container, since ICH guidelines recommend appropriate information should be provided to

		assess the extent of water loss, If the drug product is packaged in a semi-permeable container.

Decision of 335th meeting of Registration Board:
Registration Board deferred the case for submission of reply to the above cited shortcomings.

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit valid, original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate issued by relevant regulatory authority of country of origin, since the submitted CoPP was expired on 06-06-2023.	Firm submitted the copy of CoPP with the validity of 14th May 2025
2.	Submit valid Drug Sale License since the submitted DSL was expired on 09/10/2022.	Firm submitted DSL with the validity of 29/12/2027.
3.	Provide specification and analytical procedure of drug substance used for analysis by drug product manufacturer.	Submitted
4.	Provide analytical method validation report performed by drug product manufacturer.	Submitted
5.	Provide batch analysis report of drug substance by the drug product manufacturer.	Submitted
6.	Formulation contain preservative, so preservative effectiveness studies to be performed as per recommendations of pharmacopoeia and shall be submit.	Submitted
7.	How you have assess the extent of water loss from the semi-permeable container, since ICH guidelines recommend appropriate information should be provided to assess the extent of water loss, If the drug product is packaged in a semi-permeable container.	Firm submitted the data of water loss study performed on three batches, conducted under accelerated condition 25ºC ±2ºC / 60% ± 5% RH for three months with an acceptance criteria NMT 5% loss in water from initial value after 3 months.

Decision: Approved. Registration letter will be issued upon submission of following:

- **Valid, original and legalized Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate issued by relevant regulatory authority of country of origin.**
- **Analytical record for the submitted drug product stability data including chromatograms/spectrums etc…**

730.	Name, address of Applicant / Importer	Biocare Pharmaceutica. Address:- 807 Shadman-1, Lahore
	Details of Drug Sale License of importer	License No: 05-352-0063-032069D Address: 807 Shadman-1, District Lahore. Address of Godown: First floor B-C, Street No. 3, Near LGS School, Shah Jamal District Lahore. Validity: 17-04-2022. Status: License to sell drugs as distributor Renewed/New DSL: Drug sales License is renewed. New Drug Sales License is attached for DRAP reference. (New License No. 05-352-0063-032069D), Validity: - 17.04.2027.
	Name and address of marketing authorization holder (abroad)	License Holder/Supplier: PT Pratapa Nirmala (Fahrenheit) Address: Jl. Industri VI, Tangerang 15135, Indonesia Phone: +62-21-5901876 / 77 E-mail: john@fahrenheit.co.id
	Name, address of manufacturer(s)	Manufactured by: - PT Pratapa Nirmala (Fahrenheit) Address: Jl. Industri VI, Tangerang 15135, Indonesia Phone: +62-21-5901876 / 77, Fax: +62-21-5901984

		E-mail: john@fahrenheit.co.id
	Name of exporting country	Indonesia
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	CoPP: Firm has submitted original, legalized copy of CoPP with certificate No. RG.01.05.32.321.01.21.2397, dated January 21, 2021 issued by National Agency of Drug and Food Control, Indonesia. 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. The name of importing country on CoPP is mentioned as Pakistan. Embassy Attested/Legalized GMP is also attached. GMP Validity is December, 20, 2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of legalized distribution agreement signed by both parties Biocare Pharmaceutica & PT Pratapa Nirmala (Fahrenheit). Agreement clearly mention Aboard License Holder PT Pratapa Nirmala (Fahrenheit) (Indonesia) appoints M/s Biocare Pharmaceutica to register/market/sell/Distribute their product Farpresin (Vasopressin)20 IU/ml. Inj.in Pakistan. Agreement validity is 5 years with additional 5-years renewal clause.
	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. 2945 dated 31-01-2022
	Details of fee submitted	PKR 150,000 /-: Slip # 6700351198, Date:- 05/01/2022
	The proposed proprietary name / brand name	FARPRESIN
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	20 IU/mL. Each 1 mL contains Vasopressin.
	Pharmaceutical form of applied drug	Farpresin (Vasopressin) is a clear, colorless solution for intravenous administration available as 20 units/mL in 1-mL vial
	Pharmacotherapeutic Group of (API)	Vasopressin and analogues WHO ATC H01BA01
	Reference to Finished product specifications	USP43
	Proposed Pack size	5 Vials per Pack (Box 5 Vials)
	Proposed unit price	Rs 900/Vial. Rs. 4500 for 5 Vials Box
	The status in reference regulatory authorities	Vasopressin 20 IU/ml is US FDA & Health Canada approved drug. In USA it is manufacture/marketed by American Regent,

		Inc. & in Canada it is manufacture/marketed by Fresenius Kabi Canada.
	For generic drugs (me-too status)	M/s. Platinum Pharmaceuticals, Brand: - Vasopressin Injection, Strength: - 20units/ml, Composition: - Vasopressin, Reg. No. 015590, Dosage Form: - Injectable Solution in Vial for Intravenous (IV) Use
	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	Name: BCN Peptides S.A. Address: Pol. Ind. Els Vinyets-Els Fogars, II 08777 Sant Quinti de Mediona Barcelona, Spain
	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 (VP0401, VP0501, VP0701) of API at accelerated (25 °C ± 2° C 60% ± 5%) as well as real time long term (5 °C ± 2° C) conditions. The 6 months accelerated study is complete for 3 batches. The real time 3 batches stability data are conducted till 36 months. [Reference:- Specifications according to the previous Vasopressin monograph USP31-NF26 in accelerated & long term API stability testing].
	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 by conducting all the quality tests against the reference original brand Vasostrict (Vasopressin) 20 unit/ml Solution for Injection manufactured by (Par Pharmaceutical Chestnut Ridge, NY 10977), US., Lot: 36748 Exp Date: 12-2022. Based upon results comparison and details provided, Pharmaceutical equivalence is established between FARPRESIN and reference brand VASOSTRICT.
	Analytical method validation/verification of product	Firm has submitted analytical method validation studies for the applied product.
	Container closure system of the drug product	Farpresin (Vasopressin) 20 unit /ml Inj. is filled into glass type 1 vial-1ml with Bromobutyl rubber stopper.
	Stability study data of drug product, shelf life and storage conditions	24 months real time stability data (Long Term) at 30°C ± 2°C / 75% ± 5%RH of 03 batches (Zone IVB) is Submitted. 06 month accelerated stability data 40°C ± 2°C /

		75% ± 5%RH of 03 batches is submitted.

Evaluation by PEC:

S.no.	Sections	Observations/Deficiencies/ Short-comings
1.	Please provide legalized documents which established the link between Fahrenhite and PT. Partapa Nirmala,since all your legalized documents including CoPP, Free Sale certificate and GMP inspection report of Manufacturer Abroad revealed that the name of manufacturer is PT. Partapa Nirmala.	
2.	1.3.4	Justify for not having segregated manufacturing facility for preparation of hormones, since the Manufacturer Abroad have manufactured the vasopressin injection in non-betalactum Small volume injection section.
3.	3.2.S.4.2	Justify for not performing the identification test via Mass Spectral Analysis of drug substance by drug product manufacturer since the USP recommends identification test both via HPLC and Mass spectral analysis.
4.	3.2.S.4.4	Batch analysis report of batch no. VP-1803 by drug product manufacturer evident that result of bacterial endotoxin test was out of specification despite of keeping the acceptance limit <100IU/mg, while Limits of BET test recommends by the official Pharmacoepias and the acceptance limit adopted by the drug substance manufacturer (BCN Peptides) is <10IU/mg. Justify for accepting the batch of drug substance which is failed to pass the bacterial endotoxin test, further provide the Pharmaceopial/international literature which recommends the acceptance limit <100IU/mg.
5.	3.2.S.7	• Justify for not performing the test of water content, test for acetic acid in peptides, microbial enumeration test and test for specified microorganism while performing the stability study of drug substance despite these test are included in the USP monograph of vasopressin. • Justify for adapting the acceptance limit of assay NLT 300IU/mg in the stability studies comparing the acceptance criteria recommended in USP monograph i.e. NLT 95.0% and NMT 105.0% of vasopressin (C46H65N15O12S2), calculated on the anhydrous, acetic acid-free basis.
6.	3.2.P.1	• Please provide calculation along with equivalent factor to established link between 20 units /ml and 0.0667mg/ml along with evidence of reference product approved in Reference regulatory Agencies with the same composition. • Justify for using different excipient from that of 1ml composition of innovator product approved in USFDA, since 1ml of injection of innovator brand contains sodium acetate buffer and water for injection without any preservative.
7.	3.2.P.2.2.3	Justify for not performing the sterility test, Bacterial endotoxin test and particulate matter in injection test while performing the pharmaceutical equivalence against the innovator/reference product.
8.	3.2.P.5.2	Assay procedure specified in section 3.2.P.5.2 is not in accordance with USP monograph of vasopressin injection, justify for using different assay method from that recommended in USP.

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.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Please provide legalized documents which established the link between Fahrenhite and PT. Partapa Nirmala,since all your legalized documents including CoPP, Free Sale certificate and GMP inspection report of Manufacturer	Firm replied that "Our manufacturer has given undertaking stating their company name is indeed PT Pratapa Nirmala. According to them Fahrenheit is just their brand, is not an entity. It just a brand associated with PT Pratapa Nirmala.

	Abroad revealed that the name of manufacturer is PT. Partapa Nirmala.		So, they can't provide any document stated PT Pratapa Nirmala-Fahrenheit and PT Pratapa Nirmala is the same because Fahrenheit is not an entity, it's just company brand name. Actual company legalized name is PT Pratapa Nirmala and due to this reason, all legalized document including CoPP, Free Sale Certificate and GMP inspection report is associated with PT. Pratapa Nirmala, since it is their legalized name. For DRAP reference we have attached our manufacturer proper undertaking/justification on their letter head with company signed/stamp".
2.	1.3.4	Justify for not having segregated manufacturing facility for preparation of hormones, since the Manufacturer Abroad have manufactured the vasopressin injection in non-betalactum Small volume injection section.	Firm replied that "Kindly note our product FARPRESIN (Vasopressin) 20 units/ml is manufacture in segregated manufacturing room in which only Vasopressin 20 units/ml is filled in vials and no other product is manufacture in that particular room. Kindly note the approval in Indonesia is for Small Volume Injection not for hormone product as this product fall into FDA orange book i.e. Pharma product. So, as per FDA guidelines for Vasopressin we manufacturer this product in segregated room in small volume injection plant and hence therefore provide the GMP for Small Volume Injection. According to FDA Vasopressin fall into orange book i.e. for Pharma product while biological/hormones product fall into purple book. Since Vasopressin fall in orange book so as per FDA guideline we have manufacturer this product in our plant."
3.	3.2.S.4.2	Justify for not performing the identification test via Mass Spectral Analysis of drug substance by drug product manufacturer since the USP recommends identification test both via HPLC and Mass spectral analysis.	Firm submitted the revised specification of drug substance which includes identification test via Mass Spectral Analysis as recommended by USP.
4.	3.2.S.4.4	Batch analysis report of batch no. VP-1803 by drug product manufacturer evident that result of bacterial endotoxin test was out of specification despite of keeping the acceptance limit <100IU/mg, while Limits of BET test recommends by the official Pharmacoepias and the acceptance limit adopted by the drug substance manufacturer (BCN Peptides) is <10IU/mg. Justify for accepting the batch of drug substance which is failed to pass the bacterial endotoxin test, further provide the Pharmacopeia/international literature which recommends the acceptance limit <100IU/mg.	Firm replied that, previously we did use the old outdated specification during VP-1803 analysis. We've updated our specification now as per current standard. Now all limits are according to official pharmacopoeia and results of Bacterial Endotoxin test is within specifications and in its acceptance limits. For DRAP reference Pls. find attached documents that include new translated (specification) along with the analytical method for drug substance. We also include our COA in it, in which all test results fall within acceptance limits including Bacterial Endotoxin. All these test and results are according to updated official monograph which you will also find attached with Query 8 reply in last attachment.

5.	3.2.S.7	Justify for not performing the test of water content, test for acetic acid in peptides, microbial enumeration test and test for specified microorganism while performing the stability study of drug substance despite these test are included in the USP monograph of vasopressin.	Firm replied that for water and acetic acid in peptide: Specifications according to the previous Vasopressin monograph USP31-NF26. *Water and acetic acid content were not analysed at this time point because the original protocol did not establish the analysis at 6 months under accelerated ageing conditions. This protocol was updated in order to include these analyses in the calendar. Since the results obtained for the other two batches of the stability study, show that the water and the acetic acid content agree with the specifications at this time point, it can be assumed that the batch VP0401 meets the specifications for water and acetic acid content at 3 and 6 months when stored under accelerated ageing conditions. We also attached stability test with water and acetic acid parameter for DRAP reference now. • For adapting limit of assay: In this section the results and the primary data obtained from the regular stability studies performed until the moment are shown. It should be noticed that the stability study has been performed according to the USP monograph on Vasopressin (USP31-NF26), where it was stated that the Activity of the product should be not less than 300 IU/mg of Vasopressin. In July 2011 an update of the USP Vasopressin monograph has been published by a Revision Bulletin that will be incorporated in USP-NF 35-30. This update is focused on the assay specification. The update of the USP monograph has changed the Activity specification (300 IU/mg) by the Assay specification (95.0-105.0%). Therefore, future annual stability studies will be done according to the current monograph.
6.	3.2.S.7	Justify for adapting the acceptance limit of assay NLT 300IU/mg in the stability studies comparing the acceptance criteria recommended in USP monograph i.e. NLT 95.0% and NMT 105.0% of vasopressin (C46H65N15O12S2), calculated on the anhydrous, acetic acid-free basis.	
7.	3.2.P.1	Please provide calculation along with equivalent factor to established link between 20 units /ml and 0.0667mg/ml along with evidence of reference product approved in Reference regulatory Agencies with the same composition.	• We, PT. PRATAPA NIRMALA, would like to clarify the link between 20 units/ml and 0.0667 mg/ml. The calculation has been submitted. However, the innovator review literature claims that the strength of the pitressin is 20 pressor unit/ml that corresponds to 0.0377mg vasopressin/ml.
8.	3.2.P.1	Justify for using different excipient from that of 1ml composition of innovator product approved in USFDA, since 1ml of injection of innovator brand contains sodium acetate buffer and water for injection without any preservative.	• We're using chlorobutanol is because we're referring to VASOPRESSIN injection solution (dailymed). We are using Chlorobutanol because Farpresin Injection are manufactured using aseptic method thus we are add preservative to ensure the finished product are met the microbiology parameter (sterility). For DRAP reference Pls. find attached Dailymed document along with our sign/stamp undertaking on our letterhead for both queries with justification.
9.	3.2.P.2.2.3	Justify for not performing the sterility test, Bacterial endotoxin test and particulate matter in injection test while performing the	Firm replied that we have updated our pharmaceutical equivalence against the innovator/reference product now by adding the sterility test, Bacterial Endotoxin test and

		pharmaceutical equivalence against the innovator/reference product.	particulate matter in injection test result and change the comparative specification document. For reference kindly see attachment documents/test.
10	3.2.P.5.2	Assay procedure specified in section 3.2.P.5.2 is not in accordance with USP monograph of vasopressin injection, justify for using different assay method from that recommended in USP.	Firm replied that we have updated our assay procedure specified in section 3.2. P.5.2. in accordance with USP monograph of Vasopressin Injection. • For reference kindly see our updated SOP, the table (Specification) and the analytical method according to USP monograph. We also attached the USP monograph and the COA of finished product.

Decision of 339th meeting:
Deferred for clarification regarding the quantity of drug product filled per vial by the manufacturer, since the claimed quantity i.e. 0.0667 mg/ml is not in accordance with the claim label of innovator product i.e. *strength of the pitressin is 20 pressor unit/ml that corresponds to 0.0377mg vasopressin/ml*.

Response of the Firm:
In reply of above query, firm replied that Please be inform that in our calculation below
In 1 ml:
= Label Claim/Potency

= 20 IU 300 IU/mg = 0.0667 mg

The label claim is our targeted final concentration is 20 IU/ml, the 300 IU/mg is Vasopressin Raw Material potency and claimed quantity is 0.0667 mg/ml. Which means for each 0.0667 mg Vasopressin Raw material is equal to 20 IU. The label claim is fixed on 20 IU but the potency for Vasopressin Raw Material is not always fixed on 300 IU/mg therefore the claimed quantity also is not fixed on 0.0667 mg/ml. Because the Vasopressin Raw Material potency for each batch are not always the same.
The differences claimed quantity between Farpresin (Our Product) and Pitressin (innovator) it is caused by the potency differences in Vasopressin Raw Material. Also, we could not be possibly know the potency of Vasopressin Raw Material they used in Pitressin therefore our claimed quantity is different from them.

Decision: Approved in accordance with the policy for the inspection of Manufacturers Abroad and submission of analytical record for the submitted drug product stability data including chromatograms/spectrums etc.

731.	Name, address of Applicant / Importer	M/s. Revive Health Care, Office No.503, 5th Floor, 6 Main Gulberg, Jail Road, Lahore. Pakistan.
	Details of Drug Sale License of importer	License No: 05-352-0065-031159D Address: Office No.503, 5th Floor, 6 Main Gulberg, Jail Road, Lahore. Pakistan. Address of Go down: NA Validity: 21.05.2027 Status: License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s. Jenphar Bangladesh Ltd. Plant address: Vill-Faridpur, PS-Sreepur Dis- Gazipur Bangladesh Office address: SKS-Tower,Level-8,7-VIP Road, Mohakhali Dhaka-1206, Bangladesh
	Name, address of manufacturer(s)	M/s. Jenphar Bangladesh Ltd. Plant address: Vill-Faridpur, PS-Sreepur Dis- Gazipur Bangladesh Office address: SKS-Tower,Level-8,7-VIP Road, Mohakhali Dhaka-1206, Bangladesh
	Name of exporting country	Bangladesh

	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	CoPP: Original legalized COPP (Certificate# DA/6-134/09/10160 issued on 21-05-2023 by Government of the people's republic of Bangladesh, Ministry of Health & Family welfare, Directorate General of Drug Administration, Oushad Bhaban, Mohkhali Dhaka-1212, and Bangladesh. GMP: Firm has submitted Legalized GMP certificate (Certificate No. DGDA/6-134/09/195) issued by Directorate General of Drug Administration, Dhaka, Bangladesh and valid upto 30-09-2023.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of letter of authorization certificate from M/s. Jenphar Bangladesh Limited. The letter specifies that the manufacturer appoints M/s Revive Health Care. to register 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. No.24504 , Date: 06-10-2023
	Details of fee submitted	PKR 75,000/- 19/09/2023
	The proposed proprietary name / brand name	Tasso Tablet 80mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film coated tablet contains: Osimertinib (as mesylate)…..80mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Antineoplastic agents, protein kinase inhibitors (L01EB04)
	Reference to Finished product specifications	In house
	Proposed Pack size	As per SRO
	Proposed unit price	As per current pricing policy of DRAP
	The status in reference regulatory authorities	Tagrisso 80mg Tablet (USFDA Approved)
	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	ShengDa Pharmaceutical Co., Limited.
	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 3 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 3 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 Tagrisso 80mg Tablet (M/s. AstraZeneca) 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
	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:

Therapeutic indications TAGRISSO as monotherapy is indicated for:

- the adjuvant treatment after complete tumour resection in adult patients with stage IB-IIIA non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations.
- the first-line treatment of adult patients with locally advanced or metastatic NSCLC with activating EGFR mutations.
- the treatment of adult patients with locally advanced or metastatic EGFR T790M mutation-positive NSCLC.

S.no.	Section	Observations/Deficiencies/ Short-comings
1.	1.3.4	Submit product specific letter of authorization from the Product License Holder, since the submitted authorization letter was not specified the product.
2.	1.3.5	The applied product is in L01 group i.e. cytotoxic drug and as per decision of Registration Board in its 282nd meeting, "*The manufacturing of cytotoxic drug shall be carried out in a dedicated or self-contained facilities and manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drug*" Accordingly evidence of self-contained or dedicated facility of manufacturer abroad shall be submitted.
3.	3.2.S.2.1	Provide the complete manufacturing address of drug substance manufacturer, since you have only specified the title of drug substance manufacturer.
4.	3.2.S.4.1-3.2.S.4.2	Submit the specification and detailed analytical procedure of drug substance by drug product manufacturer.

5.	3.2.S.4.3	Provide analytical method validation report performed by drug product manufacturer.
6.	3.2.S.4.4	Provide batch analysis report of drug substance by the drug product manufacturer.
7.	3.2.S.5	Provide certificate of analysis of reference standard /working standard used for testing of the product.
8.	3.2.S.7	Submit stability data of drug substance performed both at accelerated and long term conditions till the claimed re-test period, since you have only submitted the data of 2 time points i.e. 1st and 3rd month.
9.	3.2.P.2.6	Innovator product claimed that tablets are formulated to be dispersible, when dosing of whole tablets is not possible, tablets may be administered as an aqueous dispersion. Reference to the innovator claim, did the applied formulation also dispersed in the similar manner as of innovator product. Further, did you performed the study for Use of Tablet Dispersion and impact of dispersion preparation on physiochemical properties of the final dosage form were assessed while formulation development.
10.	Conclusion of CDP report stated that test/applied formulation is the product of M/s. Beacon Pharmaceuticals, (Faridpur,sreepur,gazipur) Bangladesh, validation protocol claims that the Tasso tablet i.e. the applied product is of M/s. Julphar Bangladesh Ltd.(Gazipur,Sreepur) while the product license holder is M/s. Jenphar Bangladesh Ltd. (Vill-Faridpur, PS-Sreepur Dis-Gazipur).Clarification is required regarding the disparity observed related to the manufacturer of drug product in different section of CTD dossier, further, submitted the complete address of drug product manufacturer, since all three mentioned manufacturer have same address.	
11.	3.2.P.5.1	Justify the dissolution acceptance limit i.e. NLT 80% (Q) within 45 minutes adopted for the applied product comparing the acceptance limit of innovator product i.e. NLT (Q) within 30minutes.
12.	3.2.P.5.4	Submitted analytical method validation report is of Osimertinib 80mg Tablet of M/s. Julphar Bangladesh Ltd. while the applied product is Tasso 80 mg Tablet of M/s. Jenphar Bangladesh Ltd., clarification is required in this regard.
13.	2.3.R.1.1	Provide copy of Batch Manufacturing Record (BMR) of all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8.

Decision of 333rd meeting of Registration Board:
Deferred for submission of reply to above cited shortcomings.

Response of the Firm:

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Submit product specific letter of authorization from the Product License Holder, since the submitted authorization letter was not specified the product.	Firm submitted the product specific Letter of authorization from the product License Holder.
2.	The applied product is in L01 group i.e. cytotoxic drug and as per decision of Registration Board in its 282nd meeting, "*The manufacturing of cytotoxic drug shall be carried out in a dedicated or self-contained facilities and manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drug*" Accordingly evidence of self-contained or dedicated facility of manufacturer abroad shall be submitted.	Firm submitted a letter mentioning that they have separate oncology manufacturing facility without any GMP certificate or inspection report.
3.	Provide the complete manufacturing address of drug substance manufacturer, since you	Firm submitted the complete address of API manufacturer "M/s. Shengda Pharmaceuticals Co.

	have only specified the title of drug substance manufacturer.	Ltd., Block H, Zhigu Industrial Park, Yintian Road, Xixiang, Baoan, Shenzhen China".
4.	Submit the specification and detailed analytical procedure of drug substance by drug product manufacturer.	Submitted
5.	Provide analytical method validation report performed by drug product manufacturer.	Submitted
6.	Provide batch analysis report of drug substance by the drug product manufacturer.	Submitted
7.	Provide certificate of analysis of reference standard /working standard used for testing of the product.	Submitted
8.	Submit stability data of drug substance performed both at accelerated and long term conditions till the claimed re-test period, since you have only submitted the data of 2 time points i.e. 1st and 3rd month.	Firm submitted the stability data of drug substance till the re-test period of 24 months.
9.	Innovator product claimed that tablets are formulated to be dispersible, when dosing of whole tablets is not possible, tablets may be administered as an aqueous dispersion. Reference to the innovator claim, did the applied formulation also dispersed in the similar manner as of innovator product. Further, did you performed the study for Use of Tablet Dispersion and impact of dispersion preparation on physiochemical properties of the final dosage form were assessed while formulation development.	Firm submitted SmPC of the applied product in which the tablet aqueous dispersion preparation has been given. Further submit the tablet dispersion comparative study of applied product.
10.	Conclusion of CDP report stated that test/applied formulation is the product of M/s. Beacon Pharmaceuticals, (Faridpur,sreepur,gazipur) Bangladesh, validation protocol claims that the Tasso tablet i.e. the applied product is of M/s. Julphar Bangladesh Ltd.(Gazipur,Sreepur) while the product license holder is M/s. Jenphar Bangladesh Ltd. (Vill-Faridpur, PS-Sreepur Dis-Gazipur).Clarification is required regarding the disparity observed related to the manufacturer of drug product in different section of CTD dossier, further, submitted the complete address of drug product manufacturer, since all three mentioned manufacturer have same address. Firm replied that Manufacturer of the product is M/s. Jenphar Bangladesh Limited (Vill-Faridpur, PS-Sreepur Dis- Gazipur) a changed name from M/s. Julphar Bangladesh Ltd. With same address. Further applicant replied that Manufacturer has performed CDP of the applied product with innovator as well as local Me-Too available products in Bangladesh, if the conclusion of CDP report of other company is mistakenly attached then please ignore it.	
11.	Justify the dissolution acceptance limit i.e. NLT 80% (Q) within 45 minutes adopted for the applied product comparing the acceptance limit of innovator product i.e. NLT (Q) within 30minutes.	Firm replied that in submitted CDP the dissolution profile showed the dissolution results greater than 93% of all three medias after 30 minutes which meets the acceptance criteria NLT 80%(Q), where manufacturer of the product decided the time of dissolution 45minutes where results are greater than 100%. However, according to general chapter of USP <1092> "*During product development, the collection of complete dissolution profile data is recommended from biobatches and stability batches at specified intervals, such as 10, 15, 20, 30, 40, 50, and 60 min or 15, 20, 30, 45, and 60*

		min, because these data are used to establish the dissolution acceptance criterion/criteria. From the dissolution profile data, a Q value of 80% should be set at the first time point where the average dissolution is at least 85%. However, this time point should not be less than 15 min".
12.	Submitted analytical method validation report is of Osimertinib 80mg Tablet of M/s. Julphar Bangladesh Ltd. while the applied product is Tasso 80 mg Tablet of M/s. Jenphar Bangladesh Ltd., clarification is required in this regard.	Firm submitted change of company name letter from Julphar to Jenphar in the reply of this query.

Decision of 336th meeting:

Deferred for submission/clarification of following:

- Justify for adopting the dissolution acceptance limit NLT 80% (Q) within 45 minutes for the applied product comparing the acceptance limit of innovator product i.e. NLT (Q) within 30minutes, when the dissolution profile showed the dissolution results greater than 85% of all three medias within 30 minutes. Since USP general chapter <1092> recommends that "*From the dissolution profile data, a Q value of 80% should be set at the first time point where the average dissolution is at least 85%".*
- Submitted analytical method validation report is of Osimertinib 80mg Tablet of M/s. Julphar Bangladesh Ltd. while the applied product is Tasso 80 mg Tablet of M/s. Jenphar Bangladesh Ltd., clarification is required in this regard.

Response of the Firm:

- Justify for adopting the dissolution acceptance limit NLT 80% (Q) within 45 minutes for the applied product comparing the acceptance limit of innovator product i.e. NLT (Q) within 30minutes, when the dissolution profile showed the dissolution results greater than 85% of all three medias within 30 minutes. Since USP general chapter <1092> recommends that "*From the dissolution profile data, a Q value of 80% should be set at the first time point where the average dissolution is at least 85%".*

As per provided CDP the dissolution profile (limit NLT 80% (Q) within 30 minutes) complies the results, so Manufacturer of the product (Jenphar Bangladesh, Ltd) has adopted the dissolution limit NLT 80% (Q) within 30 minutes as per specification limit of Innovator's drug product.Updated Specifications, Method of Analysis and COA of the applied product is provided for you reference.

- Submitted analytical method validation report is of Osimertinib 80mg Tablet of M/s. Julphar Bangladesh Ltd. while the applied product is Tasso 80 mg Tablet of M/s. Jenphar Bangladesh Ltd., clarification is required in this regard.

Since at the stage of analytical method development and validation, the AMV of the product was performed by M/s. Julphar Bangladesh Ltd. with the product "Osimertinib 80mg Tablet. The product was applied for registration with Brand name "Tasso 80 mg Tablet by M/s. Julphar Bangladesh Ltd and later the product was placed on free sales and commercialization. After that stage & Registration of the Product Tasso 80 mg Tablet: the company name was changed from "M/s. Julphar Bangladesh Ltd." to "M/s Jenphar Bangladesh Ltd." So, Tasso 80 mg Tablet is registered brand of M/s. Jenphar Bangladesh Ltd.

(Company change name justification Vetter was provided earlier)

Decision: Deferred for confirmation of availability of separate oncology manufacturing facility at the manufacturing site of M/s. Jenphar Bangladesh Ltd. Plant address: Vill-Faridpur, PS-Sreepur Dis- Gazipur Bangladesh.

Agenda of Mr. Shahrukh

733.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s HiSun Pharmaceuticals Industries 37-A, R-2 Industrial Estate Gadoon Amazai, District Swabi Pakistan.**
	Name, address of Manufacturing site.	M/s HiSun Pharmaceuticals Industries 37-A, R-2 Industrial Estate Gadoon Amazai, District Swabi Pakistan**.**
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 22053 dated 07-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 051583188535 dated 23-01-23
	The proposed proprietary name / brand name	**Brosun Tablet 600mg.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film Coated Tablet Contains: Ibuprofen ……..…600mg
	Pharmacotherapeutic Group of (API)	NSAIDs. C01EB16
	Reference to Finished product specifications	USP specifications.
	The status in reference regulatory authorities	Ibuprofen 600 mg tablets, USFDA Approved.
	For generic drugs (me-too status)	Brufen 600 mg tablets, M/s Abbot Laboratories Pakistan (Pvt.) Ltd.,
	Proposed Pack size	1*10's
	Proposed unit price	As per S.R.O.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1	1.3.4	Valid copy of GMP certificate/Last Inspection report conducted in last 3 years of the applicant shall be submitted.	
2	3.2.S.4.2	Signed analytical procedures for drug substance from drug product manufacturer shall be submitted.	
3	3.2.S.4.4	COA of drug substance from drug product manufacturer lacks the test specified in Pharmacopoeia i.e optical rotation, sulphated Ash & LOD.	
4	3.2.P.2.2.1	In Pharmaceutical Equivalence studies no details of reference product and its pictorial evidence provided.	
5	3.2.P.3.2	Method of manufacturing doesn't show coating step.	
6	3.2.P.3.5	Performance data of verification of analytical procedure not submitted.	
7	3.2.P.5.1	Dissolution limits of NLT 80% in 45 minutes selected as in house however in official Pharmacopoeia its 60 minutes. Justification shall be submitted	
8	3.2.P.8	Stability data sheets with inclusion of API lot number as per decision of registration Board in its 293 shall be submitted.	
9		Chromatograms of assay showing maximum absorbance at 220nm however in USP absorbance is at 254nm. Justification shall be submitted.	
10		Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted	
11		Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

734.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio-labs (Pvt.) Ltd, Plot No. 145, Industrial Triangle Kahuta road, Islamabad.**
	Name, address of Manufacturing site.	M/s Bio-labs (Pvt.) Ltd, Plot No. 145, Industrial Triangle Kahuta road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 18083 dated 18-07-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 381007142037 dated 01-06-2023.
	The proposed proprietary name / brand name	**Cainav 20mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Rosuvastatin calcium eq. to Rosuvastatin ……..…20mg
	Pharmacotherapeutic Group of (API)	HMG CoA reductase inhibitors. C10AA07
	Reference to Finished product specifications	USP specifications.
	The status in reference regulatory authorities	Crestor 20mg tablets, MHRA Approved.
	For generic drugs (me-too status)	Rolip 20mg Tablets, M/s Hilton pharma, Reg. No. 042354.
	Proposed Pack size	10's, 20's, 30's, 100's.
	Proposed unit price	As per Policy.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1	1.3.4	Valid copy of GMP certificate/Last Inspection report conducted in last 3 years of the applicant shall be submitted.	GMP certificate F.3-19/2019-Addl. Dir. (QA&LT-1) issued dated 28th-12-23 is provided by firm mentioning tablet section.
2	3.2.S.4.2	Injection volume mentioned on chromatogram is 20ul however in analytical method Injection volume is 10ul. Clarification shall be submitted	Firm claimed it as a clerical mistake and they have rheodyn Injector installed with HPL and injection of sample was done manually
3	3.2.P.8	Stability data for 6 Month time point both for real time and accelerated stability shall be submitted.	Firm has provided data for 6 month time point

Decision: Approved.

735.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bio-labs (Pvt.) Ltd, Plot No. 145, Industrial Triangle Kahuta road, Islamabad.**
	Name, address of Manufacturing site.	M/s Bio-labs (Pvt.) Ltd, Plot No. 145, Industrial Triangle Kahuta road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 18083 dated 18-07-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 381007142037 dated 01-06-2023.
	The proposed proprietary name / brand name	**Cainav 10mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Rosuvastatin calcium eq. to Rosuvastatin ……..…10mg
	Pharmacotherapeutic Group of (API)	HMG CoA reductase inhibitors. C10AA07

	Reference to Finished product specifications	USP specifications.
	The status in reference regulatory authorities	Crestor 10mg tablets, MHRA Approved.
	For generic drugs (me-too status)	Rolip 10mg Tablets, M/s Hilton pharma, Reg. No. 042353.
	Proposed Pack size	10's, 20's, 30's, 100's.
	Proposed unit price	As per Policy.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1	1.3.4	Valid copy of GMP certificate/Last Inspection report conducted in last 3 years of the applicant shall be submitted.	GMP certificate F.3-19/2019-Addl. Dir. (QA&LT-1) issued dated 28th-12-23 is provided by firm mentioning tablet section.
2	3.2.S.4.2	Injection volume mentioned on chromatogram is 20ul however in analytical method Injection volume is 10ul. Clarification shall be submitted	Firm claimed it as a clerical mistake and they have rheodyn Injector installed with HPL and injection of sample was done manually
3	3.2.P.8	Stability data for 6 Month time point both for real time and accelerated stability shall be submitted.	Firm has provided data for 6 month time point

Decision: Approved.

736.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals, Pvt. Limited Plot No 129, Sunder Industrial Estate, Lahore Pakistan.**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals, Pvt. Limited Plot No 129, Sunder Industrial Estate, Lahore Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 25429 dated 19-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 110418936217 dated 5-10-23.
	The proposed proprietary name / brand name	**Vortix 5mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Vortioxetine Hydrobromide eq to Vortioxetine ……..…5mg
	Pharmacotherapeutic Group of (API)	Serotonin modulating antidepressant N06AX26
	Reference to Finished product specifications	In-house specifications.
	The status in reference regulatory authorities	Brintellix 5mg tablets, USFDA Approved.
	For generic drugs (me-too status)	Vrontil 5mg Tablets, M/s Genix Pharmaceutical (Pvt.) Ltd.,.
	Proposed Pack size	1*10's, 2*10's, 2*7's, 4*7's, 3*10's.
	Proposed unit price	As per S.R.O.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply submitted by the firm.

1	1.3.4	Valid copy of DML of the applicant shall be submitted.	Fee submission receipt submitted
2	1.6.5	GMP certificate of Drug product manufacturer of relevant section shall be submitted.	GMP certificate Ref No 188/2023-DRAP(AD-3489860170) dated 14-11-23 mentioning Tablet section submitted.
3	P2.2.1	Pharmaceutical equivalence pictorial evidence & batch details of reference product not provided.	Firm has provided batch details of Brintellix Tablet
4	P5.3	Validation of analytical procedures raw data sheets are not provided	Firm has submitted method validation sheet.

Decision: Approved.

737.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals**, **Pvt. Limited Plot No 129, Sunder Industrial Estate, Lahore Pakistan**.
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals, Pvt. Limited Plot No 129, Sunder Industrial Estate, Lahore Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 25430 dated 19-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 741482499 dated 5-10-23.
	The proposed proprietary name / brand name	**Vortix 10mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Vortioxetine Hydrobromide eq to Vortioxetine ……..…10 mg
	Pharmacotherapeutic Group of (API)	Serotonin modulating antidepressant N06AX26
	Reference to Finished product specifications	In-house specifications.
	The status in reference regulatory authorities	Brintellix 10 mg tablets, USFDA Approved.
	For generic drugs (me-too status)	Vrontil 10 mg Tablets, M/s Genix Pharmaceutical (Pvt.) Ltd.,.
	Proposed Pack size	1*10's, 2*10's, 2*7's, 4*7's, 3*10's.
	Proposed unit price	As per S.R.O.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply submitted by the firm.
1	1.3.4	Valid copy of DML of the applicant shall be submitted.	Fee submission receipt submitted
2	1.6.5	GMP certificate of Drug product manufacturer of relevant section shall be submitted.	GMP certificate Ref No 188/2023-DRAP(AD-3489860170) dated 14-11-23 mentioning Tablet section submitted.
3	P2.2.1	Pharmaceutical equivalence pictorial evidence & batch details of reference product not provided.	Firm has provided batch details of Brintellix Tablet
4	P5.3	Validation of analytical procedures raw data sheets are not provided	Firm has submitted method validation sheet.

Decision: Approved.

738.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals**, **Pvt. Limited Plot No 129, Sunder Industrial Estate, Lahore Pakistan**.
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals, Pvt. Limited Plot No 129,

		Sunder Industrial Estate, Lahore Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 25431 dated 19-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 5884971526 dated 5-10-23.
	The proposed proprietary name / brand name	**Vortix 15mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Vortioxetine Hydrobromide eq to Vortioxetine ……..…15 mg
	Pharmacotherapeutic Group of (API)	Serotonin modulating antidepressant N06AX26
	Reference to Finished product specifications	In-house specifications.
	The status in reference regulatory authorities	Brintellix 15 mg tablets, USFDA Approved.
	For generic drugs (me-too status)	Vrontil 15 mg Tablets, M/s Genix Pharmaceutical (Pvt.) Ltd.,.
	Proposed Pack size	1*10's, 2*10's, 2*7's, 4*7's, 3*10's.
	Proposed unit price	As per S.R.O.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply submitted by the firm.
1	1.3.4	Valid copy of DML of the applicant shall be submitted.	Fee submission receipt submitted
2	1.6.5	GMP certificate of Drug product manufacturer of relevant section shall be submitted.	GMP certificate Ref No 188/2023-DRAP(AD-3489860170) dated 14-11-23 mentioning Tablet section submitted.
3	P2.2.1	Pharmaceutical equivalence pictorial evidence & batch details of reference product not provided.	Firm has provided batch details of Brintellix Tablet
4	P5.3	Validation of analytical procedures raw data sheets are not provided	Firm has submitted method validation sheet.

Decision: Approved.

739.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals**, **Pvt. Limited Plot No 129, Sunder Industrial Estate, Lahore Pakistan**.
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals, Pvt. Limited Plot No 129, Sunder Industrial Estate, Lahore Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 25432 dated 19-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 418356205131 dated 5-10-23.
	The proposed proprietary name / brand name	**Vortix 20mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Vortioxetine Hydrobromide eq to Vortioxetine ……..…20 mg
	Pharmacotherapeutic Group of (API)	Serotonin modulating antidepressant

		N06AX26
	Reference to Finished product specifications	In-house specifications.
	The status in reference regulatory authorities	Brintellix 20 mg tablets, USFDA Approved.
	For generic drugs (me-too status)	Vrontil 20 mg Tablets, M/s Genix Pharmaceutical (Pvt.) Ltd.,.
	Proposed Pack size	1*10's, 2*10's, 2*7's, 4*7's, 3*10's.
	Proposed unit price	As per S.R.O.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply submitted by the firm.
1	1.3.4	Valid copy of DML of the applicant shall be submitted.	Fee submission receipt submitted
2	1.6.5	GMP certificate of Drug product manufacturer of relevant section shall be submitted.	GMP certificate Ref No 188/2023-DRAP(AD-3489860170) dated 14-11-23 mentioning Tablet section submitted.
3	P2.2.1	Pharmaceutical equivalence pictorial evidence & batch details of reference product not provided.	Firm has provided batch details of Brintellix Tablet
4	P5.3	Validation of analytical procedures raw data sheets are not provided	Firm has submitted method validation sheet.

Decision: Approved.

740.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals Pvt Ltd Plot No. A-94 , S.I.T.E. Super highway Karachi Pakistan.**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals Pvt Ltd Plot No. A-94 , S.I.T.E. Super highway Karachi Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 26036 dated 27-10-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 43571526733 dated 6-10-22
	The proposed proprietary name / brand name	**Novamet 10% w/w vaginal cream.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gm Contains: Metronidazole ……..…1000mg
	Pharmacotherapeutic Group of (API)	Nitroimidazoles. J01XD01
	Reference to Finished product specifications	Innovator specifications.
	The status in reference regulatory authorities	Flagyl 10% vaginal cream, Health Canada.
	For generic drugs (me-too status)	New drug
	Proposed Pack size	60gm (as per S.R.O)
	Proposed unit price	As per S.R.O.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply submitted by the firm.
1	1.6.5	Valid copy of GMP certificate of API manufacturer.	
2	2.3	Copies of executed BMRs with a copy of blank production document shall be submitted	

3	3.2.S.4.1	Specification of drug substance from drug substance manufacturer shall be submitted	
4	3.2.S.4.2	Signed analytical procedures for drug substance from drug product manufacturer shall be submitted.	
5	3.2.S.4.3	Analytical method verification studies of the drug substance performed by the drug product manufacturer shall be submitted	
6	3.2.S.4.4	Justification shall be submitted for providing exactly same results for all the test performed as that of the drug substance manufacturer by drug product manufacteurer.	
7	3.2.P.1	Qualitative composition of the applied formulation (excipients) is different from the innovator product. Clarification shall be submitted	
8	3.2.P.2.2 .1	CDP studies in all three mediums with complete information and different time points along with analytical record shall be submitted	
9	3.2.P.5.1	Official monograph has mentioned content uniformity test while submitted specification has not mentioned the same. Clarification shall be submitted	
10	3.2.P.8	Stability data sheets with inclusion of API lot number as per decision of registration Board in its 293 shall be submitted	
11		Raw data sheets for calculation of assay and dissolution as per calculation formula for each time interval shall be submitted	
12		Justification shall be submitted for not performing content uniformity in the stability data sheets as recommended by the monograph	
13		Chromatograms for each time interval for both accelerated and real time shall be submitted	
14		Justify the standard and sample concentration in the submitted raw data sheets with respect to that concentration submitted in the analytical method, as analytical method has mentioned final concentration of 0.5mg/ml while raw data sheets has 0.1mg/ml	
15		Documents for procurement of API with approval from DRAP shall be submitted	
16		Compliance Record of HPLC software 21CFR & audit trail reports on product testing shall be submitted	
17		Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) shall be submitted	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

741.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s BJ Pharmaceuticals**, **Mandialai Stop, Bhattianwala Road,18-Km Sheikhupura Road, Lahore Pakistan**.
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals, Mandialai Stop, Bhattianwala Road,18-Km Sheikhupura Road, Lahore Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 26019 dated 27-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 7456068997 dated 11-10-23.
	The proposed proprietary name / brand name	**B-Low 10mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet Contains: Amlodipine Besylate eq to Amlodipine(USP) ……..…10mg
	Pharmacotherapeutic Group of (API)	Calcium Channel Blocker C09CA01
	Reference to Finished product specifications	USP specifications.

	The status in reference regulatory authorities	Norvasc 10mg tablets, FDA Approved.
	For generic drugs (me-too status)	Caloc 10mg Tablets, M/s Bosch Pharmaceuticals Pakistan (Pvt.) Ltd., Reg. No. 027174.
	Proposed Pack size	10's, 20's & 30's.
	Proposed unit price	As per S.R.O.

Evaluation by PEC:

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 notarized copy of receiving for DML renewal application.
2	1.6.5	GMP certificate of Drug product manufacturer shall be submitted.	Not submitted
3	S4.4	COA of API by Drug substance manufacturer shows water content that is outside specified limits i.e 0.8% however same batch tested by Drug product manufacturer shows water content 0.1%. Please submit clarification.	Firm without evidence claimed that Drug substance manufacturer has made a clerical mistake however no revised COA or justification from Drug substance manufacturer received.
4	S4.4	As per B.P monograph for drug substance the run time should be twice retention time of Amlodipine. As per chromatograms submitted, retention time of Amlodipine is around 6.2 minutes, and run time is 10 minutes. The run time should have been 13 minutes (6.2x 2= 12.5). Please submit clarification.	Clarification received as test runs were 30 minutes however no data sheets were provided to support evidence.
5	3.2.P.5	As per U.S.P monograph for drug product the run time should be thrice retention time of Amlodipine. As per chromatograms submitted, retention time of Amlodipine is around 6.2 minutes, and run time is 10 minutes. The run time should have been 19 minutes (6.2x 3= 18.6). Please submit clarification.	Clarification received as test runs were 30 minutes however no data sheets were provided to support evidence.

Decision: Registration Board deferred the case for:

- **confirmation of restoration of manufacturing facility as suspended by QA&LT Division**.
- **Data sheets confirming the claim of 30-minutes run time for drug substance & drug product.**
- **Justification required from Drug substance manufacturer as COA of API shows water content that is outside specified limits i.e., 0.8%.**

742.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s BJ Pharmaceuticals**, **Mandialai Stop, Bhattianwala Road,18-Km Sheikhupura Road, Lahore Pakistan**.
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals, Mandialai Stop, Bhattianwala Road,18-Km Sheikhupura Road, Lahore Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 26014 dated 27-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 7305589230 dated 28-06-22.
	The proposed proprietary name / brand name	**Dompera 5mg/5ml Suspension.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml suspension Contains: Domperidone ……..…5mg(Innovator Specs)

	Pharmacotherapeutic Group of (API)	Dopamine-2 receptor antagonist A03FA03
	Reference to Finished product specifications	Innovator specifications.
	The status in reference regulatory authorities	Domperidone 1mg/1ml oral suspension, MHRA Approved.
	For generic drugs (me-too status)	Domel 5mg/5ml Suspension, M/s Barrett Hodgson Pakistan (Pvt.) Ltd., Reg. No. 028758.
	Proposed Pack size	60ml,90ml, 120ml
	Proposed unit price	As per S.R.O.

Evaluation by PEC:

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 notarized copy of receiving for DML renewal application.
2	1.6.5	GMP certificate of Drug product manufacturer shall be submitted.	Not submitted
3	1.6.5	ADC attested invoice for raw material clearance	Not submitted

Decision: Registration Board deferred the case for:

- **confirmation of restoration of manufacturing facility as suspended by QA&LT Division**.
- **AD attested invoice for raw material clearance.**

743.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s BJ Pharmaceuticals**, **Mandialai Stop, Bhattianwala Road,18-Km Sheikhupura Road, Lahore Pakistan**.
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals, Mandialai Stop, Bhattianwala Road,18-Km Sheikhupura Road, Lahore Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 26015 dated 27-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 5573395923 dated 11-10-23.
	The proposed proprietary name / brand name	**Dompera 10mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film tablet Contains: Domperidone Maleate eq to Domperidone(BP) ……..…10mg
	Pharmacotherapeutic Group of (API)	Dopamine-2 receptor antagonist A03FA03
	Reference to Finished product specifications	BP specifications.
	The status in reference regulatory authorities	Motilium 10mg tablets, TGA Approved.
	For generic drugs (me-too status)	Domel 10mg Tablets, M/s Barrett Hodgson Pakistan (Pvt.) Ltd., Reg. No. 028759.
	Proposed Pack size	10’s, 20’s & 30’s & 50’s.
	Proposed unit price	As per S.R.O.

Evaluation by PEC:

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 notarized copy of receiving for DML renewal application.
2	1.6.5	GMP certificate of Drug product manufacturer shall be submitted.	Not submitted
3	1.6.5	ADC attested invoice for raw material clearance	Not submitted

Decision: Registration Board deferred the case for:

- **confirmation of restoration of manufacturing facility as suspended by QA&LT Division**.
- **AD attested invoice for raw material clearance.**

744.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s BJ Pharmaceuticals**, **Mandialai Stop, Bhattianwala Road,18-Km Sheikhupura Road, Lahore Pakistan**.
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals, Mandialai Stop, Bhattianwala Road,18-Km Sheikhupura Road, Lahore Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 26016 dated 27-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 20122505243 dated 11-10-23.
	The proposed proprietary name / brand name	**Montik 10mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film tablet Contains: Montelukast Sodium eq to Montelukast (USP) ……..…10mg
	Pharmacotherapeutic Group of (API)	Leukotriene Antagonist R03DC03
	Reference to Finished product specifications	USP specifications.
	The status in reference regulatory authorities	Singulair 10mg tablets, FDA Approved.
	For generic drugs (me-too status)	Montiget 10mg Tablets, M/s Getz Pharmaceuticals Pakistan (Pvt.) Ltd., Reg. No..
	Proposed Pack size	10’s, 20’s & 30’s.
	Proposed unit price	As per S.R.O.

Evaluation by PEC:

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 notarized copy of receiving for DML renewal application.
2	1.6.5	Valid copy of GMP certificate/Last Inspection report conducted in last 3 years of the applicant shall be submitted.	Not submitted
3		GMP certificate of Drug substance manufacturer shall be submitted.	Not submitted
4		AD attested invoice for clearance of raw material is required	AD attested invoice for clearance of raw material Submitted
5	3.2.P.5.3	Complete validation of analytical procedures required only verification studies of drug	Validation of analytical procedures precision and accuracy data submitted

		product is provided, precision and accuracy data required.	

Decision: Registration Board deferred the case for:

- **confirmation of restoration of manufacturing facility as suspended by QA&LT Division**
- **GMP certificate of Drug substance manufacturer shall be submitted.**

745.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s BJ Pharmaceuticals**, **Mandialai Stop, Bhattianwala Road,18-Km Sheikhupura Road, Lahore Pakistan**.
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals, Mandialai Stop, Bhattianwala Road,18-Km Sheikhupura Road, Lahore Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 26017 dated 27-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 9489254951 dated 11-10-23.
	The proposed proprietary name / brand name	**Montik** 5**mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each chewable tablet Contains: Montelukast Sodium eq to Montelukast (USP) ……..…5mg (USP Specs)
	Pharmacotherapeutic Group of (API)	Leukotriene Antagonist R03DC03
	Reference to Finished product specifications	USP specifications.
	The status in reference regulatory authorities	Singulair 5mg tablets, USFDA Approved.
	For generic drugs (me-too status)	Beasy 5mg Tablets, M/s Bosch Pharmaceuticals Pakistan (Pvt.) Ltd., Reg. No..035545
	Proposed Pack size	10’s, 20’s & 30’s.
	Proposed unit price	As per S.R.O.

Evaluation by PEC:

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 notarized copy of receiving for DML renewal application.
2	1.6.5	Valid copy of GMP certificate/Last Inspection report conducted in last 3 years of the applicant shall be submitted.	Not submitted
3		GMP certificate of Drug substance manufacturer shall be submitted.	
4		AD attested invoice for clearance of raw material is required	AD attested invoice for clearance of raw material Submitted
5	3.2.P.5.3	Complete validation of analytical procedures required only verification studies of drug product is provided, precision and accuracy data required.	Validation of analytical procedures precision and accuracy data submitted

Decision: Registration Board deferred the case for:

- **confirmation of restoration of manufacturing facility as suspended by QA&LT Division**
- **GMP certificate of Drug substance manufacturer shall be submitted.**

746.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s BJ Pharmaceuticals**, **Mandialai Stop, Bhattianwala Road,18-Km Sheikhupura Road, Lahore Pakistan**.
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals, Mandialai Stop, Bhattianwala

		Road,18-Km Sheikhupura Road, Lahore Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 26552 dated 03-11-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 304925205 dated 30-10-23.
	The proposed proprietary name / brand name	**B-Lor 0.5mg/1ml syrup.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml Contains: Desloratadine(Innovator's specs) ……..…0.5mg
	Pharmacotherapeutic Group of (API)	Antihistamines – H1 antagonist R06AX27
	Reference to Finished product specifications	Innovator specifications.
	The status in reference regulatory authorities	Aerius 0.5mg/1ml syrup, TGA Approved.
	For generic drugs (me-too status)	Delta Fast 0.5mg/1ml Syrup, M/s Schazoo Pharmaceuticals Pakistan (Pvt.) Ltd., Reg. No. 047919.
	Proposed Pack size	60ml, 90ml & 120ml.
	Proposed unit price	As per S.R.O.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1	1.3.4	Valid copy of DML of the applicant shall be submitted.	
2	1.6.5	GMP certificate of Drug product manufacturer& Drug substance manufacturer shall be submitted.	
3	1.6.5	AD attested invoice for raw material clearance.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings and confirmation of restoration of manufacturing facility as suspended by QA&LT Division.

747.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s BJ Pharmaceuticals**, **Mandialai Stop, Bhattianwala Road,18-Km Sheikhupura Road, Lahore Pakistan**.
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals, Mandialai Stop, Bhattianwala Road,18-Km Sheikhupura Road, Lahore Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 26553 dated 03-11-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 206044839 dated 30-10-23.
	The proposed proprietary name / brand name	**B-Lor 5mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Contains: Desloratadine (USP specs) ……..5mg
	Pharmacotherapeutic Group of (API)	Antihistamines – H1 antagonist R06AX27
	Reference to Finished product specifications	USP specifications.

	The status in reference regulatory authorities	Desloratadine 5mg Tablet, MHRA Approved.
	For generic drugs (me-too status)	Delta Fast 5mg Tablet, M/s Schazoo Pharmaceuticals Pakistan (Pvt.) Ltd., Reg. No. 045993.
	Proposed Pack size	10's, 20's & 30's.
	Proposed unit price	As per S.R.O.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1	1.3.4	Valid copy of DML of the applicant shall be submitted.	
2	1.6.5	GMP certificate of Drug product manufacturer& Drug substance manufacturer shall be submitted.	
3	1.6.5	AD attested invoice for raw material clearance.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings and confirmation of restoration of manufacturing facility as suspended by QA&LT Division.

748.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s BJ Pharmaceuticals**, **Mandialai Stop, Bhattianwala Road,18-Km Sheikhupura Road, Lahore Pakistan**.
	Name, address of Manufacturing site.	M/s BJ Pharmaceuticals, Mandialai Stop, Bhattianwala Road,18-Km Sheikhupura Road, Lahore Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 26018 dated 27-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 98558649828 dated 11-10-23.
	The proposed proprietary name / brand name	**B-Low 5mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet Contains: Amlodipine Besylate eq to Amlodipine(USP) ……..…5mg
	Pharmacotherapeutic Group of (API)	Calcium Channel Blocker C08CA01
	Reference to Finished product specifications	USP specifications.
	The status in reference regulatory authorities	Norvasc 5mg tablets, USFDA Approved.
	For generic drugs (me-too status)	Caloc 5mg Tablets, M/s Bosch Pharmaceuticals Pakistan (Pvt.) Ltd.,.
	Proposed Pack size	10's, 20's & 30's.
	Proposed unit price	As per S.R.O.

Evaluation by PEC:

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 notarized copy of receiving for DML renewal application.
2	1.6.5	GMP certificate of Drug product manufacturer shall be submitted.	Not submitted
3	S4.4	COA of API by Drug substance manufacturer shows water content that is outside specified limits i.e 0.8% however same batch tested by Drug product	Firm without evidence claimed that Drug substance manufacturer has made a clerical mistake however no revised COA or justification from Drug substance manufacturer received.

		manufacturer shows water content 0.1%. Please submit clarification.	
4	S4.4	As per B.P monograph for drug substance the run time should be twice retention time of Amlodipine. As per chromatograms submitted, retention time of Amlodipine is around 6.2 minutes, and run time is 10 minutes. The run time should have been 13 minutes (6.2x 2= 12.5). Please submit clarification.	Clarification received as test runs were 30 minutes however no data sheets were provided to support evidence.
5	3.2.P.5	As per U.S.P monograph for drug product the run time should be thrice retention time of Amlodipine. As per chromatograms submitted, retention time of Amlodipine is around 6.2 minutes, and run time is 10 minutes. The run time should have been 19 minutes (6.2x 3= 18.6). Please submit clarification.	Clarification received as test runs were 30 minutes however no data sheets were provided to support evidence.

Decision: Registration Board deferred the case for submission of

- **confirmation of restoration of manufacturing facility as suspended by QA&LT Division**.
- **Data sheets confirming the claim of 30-minutes run time for drug substance & drug product.**
- **Justification required from Drug substance manufacturer as COA of API shows water content that is outside specified limits i.e 0.8%.**

749.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s SCILIFE Pharma Private Limited Pakistan plot No.FD-57/58-A2 Korangi Creek Industrial park Karachi-Pakistan**.
	Name, address of Manufacturing site.	M/s SCILIFE Pharma Private Limited Pakistan plot No.FD-57/58-A2 Korangi Creek Industrial park Karachi-Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 26954 dated 14-11-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 17209265 dated 14-11-23.
	The proposed proprietary name / brand name	**Scicon-MR 90mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each modified release tablet Contains: Gliclazide ……..…90mg
	Pharmacotherapeutic Group of (API)	Blood Glucose lowering drugs A10BB09
	Reference to Finished product specifications	Innovator specifications.
	The status in reference regulatory authorities	Gliclada MR 90mg Tablet EMA Approved.
	For generic drugs (me-too status)	Diabetron CR 90mg Tablet, M/s Ferozsons Laboratories Ltd., Reg. No. 070312.
	Proposed Pack size	10’s, 15’s,20’s, 30’s, 50’s, 100’s & 150’s
	Proposed unit price	684.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1	1.6.5	Valid copy of GMP certificate of API manufacturer.	

2	3.2.P.2.2.1	Justification shall be submitted for proposed quantity of drug substance in master formulation i.e 10.820mg against the label claim 10mg of tablet & 21.643 against the label claim 20mg of tablet	
3	3.2.P.3.2	Justification shall be submitted for use of Atorvastatin Phosphate Monohydrate instead of Atorvastatin calcium given in Batch formula for proposed commercial batch.	
4	3.2.P.8	Stability data for 6 Month time point both for real time and accelerated stability shall be submitted.	
5	3.2.P.8	Complete BMR of stability study batches shall be provided	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

750.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s GENIX Pharma Private Limited Pakistan 44,45B Korangi Creek Road Karachi-Pakistan**.
	Name, address of Manufacturing site.	M/s GENIX Pharma Private Limited Pakistan 44,45B Korangi Creek Road Karachi-Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 27153 dated 17-11-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 344327525311 dated 03-11-23.
	The proposed proprietary name / brand name	**Depsit 1mg/ml oral solution.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Escitalopram oxalate eq to Escitalopram ……..…1mg
	Pharmacotherapeutic Group of (API)	Antidepressant/Antipsychotic N06AB10
	Reference to Finished product specifications	USP specifications.
	The status in reference regulatory authorities	Escitalopram oxalate 1mg/1ml Oral solution USFDA.
	For generic drugs (me-too status)	
	Proposed Pack size	30ml, 60ml, 120ml
	Proposed unit price	As per SRO.

Decision: Approved.

751.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals**, **Plot No. 23&24, S-1, RCCI Industrial Estate, Rawat, Rawalpindi Pakistan**.
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23&24, S-1, RCCI Industrial Estate, Rawat, Rawalpindi Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 22782 dated 25-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 54666303896 dated 25-07-23.
	The proposed proprietary name / brand name	**Dicloz 25mg Tablet.**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each enteric coated tablet Contains: Diclofenac Sodium(USP) ……..…25mg
	Pharmacotherapeutic Group of (API)	NSAIDS D11AX18
	Reference to Finished product specifications	USP specifications.
	The status in reference regulatory authorities	Diclofenac Sodium 25mg tablets, HPRA Approved.
	For generic drugs (me-too status)	Panslay 25mg Tablets, M/s Getz Pharma Pakistan (Pvt.) Ltd., Reg. No. 024907.
	Proposed Pack size	As per S.R.O.
	Proposed unit price	As per S.R.O.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1	1.6.5	Valid copy of GMP certificate/Last Inspection report conducted in last 3 years of the applicant and drug substance manufacturer shall be submitted..	
2		Material is supplied to WNS field Pharmaceutical, Agreement for taking loan or clarification required.	
3	3.S.4	Assay limits in COA of API provided by applicant does not comply with adopted BP Specification's.	
4	3.S.7	Stability data sheets provided by drug substance manufacturer are not readable.	
5	3.2.P.2.2	F_2 Calculation and absorbance shall be submitted for each medium. Submit comparison of each unit(12 units of each test and reference product).	
6	3.2.P.5	Calibration curve of UV absorbance used in dissolution is Required.	
7	3.2.P.8	• Tailing factor is increased then pharmacopoeia limits i.e NMT 1.2% • Analytical method has mentioned injection volume of 1µl while submitted chromatograms has mentioned 20 µl injection volume. Clarification shall be submitted	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

752.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals**, **Plot No. 23&24, S-1, RCCI Industrial Estate, Rawat, Rawalpindi Pakistan**.
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23&24, S-1, RCCI Industrial Estate, Rawat, Rawalpindi Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 23409 dated 21-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 04697536 dated 25-07-23.
	The proposed proprietary name / brand name	**Dicloz 100mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated extended release tablet Contains: Diclofenac Sodium(USP) ……..…100mg
	Pharmacotherapeutic Group of (API)	NSAIDS D11AX18

	Reference to Finished product specifications	USP specifications.
	The status in reference regulatory authorities	Diclofenac Sodium 100mg tablets, USFDA Approved.
	For generic drugs (me-too status)	Sintral SR 100mg Tablets, M/s Neomedix Karachi (Pvt.) Ltd., Reg. No. 081413.
	Proposed Pack size	As per S.R.O.
	Proposed unit price	As per S.R.O.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1	1.6.5	Valid copy of GMP certificate/Last Inspection report conducted in last 3 years of the applicant and drug substance manufacturer shall be submitted..	
2		Material is supplied to WNS field Pharmaceutical, Agreement for taking loan or clarification required.	
3	3.S.4	Assay limits in COA of API provided by applicant does not comply with BP Specification's.	
4	3.S.7	Stability data sheets provided by drug substance manufacturer are not readable.	
5	3.2.P.2.2	Dissolution method adopted is not complying with test method 1 of USP monograph, F_2 Calculation and absorbance shall be submitted for each medium. Submit comparison of each unit(12 units of each test and reference product).	
6	3.2.P.5	Calibration curve of UV absorbance used in dissolution is Required.	
7	3.2.P.8	• Tailing factor is increased then pharmacopoeia limits i.e NMT 1.2% • Analytical method has mentioned injection volume of 1µl while submitted chromatograms has mentioned 20 µl injection volume. Clarification shall be submitted.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

753.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals**, **Plot No. 23&24, S-1, RCCI Industrial Estate, Rawat, Rawalpindi Pakistan**.
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23&24, S-1, RCCI Industrial Estate, Rawat, Rawalpindi Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 22446 dated 12-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 27816931251 dated 5-07-23.
	The proposed proprietary name / brand name	**Dicloz 50mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each enteric coated tablet Contains: Diclofenac Sodium(USP) ……..…50mg
	Pharmacotherapeutic Group of (API)	NSAIDS D11AX18
	Reference to Finished product specifications	USP specifications.
	The status in reference regulatory authorities	Diclofenac Sodium 50mg tablets, HPRA Approved.

	For generic drugs (me-too status)	Vorenac 50mg Tablets, M/s Mission Pharma Karachi Pakistan (Pvt.) Ltd., Reg. No. 080324.
	Proposed Pack size	As per S.R.O.
	Proposed unit price	As per S.R.O.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1	1.6.5	Valid copy of GMP certificate/Last Inspection report conducted in last 3 years of the applicant and drug substance manufacturer shall be submitted..	
2		Material is supplied to WNS field Pharmaceutical, Agreement for taking loan or clarification required.	
3	3.S.4	Assay limits in COA of API provided by applicant does not comply with adopted BP Specification's.	
4	3.S.7	Stability data sheets provided by drug substance manufacturer are not readable.	
5	3.2.P.2.2	F_2 Calculation and absorbance shall be submitted for each medium. Submit comparison of each unit(12 units of each test and reference product).	
6	3.2.P.5	Calibration curve of UV absorbance used in dissolution is Required.	
7	3.2.P.8	• Tailing factor is increased then pharmacopoeia limits i.e NMT 1.2% • Analytical method has mentioned injection volume of 1µl while submitted chromatograms has mentioned 20 µl injection volume. Clarification shall be submitted	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

754.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals**, **Plot No. 23&24, S-1, RCCI Industrial Estate, Rawat, Rawalpindi Pakistan**.
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23&24, S-1, RCCI Industrial Estate, Rawat, Rawalpindi Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 22447 dated 12-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 2121837240 dated 5-07-23.
	The proposed proprietary name / brand name	**Dicloz 75mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each enteric coated tablet Contains: Diclofenac Sodium(USP) ……..…75mg
	Pharmacotherapeutic Group of (API)	NSAIDS D11AX18
	Reference to Finished product specifications `	USP specifications.
	The status in reference regulatory authorities	Diclofenac Sodium 75mg tablets, USFDA Approved.
	For generic drugs (me-too status)	Fedgesic 75mg Tablets, M/s Fedro Pharma Pakistan (Pvt.) Ltd., Reg. No. 079263.
	Proposed Pack size	As per S.R.O.
	Proposed unit price	As per S.R.O.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1	1.6.5	Valid copy of GMP certificate/Last Inspection report conducted in last 3 years of the applicant and drug substance manufacturer shall be submitted..	
2		Material is supplied to WNS field Pharmaceutical, Agreement for taking loan or clarification required.	
3	3.S.4	Assay limits in COA of API provided by applicant does not comply with adopted BP Specification's.	
4	3.S.7	Stability data sheets provided by drug substance manufacturer are not readable.	
5	3.2.P.2.2	F_2 Calculation and absorbance shall be submitted for each medium. Submit comparison of each unit(12 units of each test and reference product).	
6	3.2.P.5	Calibration curve of UV absorbance used in dissolution is Required.	
7	3.2.P.8	• Tailing factor is increased then pharmacopoeia limits i.e NMT 1.2% • Analytical method has mentioned injection volume of 1µl while submitted chromatograms has mentioned 20 µl injection volume. Clarification shall be submitted	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

755.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals**, **Plot No. 23&24, S-1, RCCI Industrial Estate, Rawat, Rawalpindi Pakistan**.
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23&24, S-1, RCCI Industrial Estate, Rawat, Rawalpindi Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 22449 dated 12-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 67853187 dated 25-07-23.
	The proposed proprietary name / brand name	**Estika 20mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each enteric coated tablet Contains: Escitalopram as Oxalate(USP) ……..…20mg
	Pharmacotherapeutic Group of (API)	Selective serotonin reuptake Inhibitors-Anti Depressants N06AB10
	Reference to Finished product specifications	USP specifications.
	The status in reference regulatory authorities	Escitalopram Oxalate 20mg M/s Brown& Burk UK ltd MHRA approved
	For generic drugs (me-too status)	Repram 20mg Tablets, M/s Regal Pharmaceuticals Pakistan (Pvt.) Ltd., Reg. No. 081963.
	Proposed Pack size	As per S.R.O.
	Proposed unit price	As per S.R.O.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1	1.6.5	Valid copy of GMP certificate of drug substance manufacturer shall be submitted..	
2	3.2.P.2.2	In CDP F_2 Calculations are not submitted. Further only average values are submitted, data of each unit of test product and reference product is require. (12 units of each test and reference product).	
3	3.2.P.5	• Submit data of system suitability run.	

		• As per USP monograph the run time should not be less than 3 times the retention time of Escitalopram. As per chromatograms submitted, retention time of Escitalopram is around 3.5 minutes, and run time is 6 minutes. The run time should have been 11 minutes (3.5x 3= 10.5). Please submit clarification. • Analytical method as in USP monograph has mentioned injection volume of 10µl while submitted chromatograms has mentioned 20 µl injection volume. Clarification shall be submitted	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

756.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wezen Pharmaceuticals**, **Plot No. 23&24, S-1, RCCI Industrial Estate, Rawat, Rawalpindi Pakistan**.
	Name, address of Manufacturing site.	M/s Wezen Pharmaceuticals, Plot No. 23&24, S-1, RCCI Industrial Estate, Rawat, Rawalpindi Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 22451 dated 12-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 51563153188 dated 25-07-23.
	The proposed proprietary name / brand name	**Estika 10mg Tablet.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each enteric coated tablet Contains: Escitalopram as Oxalate(USP) ……..…10mg
	Pharmacotherapeutic Group of (API)	Selective serotonin reuptake Inhibitors-Anti Depressants N06AB10
	Reference to Finished product specifications	USP specifications.
	The status in reference regulatory authorities	Escitalopram Oxalate 10mg M/s Brown& Burk UK ltd MHRA approved
	For generic drugs (me-too status)	Repram 10mg Tablets, M/s Regal Pharmaceuticals Pakistan (Pvt.) Ltd., Reg. No. 081962.
	Proposed Pack size	As per S.R.O.
	Proposed unit price	As per S.R.O.

Evaluation by PEC:

Sr. No.	Section	Observation	Reply by the firm
1	1.6.5	Valid copy of GMP certificate of drug substance manufacturer shall be submitted..	
2	3.2.P.2.2	In CDP F_2 Calculations are not submitted. Further only average values are submitted, data of each unit of test product and reference product is require. (12 units of each test and reference product).	
3	3.2.P.5	• Submit data of system suitability run. • As per USP monograph the run time should not be less than 3 times the retention time of Escitalopram. As per chromatograms submitted, retention time of Escitalopram is around 3.5 minutes, and run time is 6 minutes. The run time should have been 11 minutes (3.5x 3= 10.5). Please submit clarification. • Analytical method as in USP monograph has mentioned injection volume of 10µl while submitted chromatograms has mentioned 20 µl injection volume. Clarification shall be submitted	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

757.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Star Laboratories(PVT.) LTD. Lahore 23-Km, Multan Road (Chung) Pakistan**.
	Name, address of Manufacturing site.	M/s Star Laboratories(PVT.) LTD. Lahore 23-Km, Multan Road (Chung) Pakistan.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 23474 dated 22-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 6262526094 dated 22-05-23.
	The proposed proprietary name / brand name	**Rocetrax 2g Injection.**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial Contains: Sterile powder of Ceftriaxone Sodium equivalent to Ceftriaxone ……..…2g
	Pharmacotherapeutic Group of (API)	CEPHALOSPORIN C10AA05
	Reference to Finished product specifications	USP specifications.
	The status in reference regulatory authorities	Ceftriaxone Sodium 2.0g Injection, USFDA Approved.
	For generic drugs (me-too status)	Oxidil Injection 2g, M/s Sami Pharmaceuticals (Pvt.) Ltd., Reg. No. 086619.
	Proposed Pack size	1'S+10ml*2's(WFI)
	Proposed unit price	600
Decision: Approved.		

Agenda of Mr. Tahir Waqas

Agenda Item No. 01: Routine Applications of Human Drugs (Locally Manufactured) applied on Form - 5F.

758.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt.) Ltd. Plot No. E-127, E-128 & E-129, North Western Industrial Zone, Port Qasim Authority, Karachi.**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals (Pvt.) Ltd. Plot No. E-127, E-128 & E-129, North Western Industrial Zone, Port Qasim Authority, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 21771 dated 04-09-2023
	Details of fee submitted	PKR 75,000/- dated 12-07-2023 Challan / Receipt # 21849686632
	The proposed proprietary name / brand name	**URITID 100mg PR Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each prolonged release capsule contains: Nitrofurantoin … 100mg (as monohydrate 75mg & macrocrystal anhydrous 25mg).
	Pharmacotherapeutic Group of (API)	J01XE01, Antibacterial for systemic use – Nitrofuran derivatives.

	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	MacroBID 100mg Prolonged-Release Capsules of Amdipharm Limited, Health Products Regulatory Authority (HPRA), Ireland approved.
	For generic drugs (me-too status)	N/A
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide valid GMP Certificate of API Manufacturer. The enclosed certificate was valid till 18/04/2022.	Firm have submitted copy of GMP Certificate of API Manufacturer valid till Sep 2025.
ii.	Please provide summary of quantities of API imported & utilized for manufacturing / testing.	Firm have submitted summary of quantities of API imported & utilized for manufacturing / testing.

Decision: Approved.

759.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt.) Ltd. Plot No. E-127, E-128 & E-129, North Western Industrial Zone, Port Qasim Authority, Karachi.**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals (Pvt.) Ltd. Plot No. E-127, E-128 & E-129, North Western Industrial Zone, Port Qasim Authority, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 22770 dated 15-09-2023
	Details of fee submitted	PKR 75,000/- dated 12-07-2023 Challan / Receipt # 14882037
	The proposed proprietary name / brand name	**URITID 10mg/ml Oral Suspension**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Nitrofurantoin … 10mg
	Pharmacotherapeutic Group of (API)	J01XE01, Antibacterial for systemic use – Nitrofuran derivatives.
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	FURADANTIN 50mg/5ml Suspension of CASPER PHARMA LLC, USFDA approved.
	For generic drugs (me-too status)	N/A
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide API approval issued by concerned regulatory authority of country of origin.	Firm have submitted copy of GMP Certificate of API Manufacturer valid till Sep 2025.

ii.	Please provide summary of quantities of API imported & utilized for manufacturing / testing.	Firm have submitted summary of quantities of API imported & utilized for manufacturing / testing.

Decision: Approved.

760.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Kaizen Pharmaceuticals (Pvt.) Ltd. Plot No. E-127, E-128 & E-129, North Western Industrial Zone, Port Qasim Authority, Karachi.**
	Name, address of Manufacturing site.	M/s Kaizen Pharmaceuticals (Pvt.) Ltd. Plot No. E-127, E-128 & E-129, North Western Industrial Zone, Port Qasim Authority, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 22057 dated 07-09-2023
	Details of fee submitted	PKR 75,000/- dated 16-08-2023 Challan / Receipt # 9927670496
	The proposed proprietary name / brand name	**CELECOXIN 25mg/ml Oral Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Celecoxib … 25mg
	Pharmacotherapeutic Group of (API)	M01AH01, anti-inflammatory and anti-rheumatic products, non-steroids
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	ELYXYB 25mg/ml Oral Solution of SCILEX Pharms, USFDA approved.
	For generic drugs (me-too status)	N/A
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide valid GMP Certificate of API Manufacturer. The enclosed certificate was valid till 08/2024.	Firm have submitted copy of GMP Certificate of API Manufacturer valid till Aug 2025.
ii.	>5% Change from initial Assay Results were obtained in 3rd & 6th Month Testing Intervals (Accelerated Studies) of Batch Nos. TF-02 & TF-03. Please justify.	Not submitted

Decision: Approved.

761.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Surge Laboratories (Pvt.) Ltd. 10th Km, Faisalabad Road, Bikhi District, Sheikhupura.**
	Name, address of Manufacturing site.	M/s Surge Laboratories (Pvt.) Ltd. 10th Km, Faisalabad Road, Bikhi District, Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 22148 dated 08-09-2023
	Details of fee submitted	PKR 75,000/- dated 12-07-2023 Challan / Receipt # 43547261310

	The proposed proprietary name / brand name	**ATRAXUM IV 5mg/2.5ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2.5ml Ampoule Contains: Cisatracurium Besylate USP equivalent to Cisatracurium … 5mg
	Pharmacotherapeutic Group of (API)	Neuromuscular blocking agent
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	Cisatracurium 2mg/ml solution for injection / infusion, MHRA approved.
	For generic drugs (me-too status)	N/A
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide valid GMP Certificate of API Manufacturer. The enclosed certificate was valid till 11-2023.	Submitted
ii.	Please provide valid GMP Certificate of FPP Manufacturer, the enclosed GMP was valid till 10-2023.	Submitted
iii.	Stability Study of API has been conducted on 25±2°C, 60±5%RH and 5±3°C, instead of Zone IV. Please justify with supporting evidence.	The firm has submitted that the drug substance is intended for storage in refrigerator, therefore Stability Study of API has been conducted on 25±2°C, 60±5%RH and 5±3°C as per ICH guidelines.
iv.	Please provide evidence of procurement / import of API along with necessary approvals.	Submitted

Decision: Approved.

762.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmark Pharmaceuticals, Plot No. 122, Block - B, Phase V, Industrial Estate Hattar.**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals, Plot No. 122, Block - B, Phase V, Industrial Estate Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 22830 dated 18-09-2023
	Details of fee submitted	PKR 30,000/- dated 10-08-2023 Challan / Receipt # 624095523
	The proposed proprietary name / brand name	**MEGRON 25mg XR Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each extended release tablet contains: Mirabegron … 25mg
	Pharmacotherapeutic Group of (API)	G04BD12, Drugs for urinary frequency and incontinence.
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	MIRABEGRON 25mg prolonged-release Tablets of Sandoz Limited, MHRA approved.

	For generic drugs (me-too status)	MIRABET 25mg Tablet of CCL Pharmaceutical Pvt. Ltd.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide valid GMP of API Manufacturer issued by relevant authority. The enclosed GMP was valid till 03 – 2023, and issued by Medical and Chemical Industry Administration which is not the relevant authority for issuance of GMP.	Firm has submitted copy of License of API Manufacturer (M/s Zhejiang Huahai, China). Firm has provided clearance certificate issued by I&E DRAP Peshawar dated 23-11-2022
ii.	3.2.P.5 Finished products specifications have been mentioned 'as per innovator's specs' as well as 'manufacturer's specifications' on different instances. Please clarify.	Typo, Finished Product Specifications is 'as per innovator'.
iii.	Batch size has been mentioned as '1200 Packs'. Please clarify.	Typo, Batch size is 1200 Tablets.
iv.	Please provide evidence of I&E (DRAP) approval / clearance for Invoice No. HH20222745 dated NOV.08,2022.	Firm have submitted copy of Form 5 only.
v.	Please provide valid GMP status of FPP Manufacturer. The enclosed GMP Certificate was valid till 11 – 2023.	Not submitted.

Decision: Approved.

763.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmark Pharmaceuticals, Plot No. 122, Block - B, Phase V, Industrial Estate Hattar.**
	Name, address of Manufacturing site.	M/s Welmark Pharmaceuticals, Plot No. 122, Block - B, Phase V, Industrial Estate Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 22831 dated 18-09-2023
	Details of fee submitted	PKR 30,000/- dated 10-08-2023 Challan / Receipt # 06906743682
	The proposed proprietary name / brand name	**MEGRON 50mg XR Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each extended release tablet contains: Mirabegron … 50mg
	Pharmacotherapeutic Group of (API)	G04BD12, Drugs for urinary frequency and incontinence.
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	MIRABEGRON 50mg prolonged-release Tablets of Sandoz Limited, MHRA approved.
	For generic drugs (me-too status)	MIRABET 50mg Tablet of CCL Pharmaceutical Pvt. Ltd.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide valid GMP of API Manufacturer issued by relevant authority. The enclosed GMP was valid till 03 – 2023, and issued by Medical and Chemical Industry Administration which is not the relevant authority for issuance of GMP.	Firm has submitted copy of License of API Manufacturer (M/s Zhejiang Huahai, China). Firm has provided clearance certificate issued by I&E DRAP Peshawar dated 23-11-2022
ii.	3.2.P.5 Finished products specifications have been mentioned 'as per innovator's specs' as well as 'manufacturer's specifications' on different instances. Please clarify.	Typo, Finished Product Specifications is 'as per innovator'.
iii.	Batch size has been mentioned as '1200 Packs'. Please clarify.	Typo, Batch size is 1200 Tablets.
iv.	Please provide evidence of I&E (DRAP) approval / clearance for Invoice No. HH20222745 dated NOV.08,2022.	Firm have submitted copy of Form 5 only.
v.	Please provide valid GMP status of FPP Manufacturer. The enclosed GMP Certificate was valid till 11 – 2023.	Not submitted.

Decision: Approved.

764.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon Healthcare (Pvt.) Ltd. Plot No. 35-A, Small Industrial Estate, Taxila.**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt.) Ltd. Plot No. 35-A, Small Industrial Estate, Taxila.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 22951 dated 19-09-2023
	Details of fee submitted	PKR 75,000/- dated 02-06-2023 Challan / Receipt # 1223943262
	The proposed proprietary name / brand name	**PRESTIA 2gm for IV/IM Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Methylprednisolone as Sodium Succinate … 2gm (Sterile powder for reconstitution)
	Pharmacotherapeutic Group of (API)	H02AB04, Corticosteroids for Systemic Use, Plain. Glucocorticoids.
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	SOLU-MEDROL for injection 2gm of M/s Pharmacia and Upjohn, USFDA approved.
	For generic drugs (me-too status)	N/A
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response

i.	Please provide evidence of approval of manufacturing facility / approved section from Licensing Authority. The enclosed letter was valid for a period of one year (from 22nd November 2018), and approval by Central Licensing Board.	Firm have submitted copy of letter dated 8th November 2023 mentioning Dry Powder Injection (Vial) (Steroid) Revised Section.
ii.	Please provide valid GMP status of FPP Manufacturer for applied section.	Firm have submitted copy of GMP Certificate dated 17th August 2022.
iii.	Please provide valid GMP of API Manufacturer issued by relevant authority. The enclosed GMP was valid till end of 2023 (including the extension period for restrictions caused by Covid-19).	Firm have submitted valid GMP of API Manufacturer (Biofar S.P.A., Italy).
iv.	3.2.P.3.2 List of components of Drug Product mentioned in this section include 'Methylprednisolone Sodium Succinate' only, whereas the reference / innovator formulation contains monobasic sodium phosphate anhydrous and dibasic sodium phosphate dried also. Please justify.	Firm have submitted that they are using lyophilized, buffered API which is ready to fill.

The innovator product declares the warning that the formulations containing benzyl alcohol should not be used in neonates.

Decision: Approved. Registration letter will be issued with box warning as per innovator drug product

765.	**Name, address of Applicant / Marketing Authorization Holder**	**Macter International Limited, F-216, S.I.T.E., Karachi.**
	Name, address of Manufacturing site.	Macter International Limited, F-216, S.I.T.E., Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 23477 dated 22-09-2023
	Details of fee submitted	PKR 30,000/- dated 11-08-2023 Challan / Receipt # 18431433 PKR 45,000/- dated 05-03-2024 Challan / Receipt # 605866247
	The proposed proprietary name / brand name	**ENDOGOLIX 150mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Elagolix Sodium 155.20 mg equivalent to Elagolix … 150 mg
	Pharmacotherapeutic Group of (API)	H01CC03, Anti-gonadotropin-releasing hormone
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	ORILISSA 150mg Tablets of M/s AbbVie USFDA approved.
	For generic drugs (me-too status)	N/A
	Proposed Pack size	7's, 14's and 28's
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response

i.	Please provide API approval / GMP Certificate of API Manufacturer issued by concerned regulatory authority of country of origin. The enclosed GMP is from Jiaxing Pharmaceutical Association, which is not the relevant authority for issuance of GMP Certificate.	
ii.	Please provide evidence of I&E, DRAP Karachi clearance issued against Form 6 No. K-621272281258.	
iii.	3.2.S.7.1 Long Term Stability Study of API has been conducted at 30±2℃, 60±5% RH instead of 65±5% RH. Please justify.	

Decision: The Registration Board deferred the case for submission of response to above cited shortcomings.

766.	**Name, address of Applicant / Marketing Authorization Holder**	**Macter International Limited, F-216, S.I.T.E., Karachi.**
	Name, address of Manufacturing site.	Macter International Limited, F-216, S.I.T.E., Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 24552 dated 09-10-2023
	Details of fee submitted	PKR 30,000/- dated 11-08-2023 Challan / Receipt # 8749704588 PKR 45,000/- dated 05-03-2024 Challan / Receipt # 991985498179
	The proposed proprietary name / brand name	**ENDOGOLIX 200mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Elagolix Sodium equivalent to Elagolix … 200mg
	Pharmacotherapeutic Group of (API)	H01CC03, Anti-gonadotropin-releasing hormone
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	ORILISSA 200mg Tablets of M/s AbbVie USFDA approved.
	For generic drugs (me-too status)	N/A
	Proposed Pack size	7's, 14's and 28's
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide API approval / GMP Certificate of API Manufacturer issued by concerned regulatory authority of country of origin. The enclosed GMP is from Jiaxing Pharmaceutical Association, which is not the relevant authority for issuance of GMP Certificate.	
ii.	Please provide evidence of I&E, DRAP Karachi clearance issued against Form 6 No. K-621272281258.	
iii.	3.2.S.7.1 Long Term Stability Study of API has been conducted at 30±2℃, 60±5% RH instead of 65±5% RH. Please justify.	

Decision: The Registration Board deferred the case for submission of response to above cited shortcomings.

767.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scilife Pharma (Pvt.) Ltd. Plot No. FD-57/58-A2, Korangi Creek Industrial Park (KCIP), Karachi.**
	Name, address of Manufacturing site.	M/s Scilife Pharma (Pvt.) Ltd. Plot No. FD-57/58-A2, Korangi Creek Industrial Park (KCIP), Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 23147 dated 20-09-2023
	Details of fee submitted	PKR 30,000/- dated 26-07-2023 Challan / Receipt # 984410206
	The proposed proprietary name / brand name	**KESTORE-EZ 10/10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each bilayer film coated tablet contains: Rosuvastatin Calcium equivalent to Rosuvastatin … 10mg Ezetimibe … 10mg
	Pharmacotherapeutic Group of (API)	C10BA06, Combinations of various lipid modifying agents.
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	ZENON Tablets 10/10mg of M/s Aventis Pharma Limited, MHRA approved.
	For generic drugs (me-too status)	ROVISTA EZ Tablets 10/10mg of M/s Getz Pharma (Pvt.) Limited.
	Proposed Pack size	10's, 14's, 20's, 28's & 30's
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	**Rosuvastatin Calcium:** Please provide valid GMP of API Manufacturer issued by relevant authority. The enclosed GMP was valid till October – 2023.	Firm have submitted copy of GMP of API Manufacturer valid till 10 - 2028.
ii.	**Ezetimibe:** Please provide valid GMP of API Manufacturer issued by relevant authority. The enclosed GMP was valid till 12 – 2023.	Firm have submitted copy of GMP of API Manufacturer valid till 12 - 2024.
iii.	**Rosuvastatin Calcium:** 3.2.S.7 Real Time Stability Study of API has been conducted at 25±2°C and 60±5%RH, instead of Zone IV. Please justify with supporting evidence.	Firm have submitted Stability Study Data of API conducted at Zone IV.

Decision: Approved.

768.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Scilife Pharma (Pvt.) Ltd. Plot No. FD-57/58-A2, Korangi Creek Industrial Park (KCIP), Karachi.**
	Name, address of Manufacturing site.	M/s Scilife Pharma (Pvt.) Ltd. Plot No. FD-57/58-A2, Korangi Creek Industrial Park (KCIP), Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 26955 dated 14-11-2023
	Details of fee submitted	PKR 30,000/- dated 15-09-2023 Challan / Receipt # 4464971365

	The proposed proprietary name / brand name	**KESTORE-EZ 5/10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each bilayer film coated tablet contains: Rosuvastatin Calcium equivalent to Rosuvastatin … 5mg Ezetimibe … 10mg
	Pharmacotherapeutic Group of (API)	C10BA06, Combinations of various lipid modifying agents.
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	EZETIMIBE - ROSUVASTATIN SANDOZ 10mg /5mg Tablets, TGA (Australia) approved.
	For generic drugs (me-too status)	ROVISTA EZ Tablets 5/10mg of M/s Getz Pharma (Pvt.) Limited.
	Proposed Pack size	10's, 14's, 20's, 28's & 30's
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	**Rosuvastatin Calcium:** Please provide valid GMP of API Manufacturer issued by relevant authority. The enclosed GMP was valid till October – 2023.	Firm have submitted copy of GMP of API Manufacturer valid till 10 - 2028.
ii.	**Ezetimibe:** Please provide valid GMP of API Manufacturer issued by relevant authority. The enclosed GMP was valid till 12 – 2023.	Firm have submitted copy of GMP of API Manufacturer valid till 12 - 2024.
iii.	**Rosuvastatin Calcium:** 3.2.S.7 Real Time Stability Study of API has been conducted at 25±2°C and 60±5%RH, instead of Zone IV. Please justify with supporting evidence.	Firm have submitted Stability Study Data of API conducted at Zone IV.

Decision: Approved.

769.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s High-Q Pharmaceuticals, Plot# 224 and 225/1, Sector 23, Korangi Industrial area, Karachi.**
	Name, address of Manufacturing site.	M/s High-Q Pharmaceuticals, Plot# 224 and 225/1, Sector 23, Korangi Industrial area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 23749 dated 26-09-2023
	Details of fee submitted	PKR 30,000/- dated 21-08-2023 Challan / Receipt # 17585827
	The proposed proprietary name / brand name	**OBETAC 5mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Obeticholic Acid … 5mg
	Pharmacotherapeutic Group of (API)	A05AA04, Bile acids and derivatives
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	OCALIVA 5mg Tablet of M/s Intercept Pharms Inc., USFDA approved.
	For generic drugs (me-too status)	OBETICID 5mg Tablet of M/s Wilson's Pharmaceuticals.
	Proposed Pack size	10's, 20's and 30's.
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide valid GMP of API Manufacturer issued by relevant authority. The enclosed GMP was issued by Medical and Chemical Industry Administration which is not the relevant authority for issuance of GMP	GMP declaration from the drug substance manufacturer is attached for not providing state level GMP. Firm have referred to License of API Manufacturer (M/s Nantong Chanyoo, China).
ii.	3.2. S.7 Long Term Stability Study of API has been conducted on 5±3°C, instead of Zone IV. Please justify with supporting evidence.	Firm have submitted Long Term Stability Study of API conducted on Zone IV.

Decision: Approved.

770.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s High-Q Pharmaceuticals, Plot# 224 and 225/1, Sector 23, Korangi Industrial area, Karachi.**
	Name, address of Manufacturing site.	M/s High-Q Pharmaceuticals, Plot# 224 and 225/1, Sector 23, Korangi Industrial area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 23750 dated 26-09-2023
	Details of fee submitted	PKR 30,000/- dated 21-08-2023 Challan / Receipt # 0877474866
	The proposed proprietary name / brand name	**OBETAC 10mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Obeticholic Acid … 10mg
	Pharmacotherapeutic Group of (API)	A05AA04, Bile acids and derivatives
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	OCALIVA 10mg Tablet of M/s Intercept Pharms Inc., USFDA approved.
	For generic drugs (me-too status)	OBETICID 10mg Tablet of M/s Wilson's Pharmaceuticals.
	Proposed Pack size	10's, 20's and 30's.
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide valid GMP of API Manufacturer issued by relevant authority. The enclosed GMP was issued by Medical and Chemical Industry Administration which is not the relevant authority for issuance of GMP	GMP declaration from the drug substance manufacturer is attached for not providing state level GMP. Firm have referred to License of API Manufacturer (M/s Nantong Chanyoo, China).
ii.	3.2. S.7 Long Term Stability Study of API has been conducted on 5±3°C, instead of Zone IV. Please justify with supporting evidence.	Firm have submitted Long Term Stability Study of API conducted on Zone IV.

Decision: Approved.

771.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sunder Industrial Estate Raiwind Road, Lahore.**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (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)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 25891 dated 26-10-2023
	Details of fee submitted	PKR 30,000/- dated 05-10-2023 Challan / Receipt # 48237987797
	The proposed proprietary name / brand name	**ORLIX 150mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Elagolix Sodium equivalent to Elagolix … 150 mg
	Pharmacotherapeutic Group of (API)	H01CC03, Anti-gonadotropin-releasing hormone
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	ORILISSA 150mg Tablets of M/s AbbVie USFDA approved.
	For generic drugs (me-too status)	Eladiol 150mg Tablet of M/s Nabiqasim Industries (Pvt) Ltd.,
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide valid GMP of API Manufacturer issued by relevant authority. The enclosed GMP was valid till 04 – 2024.	Copy of GMP Certificate valid till 11 – 2025 has been submitted. However, the same cannot be verified online.
ii.	Finished products specifications have been mentioned 'as per innovator's specs' as well as 'in-house specs' on different instances. Please clarify.	Typo error. Firm has submitted that the Finished products specifications are 'as per innovator's specs'.
iii.	3.2.P.8 Please provide Stability Study Data along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc., for 06th Month Testing Interval of all 03 Trials.	Submitted
iv.	Please provide valid GMP status of FPP Manufacturer. The enclosed GMP Certificate does not include Tablet Section.	Submitted
v.	Please provide evidence of procurement / Import of API along with necessary I&E (DRAP) approvals / clearance.	Copy of Form 6 No. K-2011282888539.
vi.	Fee has been submitted for Registration of Generic Drug (local manufacture); Please provide evidence of Generic Drug Product (me-too status) reference.	Firm has referred to ELOX 150mg Tablet of M/s Genix Pharma, Karachi.

Decision: Approved.

772.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sunder Industrial Estate Raiwind Road, Lahore.**

	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (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)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 25892 dated 26-10-2023
	Details of fee submitted	PKR 30,000/- dated 05-10-2023 Challan / Receipt # 42240447055
	The proposed proprietary name / brand name	**ORLIX 200mg Tablets**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Elagolix Sodium equivalent to Elagolix … 200 mg
	Pharmacotherapeutic Group of (API)	H01CC03, Anti-gonadotropin-releasing hormone
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	ORILISSA 200mg Tablets of M/s AbbVie USFDA approved.
	For generic drugs (me-too status)	Eladiol 150mg Tablet of M/s Nabiqasim Industries (Pvt) Ltd.,
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide valid GMP of API Manufacturer issued by relevant authority. The enclosed GMP was valid till 04 – 2024.	Copy of GMP Certificate valid till 11 – 2025 has been submitted. However, the same cannot be verified online.
ii.	Finished products specifications have been mentioned 'as per innovator's specs' as well as 'in-house specs' on different instances. Please clarify.	**Typo error.** Firm has submitted that the Finished products specifications are 'as per innovator's specs'.
iii.	3.2.P.8 Please provide Stability Study Data along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc., for 06th Month Testing Interval of all 03 Trials.	Submitted
iv.	Please provide valid GMP status of FPP Manufacturer. The enclosed GMP Certificate does not include Tablet Section.	Submitted
v.	Please provide evidence of procurement / Import of API along with necessary I&E (DRAP) approvals / clearance.	Copy of Form 6 No. K-2011282888539.
vi.	Fee has been submitted for Registration of Generic Drug (local manufacture); Please provide evidence of Generic Drug Product (me-too status) reference.	Firm has referred to ELOX 200mg Tablet of M/s Genix Pharma, Karachi.

Decision: Approved.

773.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Healthtek (Pvt.) Ltd., Plot No. 14, Sector 19, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s Healthtek (Pvt.) Ltd., Plot No. 14, Sector 19, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer

		☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 26025 dated 27-10-2023
	Details of fee submitted	PKR 75,000/- dated 28-08-2023 Challan / Receipt # 1394728361
	The proposed proprietary name / brand name	**PENTACEF 400mg/vial for IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftaroline Fosamil Monoacetate Monohydrate (with L-Arginine) eq. to Ceftaroline Fosamil … 400mg
	Pharmacotherapeutic Group of (API)	J01DI02, Other cephalosporin and penem
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	TEFLARO 400MG/Vial Powder for Injection IV of M/s Abbvie, USFDA approved.
	For generic drugs (me-too status)	N/A
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide evidence of approval of section (Dry Powder for Injection - Cephalosporin) from Licensing.	Firm have submitted evidence of approval of section.
ii.	Please provide API approval / GMP Certificate of API Manufacturer issued by concerned regulatory authority of country of origin. The enclosed Certificate is from Pharmaceutical Industry Association, which is not the relevant authority for issuance of GMP Certificate.	Firm have referred to License of API Manufacturer (M/s Qingdao Xinnua, China) already considered in 330th Meeting of Registration Board.
iii.	Pharmaceutical / comparative equivalence studies have been performed with ZINFORO 600mg Injection instead of 400mg Injection. Please justify with supporting evidence.	Firm have submitted Pharmaceutical / comparative equivalence studies performed with TEFLARO 400mg Injection.
iv.	The container closure system has been mentioned as USP Type III Glass Vials whereas the Innovator's product is supplied in USP Type I Glass Vials. Please justify with supporting evidence.	The firm have referred to their stability study results for compatibility with container closure system. The submitted guidance document - USP <660> mentions that USP Type III Glass Vials are usually not used for Powders for Parenteral Use.
v.	Please provide evidence of I&E, DRAP Karachi clearance issued against Form 6 No. K-1142161013897, Invoice No. XN2204-PK-099 dated 03.10.2022.	Firm have submitted copy of DRAP (I&E) issued Form – 6, and Import documents (Copy of Invoice / GD-1).

Decision: Approved, with recommended USP Type I / II Glass Vials, as per innovator.

774.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Healthtek (Pvt.) Ltd., Plot No. 14, Sector 19, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s Healthtek (Pvt.) Ltd., Plot No. 14, Sector 19, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 26026 dated 27-10-2023
	Details of fee submitted	PKR 75,000/- dated 28-08-2023 Challan / Receipt # 5677754487
	The proposed proprietary name / brand name	**PENTACEF 600mg/vial for IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftaroline Fosamil Monoacetate Monohydrate (with L-Arginine) eq. to Ceftaroline Fosamil … 600mg
	Pharmacotherapeutic Group of (API)	J01DI02, Other cephalosporin and penem
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	TEFLARO 600MG/Vial Powder for Injection IV of M/s Abbvie, USFDA approved.
	For generic drugs (me-too status)	N/A
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide evidence of approval of section (Dry Powder for Injection - Cephalosporin) from Licensing.	Firm have submitted evidence of approval of section.
ii.	Please provide API approval / GMP Certificate of API Manufacturer issued by concerned regulatory authority of country of origin. The enclosed Certificate is from Pharmaceutical Industry Association, which is not the relevant authority for issuance of GMP Certificate.	Firm have referred to License of API Manufacturer (M/s Qingdao Xinnua, China) already considered in 330th Meeting of Registration Board.
iii.	The container closure system has been mentioned as USP Type III Glass Vials whereas the Innovator's product is supplied in USP Type I Glass Vials. Please justify with supporting evidence.	The firm have referred to their stability study results for compatibility with container closure system. The submitted guidance document - USP <660> mentions that USP Type III Glass Vials are usually not used for Powders for Parenteral Use.
iv.	Please provide evidence of I&E, DRAP Karachi clearance issued against Form 6 No. K-1142161013897, Invoice No. XN2204-PK-099 dated 03.10.2022.	Firm have submitted copy of DRAP (I&E) issued Form – 6, and Import documents (Copy of Invoice / GD-1).

Decision: Approved, with recommended USP Type I / II Glass Vials, as per innovator.

775.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Sami Pharmaceuticals (Pvt.) Ltd., Plot. No. F-95, Hub River Road, S.I.T.E., Karachi.**
	Name, address of Manufacturing site.	M/s Healthtek (Pvt.) Ltd., Plot No. 14, Sector 19, Korangi Industrial Area, Karachi.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 26027 dated 27-10-2023
	Details of fee submitted	PKR 75,000/- dated 13-10-2023 Challan / Receipt # 037215857569

	The proposed proprietary name / brand name	**PENTACEF 400mg/vial for IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftaroline Fosamil Monoacetate Monohydrate (with L-Arginine) eq. to Ceftaroline Fosamil … 400mg
	Pharmacotherapeutic Group of (API)	J01DI02, Other cephalosporin and penem
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	TEFLARO 400MG/Vial Powder for Injection IV of M/s Abbvie, USFDA approved.
	For generic drugs (me-too status)	N/A
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide evidence of approval of section of Manufacturer (Dry Powder for Injection - Cephalosporin) from Licensing.	Firm have submitted evidence of approval of section.
ii.	Please provide API approval / GMP Certificate of API Manufacturer issued by concerned regulatory authority of country of origin. The enclosed Certificate is from Pharmaceutical Industry Association, which is not the relevant authority for issuance of GMP Certificate.	Firm have referred to License of API Manufacturer (M/s Qingdao Xinnua, China) already considered in 330th Meeting of Registration Board.
iii.	Pharmaceutical / comparative equivalence studies have been performed with ZINFORO 600mg Injection instead of 400mg Injection. Please justify with supporting evidence.	Firm have submitted Pharmaceutical / comparative equivalence studies performed with TEFLARO 400mg Injection.
iv.	The container closure system has been mentioned as USP Type III Glass Vials whereas the Innovator's product is supplied in USP Type I Glass Vials. Please justify with supporting evidence.	The firm have referred to their stability study results for compatibility with container closure system. The submitted guidance document - USP <660> mentions that USP Type III Glass Vials are usually not used for Powders for Parenteral Use.
v.	Please provide evidence of I&E, DRAP Karachi clearance issued against Form 6 No. K-1142161013897, Invoice No. XN2204-PK-099 dated 03.10.2022.	Firm have submitted copy of DRAP (I&E) issued Form – 6, and Import documents (Copy of Invoice / GD-1).

Decision: Approved, with recommended USP Type I / II Glass Vials, as per innovator.

776.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Sami Pharmaceuticals (Pvt.) Ltd., Plot. No. F-95, Hub River Road, S.I.T.E., Karachi.**
	Name, address of Manufacturing site.	M/s Healthtek (Pvt.) Ltd., Plot No. 14, Sector 19, Korangi Industrial Area, Karachi.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 26028 dated 27-10-2023

	Details of fee submitted	PKR 75,000/- dated 13-10-2023 Challan / Receipt # 18790498078
	The proposed proprietary name / brand name	**PENTACEF 600mg/vial for IV Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Ceftaroline Fosamil Monoacetate Monohydrate (with L-Arginine) eq. to Ceftaroline Fosamil … 600mg
	Pharmacotherapeutic Group of (API)	J01DI02, Other cephalosporin and penem
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	TEFLARO 600MG/Vial Powder for Injection IV of M/s Abbvie, USFDA approved.
	For generic drugs (me-too status)	N/A
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide evidence of approval of section of Manufacturer (Dry Powder for Injection - Cephalosporin) from Licensing.	Firm have submitted evidence of approval of section.
ii.	Please provide API approval / GMP Certificate of API Manufacturer issued by concerned regulatory authority of country of origin. The enclosed Certificate is from Pharmaceutical Industry Association, which is not the relevant authority for issuance of GMP Certificate.	Firm have referred to License of API Manufacturer (M/s Qingdao Xinnua, China) already considered in 330th Meeting of Registration Board.
iii.	The container closure system has been mentioned as USP Type III Glass Vials whereas the Innovator's product is supplied in USP Type I Glass Vials. Please justify with supporting evidence.	The firm have referred to their stability study results for compatibility with container closure system. The submitted guidance document - USP <660> mentions that USP Type III Glass Vials are usually not used for Powders for Parenteral Use.
iv.	Please provide evidence of I&E, DRAP Karachi clearance issued against Form 6 No. K-1142161013897, Invoice No. XN2204-PK-099 dated 03.10.2022.	Firm have submitted copy of DRAP (I&E) issued Form – 6, and Import documents (Copy of Invoice / GD-1).

Decision: Approved, with recommended USP Type I / II Glass Vials, as per innovator.

777.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 25011 dated 13-10-2023
	Details of fee submitted	PKR 30,000/- dated 03-10-2023 Challan / Receipt # 7770430987
	The proposed proprietary name / brand name	**NEUCOLISTI 1 Million I.U. Injection**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Colistimethate Sodium (Lyophilized Powder) 80mg equivalent to 1 Million I.U.
	Pharmacotherapeutic Group of (API)	J01XB01, Other Antibacterial, Polymixins.
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	COLOMYCIN 1 million International Units (IU) Powder for solution for injection, infusion or inhalation of M/s Teva UK Limited, MHRA approved.
	For generic drugs (me-too status)	NOGOTEX Injection 1 MIU of M/s Nabiqasim Industries (Pvt) Ltd.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide valid GMP Certificate of API Manufacturer issued by relevant authority of country of origin. The enclosed copy of letter is not a GMP Certificate.	Firm have referred to License of API Manufacturer (M/s Livzon Group Fuzhou Fuxin, China).
ii.	Milligrams of Colistin base activity has not been included in label claim. Applicant is required to submit revised label claim including Colistin base activity in milligrams.	Firm have mentioned label claim as: Each vial contains: Colistimethate Sodium (1MIU) eq. to Colistimethate base activity … 34mg.
iii.	3.2.P.2.2.1 It has been mentioned that the firm have used same formulation ingredients as used by Innovator 'Colisitin Injection' manufactured by Pharmasol. Please justify. Furthermore, please provide the reason for not performing Pharmaceutical equivalence studies with the Innovator's product.	Firm have submitted that due to ready availability, comparator (Colistim Injection of Pharmasol) was used for comparative studies.

Decision: Approved. Registration Board further decided that the registration letter will be issued with label claim as decided in the 331st meeting of Registration Board.

778.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhupura Road, Lahore.**
	Name, address of Manufacturing site.	M/s Neutro Pharma (Pvt.) Ltd., 9.5-Km, Sheikhupura Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 25012 dated 13-10-2023
	Details of fee submitted	PKR 30,000/- dated 03-10-2023 Challan / Receipt # 53737466
	The proposed proprietary name / brand name	**NEUCOLISTI 2 Million I.U. Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Colistimethate Sodium (Lyophilized Powder) 160mg equivalent to 2 Million I.U.
	Pharmacotherapeutic Group of (API)	J01XB01, Other Antibacterial, Polymixins.
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory	COLOMYCIN 2 million International Units (IU)

	authorities	Powder for solution for injection, infusion or inhalation of M/s Teva UK Limited, MHRA approved.
	For generic drugs (me-too status)	NOGOTEX Injection 2 MIU of M/s Nabiqasim Industries (Pvt) Ltd.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide valid GMP Certificate of API Manufacturer issued by relevant authority of country of origin. The enclosed copy of letter is not a GMP Certificate.	Firm have referred to License of API Manufacturer (M/s Livzon Group Fuzhou Fuxin, China).
ii.	Milligrams of Colistin base activity has not been included in label claim. Applicant is required to submit revised label claim including Colistin base activity in milligrams.	Firm have mentioned label claim as: Each vial contains: Colistimethate Sodium (1MIU) eq. to Colistimethate base activity … 68mg.
iii.	Please provide evidence of Reference / Innovator's product used for Pharmaceutical Equivalence.	Firm have submitted that due to ready availability, comparator (Colistim Injection of Pharmasol) was used for comparative studies.

Decision: Approved. Registration Board further decided that the registration letter will be issued with label claim as decided in the 331st meeting of Registration Board.

779.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Magns Pharmaceuticals, Plot # 7B Value Addition City, Sahianwala Road Khurrianwala, Faisalabad.**
	Name, address of Manufacturing site.	M/s Magns Pharmaceuticals, Plot # 7B Value Addition City, Sahianwala Road Khurrianwala, Faisalabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 26691 dated 06-11-2023
	Details of fee submitted	PKR 30,000/- dated 06-10-2023 Challan / Receipt # 72950455
	The proposed proprietary name / brand name	**MAGZYL 400mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Metronidazole … 400mg
	Pharmacotherapeutic Group of (API)	P01AB01, Agents Against Amoebiasis And Other Protozoal Diseases.
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	FLAGYL 400mg Tablets of M/s Aventis Pharma Limited UK, MHRA approved.
	For generic drugs (me-too status)	FLAGYL Tablet of M/s Sanofi-Aventis Pakistan Ltd.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response

i.	Please provide evidence of I&E (DRAP) Clearance for Import against Invoice No. EXP/2509/2574/2695/22-23 dated 06-12-2022.	
ii.	3.2.P.8 Please provide Stability Study Data along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc., for 06th Month Testing Interval of all 03 Trials.	

Decision: The Registration Board deferred the case for submission of response to above cited shortcomings.

780.	**Name, address of Applicant / Marketing Authorization Holder**	**Magns Pharmaceuticals, Plot # 7B Value Addition City, Sahianwala Road Khurrianwala, Faisalabad.**
	Name, address of Manufacturing site.	Magns Pharmaceuticals, Plot # 7B Value Addition City, Sahianwala Road Khurrianwala, Faisalabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 26690 dated 06-11-2023
	Details of fee submitted	PKR 30,000/- dated 06-10-2023 Challan / Receipt # 2256138857
	The proposed proprietary name / brand name	**VELOFT-K 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each sugar coated tablet contains: Diclofenac Potassium … 50mg
	Pharmacotherapeutic Group of (API)	M01AB05, Anti-inflammatory And Anti-rheumatic Products, Non-Steroids.
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	CATAFLAM 50mg Tablet of M/s Novartis, USFDA approved. **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	For generic drugs (me-too status)	CAFLAM 50mg Tablet of M/s Novartis Pharma (Pakistan) Limited.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	3.2.P.5 It has been mentioned that Product complies with USP Specifications, whereas in 3.2.P.2 Pharmaceutical Equivalence with Innovator, it has been mentioned that both products comply with BP Specifications. Please justify.	
ii.	Please provide evidence of I&E (DRAP) Clearance for Import against Invoice No. EXP/2509/2574/2695/22-23 dated 06-12-2022.	
iii.	3.2.P.8 Please provide Stability Study Data along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc., for 06th Month Testing Interval of all 03 Trials.	

Decision: The Registration Board deferred the case for submission of response to above cited shortcomings.

781.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmedic Laboratories (Pvt.) Ltd. 16-km, Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s Pharmedic Laboratories (Pvt.) Ltd. 16-km, Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 13642 dated 01-06-2023
	Details of fee submitted	PKR 30,000/- dated 10-05-2023 Challan / Receipt # 850935407
	The proposed proprietary name / brand name	**NUCENT 75mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Tapentadol (as HCl) … 75mg
	Pharmacotherapeutic Group of (API)	N02AX06, Analgesics.
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	NUCYNTA 75mg Tablets of M/s Collegium Pharm Inc., USFDA approved.
	For generic drugs (me-too status)	TAPENTO IR 75mg Tablets of M/s SAMI Pharmaceuticals (Pvt.) Limited.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):
The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide valid GMP status of the firm (FPP Manufacturer). The enclosed copy of GMP Certificate was valid for two years from the date of inspection (04-02-2020).	
ii.	Please provide valid evidence of approval of manufacturing facility issued by concerned division (Section approval letter).	
iii.	3.2.P.2.2.1 Please provide evidence of Reference / Innovator's Pack used for Pharmaceutical equivalence / CDP.	
iv.	Please provide summary of quantity of API consumed in product development / manufacturing / test analysis etc. of trial batches & its remaining quantity.	

Copy of DRAP I&E Clearance Certificate No. E-300448487384 for Import of Tapentadol HCl (5Kgs, Batch No. TPT/5001012) from AMI Lifesceinces Pvt. Ltd., India, approved for test/analysis only, has been submitted.

Decision: The Registration Board deferred the case for submission of response to above cited shortcomings.

782.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmedic Laboratories (Pvt.) Ltd. 16-km, Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s Pharmedic Laboratories (Pvt.) Ltd. 16-km, Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 24304 dated 04-10-2023
	Details of fee submitted	PKR 30,000/- dated 11-08-2023 Challan / Receipt # 8829134136

	The proposed proprietary name / brand name	**PROCEF 200mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet contains: Cefixime (as trihydrate) … 200mg
	Pharmacotherapeutic Group of (API)	J01DD08, Third-generation cephalosporin
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	SUPRAX 200mg Tablet, USFDA approved. **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	For generic drugs (me-too status)	CARICEF 200mg Tablets of M/s SAMI Pharmaceuticals (Pvt.) Limited.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide valid GMP status of the firm (FPP Manufacturer). The enclosed copy of GMP Certificate was valid for two years from the date of inspection (04-02-2020).	
ii.	Please provide valid evidence of approval of manufacturing facility issued by concerned division (Section approval letter).	
iii.	1.6.5 (b) Please provide evidence of approval of local manufacturing of API 'Cefixime Trihydrate' issued by Licensing Division – DRAP to M/s Citi Pharma (Pvt.) Ltd., Kasur.	
iv.	3.2.S.4.4 COA of API by FPP Manufacturer is enclosed of 'Cefixime trihydrate Micronized' whereas in 3.2.P1 (a) Master Formulation it has been mentioned that 'Cefixime trihydrate Compacted'. Please justify.	
v.	3.2.P.2.2.1 It has been mentioned that Pharmaceutical Equivalence has been performed with available reference product (SUPRAX 200mg Tablet of Sanofi-Aventis Ireland) whereas enclosed report is of CARICEF 200mg Tablet of M/s Sami Pharma. Please clarify.	
vi.	3.2.P.8 Please provide Stability Study Data - Summary Sheets, Chromatograms and Raw Data / Calculation Sheets etc. for 6th Month Study Time Point (Accelerated and Real Time).	
vii.	Invoice of procurement of API (Cefixime Micronized) from M/s Citi Pharma (Pvt.) Ltd., Kasur, vide No. 10000540 is of 08th June 2023, whereas all 03 Trials have been manufactured in February 2023. Please justify with supporting evidence.	

Decision: The Registration Board deferred the case for submission of response to above cited shortcomings.

783.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmedic Laboratories (Pvt.) Ltd. 16-km, Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s Pharmedic Laboratories (Pvt.) Ltd. 16-km, Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 12100 dated 17-05-2023
	Details of fee submitted	PKR 30,000/- dated 22-03-2023 Challan / Receipt # 21389892

	The proposed proprietary name / brand name	**AZYTHRA 500mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Azithromycin as Dihydrate…500mg
	Pharmacotherapeutic Group of (API)	J01FA10, Anti-infective for systemic use, Macrolides.
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	ZITHROMAX 500mg Tablet of M/s Pfizer, USFDA approved.
	For generic drugs (me-too status)	AZOMONT 500mg Tablet of M/s Himont Pharmaceuticals (Pvt.) Ltd.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

The following deficiencies / shortcomings have been communicated to the firm:

Sr. No.	Observations	Firm's response
i.	Please provide valid GMP status of the firm (FPP Manufacturer). The enclosed copy of GMP Certificate was valid for two years from the date of inspection (04-02-2020).	
ii.	Please provide valid evidence of approval of manufacturing facility issued by concerned division (Section approval letter).	
iii.	Please provide valid GMP of API Manufacturer issued by regulatory authority of country of origin. The enclosed letter (written commitment for export) is not a GMP Certificate.	
iv.	3.2.P.2.2.1 Please provide evidence of Reference / Innovator's Pack used for Pharmaceutical equivalence / CDP.	

Decision: The Registration Board deferred the case for submission of response to above cited shortcomings.

784.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pearl Pharmaceuticals, Plot No. 204, Street 1 I-10/3, Industrial Area, Islamabad.**
	Name, address of Manufacturing site.	M/s Pearl Pharmaceuticals, Plot No. 204, Street 1 I-10/3, Industrial Area, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 22454 dated 12-09-2023
	Details of fee submitted	PKR 30,000/- dated 02-08-2023 Challan / Receipt # 336923412
	The proposed proprietary name / brand name	**ZOPIUM 40mg Powder for Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Pantoprazole Sodium (Lyophilized) equivalent to Pantoprazole … 40mg
	Pharmacotherapeutic Group of (API)	A02BC02, Proton pump inhibitors
	Reference to Finished product specifications	BP Specifications
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	PANZIUM Lyophilized Powder for Injection 40mg of M/s The Searle Company Limited.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):		
Decision: The Registration Board deferred the case for submission of evidence of approval of requisite manufacturing facility i.e, "Dry Powder Injection (Lyophilisation) section, from CLB, since applied formulation is to be manufactured by way of lyophilisation.		
785.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pearl Pharmaceuticals, Plot No. 204, Street 1 I-10/3, Industrial Area, Islamabad.**
	Name, address of Manufacturing site.	M/s Pearl Pharmaceuticals, Plot No. 204, Street 1 I-10/3, Industrial Area, Islamabad.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 26686 dated 06-11-2023
	Details of fee submitted	PKR 30,000/- dated 02-08-2023 Challan / Receipt # 77380997596
	The proposed proprietary name / brand name	**ESOPRIME 40mg Dry Powder for Injection (IV)**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Esomeprazole sodium (lyophilized) equivalent to Esomeprazole … 40mg
	Pharmacotherapeutic Group of (API)	A02BC01, Proton pump inhibitor
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	NEXUM Lyophilized Powder for Injection 40mg of M/s Getz Pharma.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO
Evaluation by PEC (XXI):		
Decision: Approved.		

Agenda Item No. 02: Deferred Cases of Previous Meetings

786.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pasteur & Fleming Pharma, Plot No. P-70-A, Phase-3, Road No. 4, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	M/s Pasteur & Fleming Pharma, Plot No. P-70-A, Phase-3, Road No. 4, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 23148 dated 20 SEP 2023
	Details of fee submitted	PKR 30,000/- Dated 15-09-2022 (Challan / Receipt # 9767511751)
	The proposed proprietary name / brand name	**PASTELO 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Escitalopram as oxalate (USP) … 10mg
	Pharmacotherapeutic Group of (API)	N06AB10, Selective serotonin reuptake inhibitors
	Reference to Finished product specifications	(USP Specifications)
	The status in reference regulatory authorities	CIPRALEX 10mg Tablet by M/s Lundbeck Limited, MHRA Approved.

	For generic drugs (me-too status)	CIPRALEX 10mg Tablet by M/s Lundbeck Pakistan, Reg. No. 028467.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Decision of 333rd Meeting:
Registration Board deferred the case for submission of:

- Requisite fee for pre-registration correction for each Typographical Mistake / Revision of Information.
- Scientific Rationale for obtaining dissolution results >100% (up to 110%) on multiple instances.
- Approval of API/ DML/ valid GMP of API manufacturer issued by concerned regulatory authority of country of origin.

Registration Board further decided to proceed for onsite investigation to confirm genuineness authenticity of stability data, related documents, import of API, quality, specification, test analysis, facilities etc., once the above mentioned shortcomings have been submitted.

787.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pasteur & Fleming Pharma, Plot No. P-70-A, Phase-3, Road No. 4, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	M/s Pasteur & Fleming Pharma, Plot No. P-70-A, Phase-3, Road No. 4, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 23148 dated 20 SEP 2023
	Details of fee submitted	PKR 30,000/- Dated 15-09-2022 (Challan / Receipt # 54642634458)
	The proposed proprietary name / brand name	**PASTELO 20mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet contains: Escitalopram as oxalate (USP) … 20mg
	Pharmacotherapeutic Group of (API)	N06AB10, Selective serotonin reuptake inhibitors
	Reference to Finished product specifications	(USP Specifications)
	The status in reference regulatory authorities	CIPRALEX 20mg Tablet by M/s Lundbeck Limited, MHRA Approved.
	For generic drugs (me-too status)	CIPRALEX 20mg Tablet by M/s Lundbeck Pakistan, Reg. No. 059035.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Decision of 333rd Meeting:
Registration Board deferred the case for submission of:

- Requisite fee for pre-registration correction for each Typographical Mistake / Revision of Information.
- Scientific Rationale for obtaining dissolution results >100% (up to 110%) on multiple instances.
- Approval of API/ DML/ valid GMP of API manufacturer issued by concerned regulatory authority of country of origin.

Registration Board further decided to proceed for onsite investigation to confirm genuineness authenticity of stability data, related documents, import of API, quality, specification, test analysis, facilities etc., once the above mentioned shortcomings have been submitted.

Evaluation by PEC (XXI):
Following Inspection Report vide letter No. 1899/PDTL dated 18/11/2024 has been received w.r.t. letter No. F.15-1/2022-PEC-P-001 dated 18th October, 2024.

Inspection Report

General Information.

Name of Manufacturer	M/s Pasteure and Fleming Pharma, Plot # p-70-A, Phase-3, Road #4, Industrial estate Hattar.
Physical Address	Plot # P-70-A, Phase-3, Road #4, Industrial estate Hattar.
Drug Manufacturing License No. and validity	000945 by way of formulation Renewal date: New DML.
Date of Inspection.	15-11-2024.
Purpose of Inspection	Verification of Authenticity of Stability Data for Purpose of Registration of Drugs with reference DRAP's letter No. F.15-1/2022-PEC-P-001 dated 18-10-2024.
Name of Inspector	1. Mr. Imran Ullah khan (Member, Registration Board/Director DTL, Peshawar 2. Ms. Shahid Nawaz Deputy Director, DRAP, Islamabad.
Name of firm Representatives present during the course of inspection	Mr. Muhammad Yaseen Shah CEO. Mr. Ghulam Qasim Ali khan (R&D Manager) Mr. Haqnawaz Khan (Production Incharge) Mr. Shams Ul Islam (Quality Control Manager)

Details of the inspection are as follows:

Sr. No.	Questions	Observations of the panel
1.	Do you have documents confirming the import of API including approval from DRAP?	Material was taken as a loan from legacy pharmaceuticals Peshawar and attested commercial invoice from M/S legacy Pharmaceuticals Peshawar is also provided.
2.	What was the rationale behind selecting the particular manufacturer of API?	The applicant is new DML that's why they take the material as loan from legacy pharmaceuticals Peshawar as per notification of the registration Board.
3.	Do you have documents confirming the import of reference standard and impurity standards?	Reference standards were not available. The firm management/ technical person informed the panel that they had taken working standard from the legacy Pharmaceuticals for development of trial batches. Impurity standards were not available.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	COAs of API, Working Standards were available.
5.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Yes, however certificate is valid till 01-05-2024. GMP certificate has mentioned that DML in Form 25 is valid 12-03-2027.
6.	Do you use API manufacturer method of testing for testing API?	Yes, the finished product manufacturer uses the same method of testing as that of the Drug substance manufacturer.
7.	Do you have stability studies reports on API?	Yes, stability studies reports were provided by the API manufacturer.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	No.

9.	Do you have method for quantifying the impurities in the API?	Available.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	Very minor quantity of API that was taken as loan from legacy pharmaceuticals was available with the firm.
11.	Have you used pharmaceutical grade excipients?	All the excipients used in the formulation development are of pharmaceuticals grade.
12.	Do you have documents confirming the import of the used excipients?	The firm had used locally purchased excipient.
13.	Do you have test reports and other records on the excipient used?	COA's were available.
14.	Do you have written and authorized protocols for the development of applied product?	Yes
15.	Have you performed Drug-excipients compatibility studies?	No.
16.	Have you performed comparative dissolution studies?	Yes and the data was available with the firm. Initially they performed CDP with cipralex tablet in which the results of both reference and applied formulation were upto 110%. They performed revised CDP studies with the same reference product in which the results were within the limits i.e. 100%. These results were shown to the panel.
17.	Do you have product development (R&D) section	Physically separate R&D section was available with the firm; however, in section approval letter it is not mentioned. The management of the firm informed that they are applying for the approval of said section.
18.	Do you have necessary equipments available in product development section for development of applied product?	Commercial production facility was used.
19.	Are the equipments in product development section qualified?	Yes
20.	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	Available for the equipment used.
21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	Yes
22.	Have you manufactured three stability batches for the stability studies of applied product as required?	Yes.
23.	Do you have any criteria for fixing the batch size of stability batches?	According to the management of the firm, Batch size was developed according to the size of the production equipment and samples required for stability testing as per the CTD guidance documents issued by the DRAP.
24.	Do you have complete record of production of stability batches?	BMRs were available. However, the technical staff was advised to make them more comprehensive and revised their SOPs for the same procedure.
25.	Do you have protocols for stability testing of stability batches?	Yes, firm had protocols for stability testing of stability batches.

26.	Do you have developed and validated the method for testing of stability batches?	Firm has performed method verification studies for the applied formulation. Verification protocol and results were shown to the panel.
27.	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Not Applicable.
28.	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug?	Calibration certificates of all testing equipments were available.
29.	Is your method of analysis stability indicating?	Yes.
30.	Is your HPLC software is 21CFR compliant? (Details of Model, software, description/version (i.e. software validation report for 21 CFR Part 11 compliance including audit trail, password protection, date & time lock and user authorizations shall also be reported.)	Yes, 21CFR part 11 compliance assessment report is provided. Password protected accounts were enabled, date and time lock were available.
31.	Can you show Audit Trail reports on stability studies testing?	Yes, but for the applied product it was not available as software was corrupted and new software is installed now.
32.	Do you have some remaining quantities of degradation products and stability batches?	No.
33.	Do you have stability batches kept on stability testing?	Yes, sample of both pastelo 10mg and 20mg Tablets were available in the real time stability chamber.
34.	Do you have valid calibration status for the equipments used in production and analysis?	Yes.
35.	Do proper and continuous monitoring and control are available for stability chamber?	Data loggers were placed in the chambers for monitoring. Accelerated Stability Chamber: Company: Organa International Model No: ESC-400L-TCH Real Time Stability Chamber: Company: Western Analytical Model No: WSC-20
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Manufacturing are of the firm was inspected by the panel however, no production activity carried out at the time of inspection. Furthermore, the management informed due to limited number registration i.e. 12 products their manufacturing is very limited.

Remarks:

In addition to the details given in table above, the documents shown to the panel, the materials and testing facilities available at the premises at the time of inspection and the personnel interviewed, it seemed that the firm had conducted Stability testing of the said products i.e. **PASTELO 10mg and 20mg Tablet**.

Submitted for consideration and necessary action, please.

Decision: Registration Board while considering the recommendations of the panel inspection report of onsite investigationdecided to approve the applications of PASTELO 10mg Tablet and PASTELO 20mg Tablet of M/s Pasteur & Fleming Pharma, Hattar.

788.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Maxitech Pharma (Pvt.) Ltd. Plot No. E-178, S.I.T.E., Phase-II, Super Highway, Karachi.**
	Name, address of Manufacturing site.	M/s Maxitech Pharma (Pvt.) Ltd. Plot No. E-178, S.I.T.E., Phase-II, Super Highway, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 17162 dated 10-JUL-2023
	Details of fee submitted	PKR 30,000/- dated 21-02-2023 Challan / Receipt # 980825778142
	The proposed proprietary name / brand name	**REFLAZIN 0.3% Ophthalmic Solution**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Ciprofloxacin HCl…3mg
	Pharmacotherapeutic Group of (API)	S01AE03, Fluoroquinolones
	Reference to Finished product specifications	USP Specifications
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	CIPROXOL Eye Drops by M/s Pharmasol (Pvt.) Ltd.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Decision of 340th Meeting:
Registration Board deferred the case for submission of reply to the cited shortcomings.

Evaluation by PEC (XXI):
The following deficiencies / shortcomings were communicated to the firm:

Sr. No.	Observations	Firm's response
i.	3.2.P.1 Label claim has been mentioned incorrectly as 'Ciprofloxacin HCl 3mg'. Please justify / mention correct label claim.	Firm has submitted correction of label claim as: Each ml contains: Ciprofloxacin (as HCl) … 3mg Fee for correction of label claim has not been submitted.
ii.	3.2.P.8 Sterility Test has not been conducted at any time point of (both Accelerated and Real Time) Stability Study Data. Please justify.	Firm has submitted that the Sterility Test will be performed at the end of Shelf Life.
iii.	Please provide valid GMP status of the firm (FPP Manufacturer).	Firm have submitted copy of GMP Certificate dated 30th August 2024.

Decision: Approved. Registration Letter will be issued after submission of requisite fee for correction of label claim.

Agenda of Mr. Waqar

Agenda item 01. Routine applications of human drugs (Locally manufactured) applied on Form-5F (CTD).

789.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Mission Pharmceuticals. Plot No. A-94, S.I.T.E, Super Highway, Karachi.**
	Name, address of Manufacturing site.	M/s. Mission Pharmceuticals. Plot No. A-94, S.I.T.E, Super Highway, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 22338 dated 11-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 13951280439 dated 16-09-2022.
	The proposed proprietary name / brand name	**Misogyl 200mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Metronidazole ……. 200mg
	Pharmacotherapeutic Group of (API)	Antibacterial
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Flagyl 200mg Tablet. Manufactured by M/s. Sanofi Aventis, USA. UK MHRA Approved.
	For generic drugs (me-too status)	Shirazole 200mg Tablet Manufactured by M/s. Werrick Pharmaceutical.
	Proposed Pack size	Pack size 100's, 200's. MRP as per SRO.

Evaluation by PEC :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	
2.	Submit verification studies of the analytical method of drug substance in section 3.2.S.4.3.	
3.	Submit complete report of verification studies of the analytical method of drug product.	
4.	Submit details of the reference product against which pharmaceutical equivalence studies and CDP studies are conducted.	
5.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
6.	Documents for the procurement of API with approval from DRAP (in case of import).	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

790.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Winbrains Research laboratories. Plot No. 69/1, Block B, Phase-I&II, Industial Estate, Hsttar.**
	Name, address of Manufacturing site.	M/s. Winbrains Research laboratories. Plot No. 69/1, Block B, Phase-I&II, Industial Estate, Hsttar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 25301 dated 18-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 5107755554 dated 25-10-2023.

	The proposed proprietary name / brand name	**Odbrain 4mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Ondansetron as hydrochloride Dihydrate ….. 4mg
	Pharmacotherapeutic Group of (API)	Anti-Emetic
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Milpharm Limited. Ares Block Odyssey Business Park West End Road Ruislip HA4 6QD United Kingdom. MHRA Approved.
	For generic drugs (me-too status)	Oniron 4mg Tablet, (Registration No. 068374) M/s. Genome Pharmaceuticals Private limited.
	Proposed Pack size	As per SRO
Evaluation by PEC :		
Decision: Approved.		
791.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Winbrains Research laboratories. Plot No. 69/1, Block B, Phase-I&II, Industial Estate, Hsttar.**
	Name, address of Manufacturing site.	M/s. Winbrains Research laboratories. Plot No. 69/1, Block B, Phase-I&II, Industial Estate, Hsttar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 25302 dated 18-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 5756922055 dated 25-10-2023.
	The proposed proprietary name / brand name	**Odbrain 8mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Ondansetron as hydrochloride Dihydrate ….. 8mg
	Pharmacotherapeutic Group of (API)	Anti-Emetic
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Milpharm Limited. Ares Block Odyssey Business Park West End Road Ruislip HA4 6QD United Kingdom. MHRA Approved.
	For generic drugs (me-too status)	Oniron 8mg Tablet, (Registration No. 068375) M/s. Genome Pharmaceuticals Private limited.
	Proposed Pack size	As per SRO
Evaluation by PEC :		
Decision: Approved.		
792.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Winbrains Research laboratories. Plot No. 69/1, Block B, Phase-I&II, Industial Estate, Hsttar.**

	Name, address of Manufacturing site.	M/s. Winbrains Research laboratories. Plot No. 69/1, Block B, Phase-I&II, Industial Estate, Hsttar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 26694 dated 06-11-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 5107755554 dated 25-10-2023.
	The proposed proprietary name / brand name	**Odbrain 4mg / 2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml Ampoule Contains: Ondansetron as hydrochloride Dihydrate …… 4mg
	Pharmacotherapeutic Group of (API)	Anti-Emetic
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Hameln Pharm Ltd Nexus, Gloucester Business Park, Gloucester, GL3 4AG, United Kingdom. MHRA Approved.
	For generic drugs (me-too status)	Doston 4mg / 2ml Injection, (Registration No. 081891) M/s. Vision Pharmaceuticals Private limited.
	Proposed Pack size	As per SRO
Evaluation by PEC :		
Decision: Approved.		
793.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Wezen Pharmaceutical. Plot No. 23 & 24, S-1, RCCI, Industries Estate, Rawat.**
	Name, address of Manufacturing site.	M/s. Wezen Pharmaceutical. Plot No. 23 & 24, S-1, RCCI, Industries Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 22450 dated 12-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 972209159 dated 25-07-2023.
	The proposed proprietary name / brand name	**Odenzz 4mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Ondansetron as hydrochloride Dihydrate ….. 4mg
	Pharmacotherapeutic Group of (API)	Anti-Emetic
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Milpharm Limited. Ares Block Odyssey Business Park West End Road Ruislip HA4 6QD United Kingdom.

		MHRA Approved.
	For generic drugs (me-too status)	Oniron 4mg Tablet, (Registration No. 068374) M/s. Genome Pharmaceuticals Private limited.
	Proposed Pack size	As per SRO
Evaluation by PEC :		
Decision: Approved.		
794.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Wezen Pharmaceutical. Plot No. 23 & 24, S-1, RCCI, Industries Estate, Rawat.**
	Name, address of Manufacturing site.	M/s. Wezen Pharmaceutical. Plot No. 23 & 24, S-1, RCCI, Industries Estate, Rawat.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 22448 dated 12-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 4665062071 dated 25-07-2023.
	The proposed proprietary name / brand name	**Odenzz 8mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Ondansetron as hydrochloride Dihydrate ….. 8mg
	Pharmacotherapeutic Group of (API)	Anti-Emetic
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Milpharm Limited. Ares Block Odyssey Business Park West End Road Ruislip HA4 6QD United Kingdom. MHRA Approved.
	For generic drugs (me-too status)	Oniron 8mg Tablet, (Registration No. 068375) M/s. Genome Pharmaceuticals Private limited.
	Proposed Pack size	As per SRO
Evaluation by PEC :		
Decision: Approved.		
795.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Allmed (Pvt) Ltd.** **Plot No. 590, Sunder Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s. Allmed (Pvt) Ltd. Plot No. 590, Sunder Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 24502 dated 06-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 1091083124 dated 29-08-2023.
	The proposed proprietary name / brand name	**Suprimun S 180mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Delayed Released Tablet Contains: Mycophenolate Sodium, Equivalent to Mycophenolic Acid …….. 180mg
	Pharmacotherapeutic Group of (API)	Immunosuppressant
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Myfortic 180mg Tablet. Novartis Ireland Limited. Vista Building, Elm Park, Merrion Road, Ballsbridge, Dublin 4, Ireland. HPRA Approved.
	For generic drugs (me-too status)	Myfortic 180mg Tablet. (Registration No. 033172) M/s. Novartis Pharma Pakistan limited.
	Proposed Pack size	Pack size 120's, MRP As per SRO.

Evaluation by PEC :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	
2.	Specify the polymorphic form of the drug substance used	
3.	Submit verification studies of the analytical method of drug substance in section 3.2.S.4.3.	
4.	Submit COA of relevant batch of API from the API manufacturer.	
5.	Submit details of the reference product against which pharmaceutical equivalence studies and CDP studies are conducted.	
6.	Justify why compatibility studies are not performed while your qualitative composition is different from that of innovator's product.	
7.	Submit details of all excipients used in section 3.2.P.4.	
8.	Submit complete report of verification studies of the analytical method of drug product.	
9.	Submit COA of reference standard used for analysis of drug product.	
10.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data	
11.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
12.	Documents for the procurement of API with approval from DRAP (in case of import).	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

796.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Allmed (Pvt) Ltd. Plot No. 590, Sunder Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s. Allmed (Pvt) Ltd. Plot No. 590, Sunder Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 25737 dated 24-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 4766216941 dated 11-09-2023.
	The proposed proprietary name / brand name	**Suprimun S 360mg Tablet**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Delayed Released Tablet Contains: Mycophenolate Sodium, Equivalent to Mycophenolic Acid …….. 360mg
	Pharmacotherapeutic Group of (API)	Immunosuppressant
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Myfortic 360mg Tablet. Novartis Ireland Limited. Vista Building, Elm Park, Merrion Road, Ballsbridge, Dublin 4, Ireland. HPRA Approved.
	For generic drugs (me-too status)	Myfortic 360mg Tablet. (Registration No. 033173) M/s. Novartis Pharma Pakistan limited.
	Proposed Pack size	Pack size 120's, MRP As per SRO.

Evaluation by PEC :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit specifications and analytical procedures of the drug substance from both API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2	
2.	Specify the polymorphic form of the drug substance used	
3.	Submit verification studies of the analytical method of drug substance in section 3.2.S.4.3.	
4.	Submit COA of relevant batch of API from the API manufacturer.	
5.	Submit details of the reference product against which pharmaceutical equivalence studies and CDP studies are conducted.	
6.	Justify why compatibility studies are not performed while your qualitative composition is different from that of innovator's product.	
7.	Submit details of all excipients used in section 3.2.P.4.	
8.	Submit complete report of verification studies of the analytical method of drug product.	
9.	Submit COA of reference standard used for analysis of drug product.	
10.	Submit stability study data as per 6 points checklist provided in CTD guidance document in section 3.2.P.8.3 with proper tagging and data	
11.	Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	
12.	Documents for the procurement of API with approval from DRAP (in case of import).	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

797.	**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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 22336 dated 11-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 091891168 dated 11-08-2023.

	The proposed proprietary name / brand name	**Onix 4mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Ondansetron as hydrochloride Dihydrate ….. 4mg
	Pharmacotherapeutic Group of (API)	Anti-Emetic
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Novartis Pharmaceuticals UK Limited. (Zofran Tablet 4mg). USFDA Approved.
	For generic drugs (me-too status)	Onset 4mg Tablet, M/s. Pharmedic Laboratories Private limited.
	Proposed Pack size	10's
Evaluation by PEC :		
Decision: Approved.		
798.	**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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 22337 dated 11-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 0647118955 dated 11-08-2023.
	The proposed proprietary name / brand name	**Onix 8mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Ondansetron as hydrochloride Dihydrate …... 8mg
	Pharmacotherapeutic Group of (API)	Anti-Emetic
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Novartis Pharmaceuticals UK Limited. (Zofran Tablet 8mg). USFDA Approved.
	For generic drugs (me-too status)	Onset 8mg Tablet, M/s. Pharmedic Laboratories Private limited.
	Proposed Pack size	10's
Evaluation by PEC :		
Decision: Approved.		
799.	**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)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 22335 dated 11-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 5194231280 dated 11-08-2023.
	The proposed proprietary name / brand name	**Onix Syrup 4mg/5ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml Contains: Ondansetron as hydrochloride Dihydrate ….. 4mg
	Pharmacotherapeutic Group of (API)	Anti-Emetic
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Novartis Pharmaceuticals UK Limited. (Zofran Syrup). USFDA Approved.
	For generic drugs (me-too status)	Onseron 4mg/5ml syrup, M/s. Indus Laboratories Private limited.
	Proposed Pack size	As per SRO.
Evaluation by PEC :		
Decision: Approved.		
800.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. English Pharmaceutical Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s. English Pharmaceutical Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 24300 dated 04-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 67113797587 dated 15-09-2023.
	The proposed proprietary name / brand name	**Zofton 4mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Ondansetron as hydrochloride Dihydrate ….. 4mg
	Pharmacotherapeutic Group of (API)	Anti-Emetic
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Novartis Pharmaceuticals UK Limited. (Zofran Tablet 4mg). USFDA Approved.
	For generic drugs (me-too status)	Onset 4mg Tablet, M/s. Pharmedic Laboratories Private limited.

	Proposed Pack size	As per SRO
Evaluation by PEC :		
Decision: Approved.		
801.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. English Pharmaceutical Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s. English Pharmaceutical Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 25889 dated 26-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 578261139 dated 03-10-2023.
	The proposed proprietary name / brand name	**Zofton 8mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Ondansetron as hydrochloride Dihydrate …... 8mg
	Pharmacotherapeutic Group of (API)	Anti-Emetic
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Novartis Pharmaceuticals UK Limited. (Zofran Tablet 8mg). USFDA Approved.
	For generic drugs (me-too status)	Onset 8mg Tablet, M/s. Pharmedic Laboratories Private limited.
	Proposed Pack size	As per SRO
Evaluation by PEC :		
Decision: Approved.		
802.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. English Pharmaceutical Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s. English Pharmaceutical Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 21770 dated 04-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 783803075 dated 30-08-2023.
	The proposed proprietary name / brand name	**Zofton 4mg/5ml Syrup**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 5ml syup contains:

		Ondansetron as hydrochloride Dihydrate …... 4mg
	Pharmacotherapeutic Group of (API)	Anti-Emetic
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Novartis Pharmaceuticals UK Limited. (Zofran Syrup 4mg/5ml). USFDA Approved.
	For generic drugs (me-too status)	Onset 4mg/5ml, M/s. Pharmedic Laboratories Private limited.
	Proposed Pack size	50ml
Evaluation by PEC :		
Decision: Approved.		
803.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. English Pharmaceutical Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s. English Pharmaceutical Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 21678 dated 01-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 07548160 dated 30-08-2023.
	The proposed proprietary name / brand name	**Zofton 4mg/2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml ampule contains: Ondansetron as hydrochloride Dihydrate …... 4mg
	Pharmacotherapeutic Group of (API)	Anti-Emetic
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Novartis Pharmaceuticals UK Limited. (Zofran Injection 4mg/2ml). USFDA Approved.
	For generic drugs (me-too status)	Onset 4mg/2ml Injection. M/s. Pharmedic Laboratories Private limited.
	Proposed Pack size	As per SRO.
Evaluation by PEC :		
Decision: Approved.		
804.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. English Pharmaceutical Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s. English Pharmaceutical Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 21769 dated 04-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 08574551502 dated 30-08-2023.
	The proposed proprietary name / brand name	**Zofton 8mg/4ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml ampule contains: Ondansetron as hydrochloride Dihydrate …... 8mg
	Pharmacotherapeutic Group of (API)	Anti-Emetic
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Novartis Pharmaceuticals UK Limited. (Zofran Injection 8mg/4ml). USFDA Approved.
	For generic drugs (me-too status)	Onset 8mg/4ml Injection. M/s. Pharmedic Laboratories Private limited.
	Proposed Pack size	As per SRO.
Evaluation by PEC :		
Decision: Approved.		
805.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Wenovo Pharmaceuticals.** **Plot No. 31-32, Punjab Small Industries Estate, Taxila, Rawalpindi.**
	Name, address of Manufacturing site.	M/s. Wenovo Pharmaceuticals. Plot No. 31-32, Punjab Small Industries Estate, Taxila, Rawalpindi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 26286 dated 31-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 6899192054 dated 16-10-2023.
	The proposed proprietary name / brand name	**Vosul 25mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet Contains: Levosulpride ……. 25mg
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	Innovactor's Specifications.
	The status in reference regulatory authorities	Livodomed 25mg Tablet. Manufactured by M/s. Medochemie Ltd. Approved by AIFA of Italy.
	For generic drugs (me-too status)	Hi Pride Tablet 25mg Manufactured by M/s. Bloom Pharmaceutical. (077423)
	Proposed Pack size	As per SRO
Evaluation by PEC :		

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit evidence of approval of requisite manufacturing facility / section approval leter from Licensing Division	
2.	Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3.	
3.	Submit details of reference product against which PE studies are conducted.	
4.	Submit evidence of procurement of API.	
5.	Submit BMR of stability batches	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

806.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Wenovo Pharmaceuticals. Plot No. 31-32, Punjab Small Industries Estate, Taxila, Rawalpindi.**
	Name, address of Manufacturing site.	M/s. Wenovo Pharmaceuticals. Plot No. 31-32, Punjab Small Industries Estate, Taxila, Rawalpindi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 26287 dated 31-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 125104739719 dated 16-10-2023.
	The proposed proprietary name / brand name	**Vosul 50mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet Contains: Levosulpride ……. 50mg
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	Innovactor's Specifications.
	The status in reference regulatory authorities	Livodomed 50mg Tablet. Manufactured by M/s. Medochemie Ltd. Approved by AIFA of Italy.
	For generic drugs (me-too status)	Hi Pride Tablet 50mg Manufactured by M/s. Bloom Pharmaceutical. (077424)
	Proposed Pack size	As per SRO

Evaluation by PEC :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit evidence of approval of requisite manufacturing facility / section approval leter from Licensing Division	
2.	Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3.	
3.	Submit details of reference product against which PE studies are conducted.	
4.	Submit evidence of procurement of API.	
5.	Submit BMR of stability batches	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.		
807.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Wenovo Pharmaceuticals. Plot No. 31-32, Punjab Small Industries Estate, Taxila, Rawalpindi.**
	Name, address of Manufacturing site.	M/s. Wenovo Pharmaceuticals. Plot No. 31-32, Punjab Small Industries Estate, Taxila, Rawalpindi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 26288 dated 31-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 3649377329 dated 16-10-2023.
	The proposed proprietary name / brand name	**Vosul 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet Contains: Levosulpride ……. 100mg
	Pharmacotherapeutic Group of (API)	Antipsychotic
	Reference to Finished product specifications	Innovactor's Specifications.
	The status in reference regulatory authorities	Livodomed 100mg Tablet. Manufactured by M/s. Medochemie Ltd. Approved by AIFA of Italy.
	For generic drugs (me-too status)	Hi Pride Tablet 100mg Manufactured by M/s. Bloom Pharmaceutical. (077423)
	Proposed Pack size	As per SRO

Evaluation by PEC :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit evidence of approval of requisite manufacturing facility / section approval leter from Licensing Division	
2.	Submit verification studies of the analytical method of drug substance, performed by drug product manufacturer in section 3.2.S.4.3.	
3.	Submit details of reference product against which PE studies are conducted.	
4.	Submit evidence of procurement of API.	
5.	Submit BMR of stability batches	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.		
808.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Martin Dow Marker Limited. 07-Jail Road, Quetta.**
	Name, address of Manufacturing site.	M/s. Martin Dow Marker Limited. 07-Jail Road, Quetta.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 22060 dated 07-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 54596496523 dated 10-08-2023.
	The proposed proprietary name / brand name	**Seroblock 4mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Ondansetron as hydrochloride Dihydrate ….. 4mg
	Pharmacotherapeutic Group of (API)	Anti-Emetic
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Ondansetron Hydrochloride. USFDA Approved.
	For generic drugs (me-too status)	Onden 4mg Tablet, (Registration # 057754) M/s. Macter International limited.
	Proposed Pack size	As per SRO
Evaluation by PEC :		
Decision: Approved.		
809.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Martin Dow Marker Limited. 07-Jail Road, Quetta.**
	Name, address of Manufacturing site.	M/s. Martin Dow Marker Limited. 07-Jail Road, Quetta.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 22061 dated 07-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 7499119789 dated 10-08-2023.
	The proposed proprietary name / brand name	**Seroblock 8mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Ondansetron as hydrochloride Dihydrate ….. 8mg
	Pharmacotherapeutic Group of (API)	Anti-Emetic
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Ondansetron Hydrochloride. USFDA Approved.
	For generic drugs (me-too status)	Onden 8mg Tablet, (Registration # 057754) M/s. Macter International limited.
	Proposed Pack size	As per SRO
Evaluation by PEC :		
Decision: Approved.		
810.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Nabi Qasim Industries Private Limited. 17/24, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s. Nabi Qasim Industries Private Limited. 17/24, Korangi Industrial Area, Karachi.

	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 24691 dated 10-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 45777047377 dated 16-09-2023.
	The proposed proprietary name / brand name	**Vesiva 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Solifenacin succinate …….. 5mg
	Pharmacotherapeutic Group of (API)	Urinary Antispasmodic
	Reference to Finished product specifications	BP Specifications.
	The status in reference regulatory authorities	Tablet Vesicare 5mg. Registered & Marketed by M/s. Astellas Pharma US, Inc. USA. US FDA Approved. MHRA Approved.
	For generic drugs (me-too status)	Solifen 5mg Tablet, (Registration # 061202) M/s. Getz Pharmaceutical Private limited.
	Proposed Pack size	10', 20, 30's Tablets. MRP as per SRO.
Evaluation by PEC :		
Decision: Approved.		
811.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Nabi Qasim Industries Private Limited. 17/24, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s. Nabi Qasim Industries Private Limited. 17/24, Korangi Industrial Area, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 25002 dated 13-10-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 0018147812 dated 16-09-2023.
	The proposed proprietary name / brand name	**Vesiva 10mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Solifenacin succinate …….. 10mg
	Pharmacotherapeutic Group of (API)	Urinary Antispasmodic
	Reference to Finished product specifications	BP Specifications.
	The status in reference regulatory authorities	Tablet Vesicare 10mg. Registered & Marketed by M/s. Astellas Pharma US, Inc. USA. US FDA Approved. MHRA Approved.
	For generic drugs (me-too status)	Solifen 10mg Tablet, (Registration # 061203) M/s. Getz Pharmaceutical Private limited.

	Proposed Pack size	10', 20, 30's Tablets. MRP as per SRO.
Evaluation by PEC :		
Decision: Approved.		
812.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. WnsFeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	M/s. WnsFeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 22788 dated 15-09-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 333805233407 dated 05-09-2023.
	The proposed proprietary name / brand name	**Cinkal 30mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Cinacalcet Hcl Eq. to Cinacalcet …….. 30mg
	Pharmacotherapeutic Group of (API)	Calcimimetics. Anti-Parathyroid Agent.
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Milpharm Limited. Ares Block Odyssey Business Park West End Road Ruislip HA4 6QD United Kingdom. MHRA Approved.
	For generic drugs (me-too status)	Censipar Tablet 30mg Tablet. M/s. CCL Pharmaceutical Private limited.
	Proposed Pack size	As per SRO.

Evaluation by PEC :

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit IR spectra for characterization of drug substance performed by drug product manufacturer	
2.	Submit copy of drug substance specifications from API manufacturer as well as drug product manufacturer.	
3.	Submit detailed validation report of the analytical method of drug product.	
4.	Submit evidence of procurement of API.	
5.	Submit valid GMP certificate of API manufacturer.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

813.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. WnsFeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	M/s. WnsFeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer

		☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 27578 dated 24-11-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 3956522221 dated 25-10-2023.
	The proposed proprietary name / brand name	**C-Kolin 250mg/2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml Ampule Contains: Citicoline as Sodium salt …….. 250mg
	Pharmacotherapeutic Group of (API)	Psychostimulants and Nootropics
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Citicoline Sodium 250mg / 2ml Injection. CIMA Spain Approved.
	For generic drugs (me-too status)	Coli wan 250mg / 2ml Injection. (Registration No. 082034) M/s. Swan Pharmaceutical Private limited.
	Proposed Pack size	As per SRO.
Evaluation by PEC :		
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.		
814.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. WnsFeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.**
	Name, address of Manufacturing site.	M/s. WnsFeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 27577 dated 24-11-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 368927696 dated 25-10-2023.
	The proposed proprietary name / brand name	**C-Kolin 1000mg/4ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 4ml Ampule Contains: Citicoline as Sodium salt …….. 1000mg
	Pharmacotherapeutic Group of (API)	Psychostimulants and Nootropics
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Citicoline Sodium 1000mg / 4ml Injection. CIMA Spain Approved.
	For generic drugs (me-too status)	Neurotec 1000mg / 4ml Injection. (Registration No. 045995) M/s. Schazoo Laboratories Private limited.
	Proposed Pack size	As per SRO.
Evaluation by PEC :		

Decision: Approved.		
815.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Pharmedic Laboratories (Pvt) Ltd. 16-km, Multan Road, Lahore.**
	Name, address of Manufacturing site.	M/s. Pharmedic Laboratories (Pvt) Ltd. 16-km, Multan Road, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 27663 dated 27-11-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 348631218419 dated 10-10-2022.
	The proposed proprietary name / brand name	**Arimex 1mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated tablet Contains: Anastrozole ……. 1mg
	Pharmacotherapeutic Group of (API)	Harmone Antagonists and Related agents Aromatase inhibitors.
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Arimidex 1mg Tablet. US FDA Approved.
	For generic drugs (me-too status)	Arimidex 1mg Tablet (Registration No. 021148) By M/s. ICI Pharmaceutical Pakistan.
	Proposed Pack size	Pack size 20's, MRP as per SRO.
Evaluation by PEC : Kindly provide valid GMP status of the firm (FPP Manufacturer). The enclosed copy of GMP Certificate was valid for two years from the date of inspection (04-02-2020). Please provide valid evidence of approval of manufacturing facility issued by concerned division (Section approval letter).		
Decision: Approved. Manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of this drug.		

Case No. 01: Decision of USFDA to Withdraw Approval of Makena (Hydroxyprogesterone Caproate Injection) and its Generics.

On April, 06, 2023, U.S. Food and Drug Administration announced the final decision to withdraw approval of Makena—a drug that had been approved under the accelerated approval pathway. This drug was approved to reduce the risk of preterm birth in women pregnant with one baby who have a history of spontaneous preterm birth. The decision was issued jointly by the FDA Commissioner and Chief Scientist. Effective today, Makena and its generics are no longer approved and cannot lawfully be distributed in interstate commerce.

2. In 2011, FDA approved Makena to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. This accelerated approval was based on a trial that showed the drug reduced deliveries before 37 weeks of pregnancy, an intermediate clinical endpoint that FDA determined was reasonably likely to predict clinical benefit to the newborn.

3. As a condition of Makena's accelerated approval, the sponsor was required to conduct a confirmatory clinical trial to verify and describe the predicted clinical benefit to newborns. This trial, which was nearly four times larger than the trial that supported Makena's approval, did not show improvement in the health of the babies born to mothers who were treated with Makena. Makena and its generics (i.e., generic versions of Makena) are not shown to be effective for reducing the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. Nor have Makena and its generics been shown to be effective for any subgroup of this population, including in women at high risk of preterm birth. In addition, there are known risks associated with Makena. Accordingly, these drugs do not have benefits that outweigh their risks to patients.

4. Registration Board while considering the approval of Hydroxyprogesterone Injection in USFDA registered following drug products.

Sr. No.	Reg. No.	Product Name & Composition	Registration Holder / Manufacturer	Renewal Status
1.	096479	Nandrosol 250mg Injection Each ml contains: Hydroxyprogesterone caproate....……250mg	Pharmasol (Pvt) Ltd, Plot 549, Sunder Industrial estate, Lahore., Lahore	Renewal is not yet due
2.	094205	Hygest Injection Each ml contains: Hydroxyprogesterone caproate....……250mg	Shaigan Pharmaceuticals (Pvt) Ltd	Renewal is not yet due
3.	003531	Hydroxyprogesterone Injection Each ml contains: Hydroxyprogesterone caproate....……250mg	M/s. Zafa Pharmaceutical, Karachi.	Renewal is valid
4.	030526	Globinan 2Ml Injection Hydroxy Progesterone Caproate…. 250mg	Global Pharmaceuticals Pvt Ltd	Renewal Not Submitted
5.	030525	Globinan 1Ml Injection Hydroxy Progesterone	Global Pharmaceuticals Pvt Ltd	Renewal Not Submitted
6.	013624	VIO-DEPOT INJ Each ml contains: Hydroxyprogesterone caproate....……250mg	Venus Pharma, 23 Km Multan Road Lahore. , Lahore	Renewal Not Submitted
7.	003746	HYDROXYPROGESTRONE INJECTION Each ml contains: Hydroxyprogesterone caproate....……250mg	Haji Medicines, Rawalpindi	Renewal Not Submitted
8.	003833	HYDROXYPROGESTRONE Each ml contains: Hydroxyprogesterone caproate....……250mg		Renewal Not Submitted

5. Following combination drug products containing Hydroxyprogesterone were also registered by the Registration Board.

Sr. No.	Reg. No.	Product Name & Composition	Registration Holder / Manufacturer	Renewal Status
1.	103324	Kevi Injection Each ml contains: Hydroxyprogesterone caproate_ 250 mg Estradiol valerate _ 5 mg	Hansel Pharmaceuticals (Pvt) Ltd., Plot No 2 Pharma City 30-Km Multan Road Lahore. , Lahore	Renewal is not yet due
2.	084375	Contrex Injection Each ml contains: Hydroxyprogesterone caproate_ 250 mg Estradiol valerate _ 5 mg	Shaigan Pharmaceuticals (Pvt) Ltd	Renewal is valid
3.	077108	Z-Bron Injection Each ml contains: Hydroxyprogesterone caproate_ 250 mg Estradiol valerate _ 5 mg	Pharma Health Pakistan (Pvt) Ltd.	Renewal is valid
4.	011155	VIO-DEPOT INJ HYDROXYPROGESTERONE CARPOATE 250MG QUESTRADIOL VALERATE 5MG SESAME OIL 693MG	Wilson's Pharmaceuticals	Renewal Not Submitted
5.	000798	GRAVIBINON INJECTION HYDROXY PROGESTERONE CAPROATE 250MG, , OESTRADIOL VALERATE IN OILY SOLUTION	Medipharm (Private) Limited,, 7-A, Gulberg II, Lahore, Lahore	Last renewal was submitted dated 02-10-2018

6. Sub-rule 10 (a) of Rule 30 of Drugs (L, R & A) Rules, 1976 narrates as under:

"(a) if that drug at any time, for safety reasons is withdrawn or banned or certain restrictions are imposed in any of the said countries, then it shall be the responsibility of the manufacturer in Pakistan or as the case may be, the indentors, to immediately withdraw the drug from the market in Pakistan or, as the case may be to impose similar restriction and to inform the registration Board within fourteen days of such an information having come to his knowledge and having taken the necessary action. The Registration Board after getting the said intimation shall take similar action for the same drug available from other sources within the shortest possible time;"

7. Decision of 327th Meeting:

Registration Board decided to issue show-cause notice to all registration holders having valid registration of Hydroxyprogesterone containing drug products under section 7(11) (d) read with section 42 of Drug Act 1976 that why the registration of their products may not be cancelled in the public interest. For products having in-valid registration, RRR-Section is advised to proceed for cancellation of registration.

8. **(Hydroxyprogesterone Caproate)** With reference to above decision of 327th meeting of the Board, M/s. Bayer has submitted a request for reconsideration of Drug Registration Board (327th Meeting) decision for Proluton Depot Injection (Hydroxyprogesterone Caproate) in response of withdrawal of Makena by USFDA. Request of the firm is as under:

i. Proluton Depot is Bayer's innovator product, registered in Pakistan since 1988. However, Makena was first approved by USFDA in 2012 under the accelerated approval pathway.

ii. It is important to note that approval of Makena was Withdrawn by USFDA due to lack of efficacy in approved indication i.e. To reduce the risk of preterm birth which is entirely different from approved indication of Proluton Depot i.e., Habitual and imminent abortion, infertility due to corpus luteum insufficiency, primary and secondary amenorrhea but not due to quality or safety reasons.

iii. *Bayer is the manufacturer of Drug Substance i.e., Hydroryprogesterone caproate) used for the manufacturing of Proluton Depot.*

iv. *Proluton Depot is available in many countries across the World including Austria (SRA), Bahrain, Malaysia, Afghanistan, lran, Turkey, Qatar, Yemen, Lebanon, Oman, Thailand Argentina and Singapore.*

v. *Firm has also submitted snapshot of Austria's Official Health Authority Website confirming the approval of Proluton Depot indication which are reproduced as under:*
"After the ovulation of the woman, the follicles are transformed into the corpus luteum. The corpus luteum produces the hormone progesterone and inhibits thus the premature reduction of the endometrium and causes furthermore a thickening of the cervic mucus. Thus an implantation of the fertilized egg is possible and favorable conditions for the maintenance of the pregnancy are secured.
lf your body is not producing enough progesterone (corpus luteum hormone) due to a low functioning during pregnancy, a miscarriage (abortion) may occur.
Proluton Depot contains the hormone hydroxyprogesterone caproate, comparable to the naturally produced corpus luteum, which the female body produces during pregnancy.
Proluton is used in case of repeated miscarriage (habitual abortion) due to corpus luteum deficiency."

9. Firm has further submitted a justification provided by Bayer AG, Germany, their ultimate parent company which outlines the differences between the products further and clearly sets out that the USFDA's Makena decision does not have any implication for Proluton Depot. Thus recall is not applicable.

10. **(Hydroxyprogesterone caproate + Estradiol valerate)** With reference to above decision of 327th meeting of the Board, M/s. Bayer has also submitted a request for reconsideration of Drug Registration Board (327th Meeting) decision for Gravibinan Injection (Estradiol Valerate + Hydroxyprogesterone Caproate) in response of withdrawal of Makena (Hydroryprogesterone caproate) and its generics by USFDA stating that Gravibinan, a combination product comprising Estradiol valerate and Hydroxyprogesterone caproate, should not be encompassed in the recent proceedings of the Drug Registration Board meeting regarding the decision of the USFDA to withdraw the approval of Makena (Hydroryprogesterone Caproate) and its generics due to lack of efficacy, i.e. Makena's, approved indication is to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth.

11. They have further submitted that Gravibinan should be excluded from the scope of this decision, and presented following points:

i. *Regarding Therapeutic Indication of Gravibinan Injection firm has submitted that Gravibinan is not only a distinct product as it is a combination of Estradiol valerate and Hydroxyprogesterone caproate but is also indicated for the prophylaxis of abortion and threatened abortion. Hence, its therapeutic use differs significantly from that of Makena. Furthermore, they have also enclosed a justification provided by Bayer AG, their parent company based in Germany, which outlines the differences between the products and stablishes that the USFDA's decision regarding Makena does not impact Gravibinan.*

ii. *Regarding need for Gravibinan Injection in Pakistan firm has submitted as under:*
   a. *Currantly there are no alternative options available in injectable form for the prophylaxis of abortion and threatened abortion.*
   b. *The prevalence of prophylaxis of abortion and threatened abortion is considerably high within our country.*
   c. *Gravibinan alone serves an annual patient turnover of 630,417.*

12. They have requested to reconsider the decision of 327th meeting of the Board regarding Hydroxyprogesterone caproate and Estradiol valerate + Hydroxyprogesterone caproate.

13. In USFDA, an NDA product DELALUTIN (Hydroxyprogesterone caproate) is discontinued with remarks that "***Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons***". Furthermore, one generic approval of Hydroxyprogesterone caproate Injection 250mg/ml is available as a status of prescription [Abbreviated New Drug Application (ANDA): 200271] with following indication and usage:

> **Hydroxyprogesterone Caproate Injection USP is indicated in non-pregnant women: for the treatment of advanced adenocarcinoma of the uterine corpus (Stage III or IV); in the management of amenorrhea (primary and secondary) and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as sub**

mucous fibroids or uterine cancer; as a test for endogenous estrogen production and for the production of secretory endometrium and desquamation.

14. Moreover, approved indications of Makena (Hydroxyprogesterone Caproate) are as under:

Makena is a progestin indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. The effectiveness of Makena is based on improvement in the proportion of women who delivered < 37 weeks of gestation. There are no controlled trials demonstrating a direct clinical benefit, such as improvement in neonatal mortality and morbidity.

15. Indication approved by Austria as claimed by M/s. Bayer are as under:

After the ovulation of the woman, the follicles are transformed into the corpus luteum. The corpus luteum produces the hormone progesterone and inhibits thus the premature reduction of the endometrium and causes furthermore a thickening of the cervic mucus. Thus an implantation of the fertilized egg is possible and favorable conditions for the maintenance of the pregnancy are secured.
lf your body is not producing enough progesterone (corpus luteum hormone) due to a low functioning during pregnancy, a miscarriage (abortion) may occur.
Proluton Depot contains the hormone hydroxyprogesterone caproate, comparable to the naturally produced corpus luteum, which the female body produces during pregnancy.
Proluton is used in case of repeated miscarriage (habitual abortion) due to corpus luteum deficiency.

Decision of 330th Meeting of the Board:

Registration Board decided that M/s Bayer shall be provided an opportunity of personal hearing in the next meeting to present their stance and brief the Board regarding approval status of their products in reference regulatory authorities.

As per decision of the Board firm has been called for personal hearing.

Proceedings of 331st Meeting:
Dr. Aftab Ahned Khan, Head of Regulatory Affairs and Dr Masroor Ahmed, Sr. Medcal Advisor appeared on behalf of M/s. Bayer and submitted that withdrawal of Makena is linked with its indication which are different than that of Prolutin of M/s. Bayer. Prolution is also available in Austria which was also confirmed from website
https://aspregister.basg.gv.at/aspregister/faces/aspregister.jspx;jsessionid=MBTSW0JJJ6ihyhL8nRipVJit
Ty-3qEb7-xNnE54qIcZaCU5sSJMr!2098280154?_adf.ctrl-state=11ajcl0qd9_4.
Firm has also submitted Austria approved indication of Prolutin which is as under:
After the ovulation of the woman, the follicles are transformed into the corpus luteum. The corpus luteum produces the hormone progesterone and inhibits thus the premature reduction of the endometrium and causes furthermore a thickening of the cervic mucus. Thus an implantation of the fertilized egg is possible and favorable conditions for the maintenance of the pregnancy are secured.
lf your body is not producing enough progesterone (corpus luteum hormone) due to a low functioning during pregnancy, a miscarriage (abortion) may occur.
Proluton Depot contains the hormone hydroxyprogesterone caproate, comparable to the naturally produced corpus luteum, which the female body produces during pregnancy.
Proluton is used in case of repeated miscarriage (habitual abortion) due to corpus luteum deficiency.
Furthermore, firm has also submitted that Gravibinan Injection contains Estradiol valerate + Hydroxyprogesterone caproate which is not generic of Makena.

Decision of 331st Meeting:

Keeping in view the submissions of M/s Bayer Pakistan Limited and the approval of the indications of their product i.e. Proluton Depot Injection by the Austrian Federal Office for Safety in Healthcare BASG, Registration Board withdraws its earlier show cause approved in 327th meeting.
Moreover, the show cause, approved in 327th meeting, to the products containing combination of Hydroxyprogesterone Caproate and Estradiol Valerate is also hereby withdrawn considering the fact that the aforesaid formulations have not been reported to be withdrawn in any reference regulatory authorities.

On 26 June 2024, the Coordination Group for Mutual Recognition and Decentralized Procedures – Human (CMDh) endorsed the recommendation from EMA's safety committee, Pharmacovigilance Risk Assessment Committee (PRAC), to suspend the marketing authorizations for medicines containing 17-Hydroxyprogesterone caproate (17-OHPC) in the European Union (EU). A review by the PRAC concluded that there is a possible but unconfirmed risk of cancer in people exposed to 17-OHPC in the womb. In addition, the review considered new studies which showed that 17-OHPC is not effective in preventing premature birth; there are also limited data on its effectiveness in other authorized uses.

In some EU countries, 17-OHPC medicines are authorized as injections to prevent pregnancy loss or premature birth in pregnant women. They are also authorized for the treatment of various gynecological and fertility disorders, including disorders caused by a lack of a hormone called progesterone. The study, which involved over 1,700 pregnant women with a history of preterm delivery, found that 17-OHPC is no more effective than placebo (a dummy treatment) in preventing recurrent premature birth or medical complications due to prematurity in newborns.

In view of the concern raised by the possible risk of cancer in people exposed to 17-OHPC in the womb, together with the data on the effectiveness of 17-OHPC in its authorized uses, the PRAC considered that the benefits of 17-OHPC do not outweigh its risks in any authorized use. The Committee therefore recommended the suspension of the marketing authorizations for these medicines. Alternative treatment options are available. Detail of drug products is as under:

Sr. No.	Reg. No.	Product Name & Composition	Registration Holder / Manufacturer
1.	000899	Proluton Depot 250mg Injection Hydroxyprogesterone caproate....250mg	M/s. Bayer
2.	096479	Nandrosol 250mg Injection Each ml contains: Hydroxyprogesterone caproate....250mg	Pharmasol (Pvt) Ltd, Plot 549, Sunder Industrial estate, Lahore., Lahore
3.	094205	Hygest Injection Each ml contains: Hydroxyprogesterone caproate....250mg	Shaigan Pharmaceuticals (Pvt) Ltd
4.	003531	Hydroxyprogesterone Injection Each ml contains: Hydroxyprogesterone caproate....250mg	M/s. Zafa Pharmaceutical, Karachi.
5.	030526	Globinan 2Ml Injection Hydroxy Progesterone Caproate…. 250mg	Global Pharmaceuticals Pvt Ltd
6.	030525	Globinan 1Ml Injection Hydroxy Progesterone	Global Pharmaceuticals Pvt Ltd
7.	013624	VIO-DEPOT INJ Each ml contains: Hydroxyprogesterone caproate....……250mg	Venus Pharma, 23 Km Multan Road Lahore. , Lahore
8.	003746	HYDROXYPROGESTRONE INJECTION Each ml contains: Hydroxyprogesterone caproate....……250mg	Haji Medicines, Rawalpindi

Decision: Keeping in view of recommendation from EMA's safety committee, Pharmacovigilance Risk Assessment Committee (PRAC), Registration Board decided to issue show-cause notice to all registration holders having registration of Hydroxyprogesterone containing drug products under section 7(11) (d) read with section 42 of Drug Act 1976.

Case No. 02: Registration of Baricitinib 2mg and 4mg Tablets.

M/s. CCL has submitted a letter while referring Baricitinib containing drug products (Barib 2mg & 4mg Tablet) approved in the name of their firm stated as under:

The honorable Lahore High Court, Lahore through order dated 02-05-2024 passed F.A.O No. 22656 of 2024, suspended operation of Order by the learned Intellectual Property Tribunal, Lahore, in the following words:

C.M. No. 2/2024

6. Notice for the above-said dated. Till the next date of hearing, the impugned order of the learned *Tribunal* only to the extent of the present appellant/DRAP shall remain suspended.

Case was referred to Legal Affair's Division for status of case and their opinion. Accordingly, opinion of said division is as under:

i. The background of the matter is that registration of drugs containing Baricitnib including that of CCL Pharma Pvt. Ltd. were approved in various meeting of the Registration Board. Subsequently, before the Drug Registration Certificates could be issued, Suits were filed by Incyte Holding Corporation/ Eli Lilly Pakistan Pvt. Ltd. before the learned Intellectual Property Tribunal, Lahore. The Suits contended that Drug Registration Certificates should not be issued by placing reliance on the concept of Patent-Linkage. Ad-Interim Injunctions were issued against various firms whose registration of generic/ me-too of Baricitnib containing drugs had been approved by the Registration Board including CCL Pharma Pvt. Ltd. Learned Tribunal restrained all other companies from seeking drug registration from DRAP and also simultaneously restrained DRAP from processing their applications.
   Ad-Interim Injunction was granted by the learned Intellectual Property Tribunal against CCL Pharma. Pvt. Ltd. through Order dated 03-03-2023. The Application for Interim Relief under Order 39 Rule 1 and 2 C.P.C. was decided through Order dated 03-04-2024 .

ii. Being aggrieved, DRAP filed appeal against the order dated 03.04.2024 in Lahore High Court, Lahore bearing FAO No. 22656 of 2024 in which interim relief was given by the High Court through Order dated 02-05-2024 . Relevant excerpt thereof is as under:
   "**C.M. No. 2/ 2024**
   6. Notice for the above-said date. Till the next date of hearing, the impugned order of the learned *Tribunal* only to the extent of the present appellant/ DRAP shall remain suspended."
   Subsequently, the said FAO was decided in favor of DRAP through Judgment dated 27-05-2024 (Certified copy is attached). Under the Doctrine of Merger, the Interim Order dated 02-05-2024 merged into the Final Judgment dated 27-05-2024. The Final Judgment dated 27-05-2024 set aside the Interim Injunction/ Stay Order granted by the learned Intellectual Property Tribunal, Lahore to the extent of CCL Pharmaceutical Pvt. Ltd., in the following words:
   "(ii). The interim injunction granted by the learned Tribunal, to the extent of DRAP for restraining DRAP to proceed with pending application of respondent No. 4 may be vacated;"

iii. After the grant of the above mentioned final relief by the Honorable Court, both CCL Pharma Pvt. Ltd. is free to seek Drug Registration from DRAP and further DRAP is also free to process and grant Drug Registration to CCL Pharma Pvt. Ltd. In other words, DRAP is free to perform its functions to the extent of application by CCL Pharma Pvt. Ltd.
   After Order by the Honorable Lahore High Court, Lahore dated 02-05-2024 and Final Judgment by the Honorable Court dated 27-05-2024, there is no legal impediment to the issuance of Drug Registration Certificates for drugs containing Baricitnib of CCL Pharma Pvt. Ltd. It must be emphasized that as the Honorable Court has specifically directed DRAP to proceed with CCL Pharmaceutical Pvt. Ltd.'s pending application for registration, therefore, it is a legal responsibility of the relevant persons/Board to abide by the Order and not delay the issuance of Drug Registration Certificate. Please note that any further unnecessary delay might tantamount to Contempt of Court.

iv. Furthermore, the Registration Board in its 297th Meeting held on 12th to 15th of January, 2021, held that barring the cases where interim injunction is granted by the Honorable Court, the drug registration shall not be stopped. The decision is reproduced as under:
   "After detailed deliberations, Registration Board decided that grant of marketing authorization/ registration has no linkage with patent status of the originator's product and advised to process cases for issuance of registration letters except for cases of restraining orders from any court."
   As the restraining order by the learned Tribunal has been completely set aside by the Honorable High Court through Judgment dated 27-05-2024 **only to the extent of CCL Pharma Pvt. Ltd.** therefore, as per decision of the 297th Meeting of the Registration Board, there is no legal impediment in the grant of Drug Registration to CCL pharma. **It is again clarified that any delay in complying with the aforementioned direction of the Honorable Court is contemptuous in nature and therefore, the competent authority**

should promptly issue CCL Pharma Pvt. Ltd.'s Drug Registration Certificate as long as the Company meets all requirements under the drug laws.

v. As discussed in detail above, the Honorable High Court through Judgment dated 27-05-2024 has granted relief only to the extent of CCL Pharma Pvt. Ltd. Therefore, it is a relief which is 'in personam' granted to the extent of parties to the case i.e. CCL Pharma. This concept has been defined by the Honorable High Court in judgment reported as **2014 PLC (CS) 288** in the following words:
"It differs from a judgment in personam as this judgment is in form as well as substance between the parties claiming the right, and that it is so inter parties appears by the record itself."

vi. Furthermore, since the Judgment dated 27-05-2024 does not lay down a Principle of Law, therefore, it is a judgment 'in personam' which only benefits the party to the lis i.e. CCL Pharma Pvt. Ltd.
It is pertinent to mention here that Learned Tribunal has restrained all other companies from seeking drug registration from DRAP and also simultaneously restrained DRAP from processing their applications. Therefore, unless and until the Honorable High Court sets aside the learned Tribunal's both aforementioned directions to the extent of DRAP completely in relation to all other companies, DRAP cannot issue Drug Registration Certificate to other companies. Any violation of learned Tribunal's Order would be contemptuous as noted by the Honorable High Court in judgment reported as PLD 1975 Lahore 126 in the following words:
"5… When an injunction order has been issued, it must be obeyed; and the only remedy of the aggrieved party is to come up in appeal to a superior Court to have the order vacated. So long as the order stands and its operation has not been suspended by another Court or by the Court which passed the order, it will not be tolerated that any person should disobey that order."

vii. In the light of above facts and legal position, the Judgment dated 27-05-2024 by Lahore High court is 'in personam', therefore, its benefit can only be granted to CCL Pharma Pvt. Ltd. and Drug Registration Certificate can only be issued to it. The registration letters regarding the product containing namely Baricitinib cannot be granted to the other companies against whom the Incytee Holdings and ELi Lilly filed suit in Intellectual Property Tribunal, Lahore due to the operative stay orders.

It is pertinent to mention here that it is also mentioned in Hon'ble High Court Order dated 27.05.2024 that

" 4 (iii) ''the above, however, shall not be construed as permitting respondent No. 4 to advertise, market or deal with Baricitinib in any manners and the injunctive order to the extent of respondent No. 4 may be examined in appeal No. 22665 of 2024 filed by respondent No. 4."

Proceeding of 343rd Meeting:

Registration Board was appraised that during meeting of the Board, on behalf of i. Incyte Holdings Corporation ii. Eli Lilly and company and iii. Eli Lilly Pakistan (Pvt) Ltd., Mr. Hassan Irfan Khan Advocate has sent a reference stating that CCL has submitted a letter, willfully and purposely misrepresenting the actual facts and legal position with regard to litigation by their clients against CCL for infringement of patents relating to baricitinib.

Copy of above reference has been handed over to Law expert of M/o Law & Justice, Islamabad for review and discussion in forthcoming meeting of the Board.

Decision: Registration Board, in-order to complete review of the case in light of reference submitted by Mr. Hassan Irfan and Lahore High Court deferred the case for further deliberation.

Case No. 03: Consider The Registration/Re-Grant of the All Registered Products of M/s Safina Pharmaceuticals (Pvt) Ltd DML No 000654 Which Stand Cancelled Under the Letter No.F.5-1/2021-Reg-Ii (M-297) Dated 9th April 2021 On Form -5.

M/s. Safina Pharmaceuticals, Lahore has submitted as request wherein they have stated as under:

"With reference to subject sited above it is stated that in the minutes of 297th meeting of Registration Board the Board decided to cancel our all the registered products in view of the decision of 273rd meeting of CLB held on 15th January 2020.

With the negligence of the previous management of the company the DML NO 000654 stands to be cancelled under the letter No.F.1-43/2006-Lic dated 20th February, as we take-up the

company in same status and applied for the Re-Grant of same DML and Company name on 25th February 2020.

In the meanwhile, the Registration Board in its 297th meeting held on 12-15th January 2021 considered the decision of Central Licensing Board taken in 273rd meeting held on 15th January 2020 wherein DML NO. 000654 of the firm was cancelled, accordingly the Registration Board deliberated the matter and cancelled the registration of all drugs registered in the name of the company and issue us letter No.F.5-1/2021-Reg-II(M-297) dated 9th April 2021.

Now this is to inform you that under the letter No.F.1-43/2006-Lic(Vol-1) dated 24th March 2021, the Central Licensing Board re-grant the Drugs Manufacturing License No 000654, to M/s Safina Pharmaceuticals Pvt Ltd, 7-km Lahore Sheikhupura Road Lahore in its 279th meeting held on 18th February 2021

Prayer: It is requested to please appraise the decision taken in 297th meeting regarding cancellation of products registration that we were promoting the same products in market since 2009 and spend a lot to establish the market and upgrade the company, we get Good remarks in inspection for the Re-Grant of DML NO 000654 from the respected panel members, our all products are renewed and updated, please consider our application and re grant all registered products in view of The DRAP Authority in its180th meeting held on 07th March 2024

"The Authority observed that similar matter has already been decided in previous meeting in different perspectives and there is a need to adopt a uniform approach for disposing of all such cases where registration has become invalid on administrative grounds. Given the fact that manufacturing site, machinery and formulation remain the same, the Authority decide that instant and all such applications in future:

i) Shall be considered out-of-queue and

ii) Shall be exempted form submission of registration dossier on Form 5F in exercise of Authority's power under Rule 26 of the Drugs (Licensing, Registering & Advertising (Rules, 1976 amended via SRO 713 (1)/2018 dated 08th June, 2018.

2. No such cases shall be forwarded to the Authority and shall be decided on the same analogy by the Division of PE&R and BE&R."

Keeping in view the above decision of the new registration applications which have been submitted on Form-5. we will be very great full to your kind authority on this."

It is submitted that Registration Board, in compliance with the above mentioned decision of the Authority, considered the applications on Form-5 only for those products which were cancelled due to non-submission of renewal application within prescribed time. M/s. Safina has requested to consider their applications on Form-5 as their registrations were cancelled due to cancellation of DML.

Proceedings and Decision of 343rd Meeting:
Registration Board deliberated the matter that previously DRAP Authority has allowed exemption of Form-5F to those products for which registrations were cancelled due to late / non-submission of renewal of registration applications. In instant case registrations were cancelled after cancellation of DML due to late submission of DML renewal application. Hence, Registration Board referred the case to DRAP Authority for seeking guidance to further process such cases.

Case. No. 04: M/s. Werrick Pharmaceuticals, I-10/3, Industrial Area, Islamabad

197.	Name and address of manufacturer / Applicant	M/s. Werrick Pharmaceuticals, I-10/3, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	HIGH C-D Sachet (Orange Flavor)
	Diary No. Date of R& I & fee	(Duplicate Dossier) Dy.188 No. dated 19/12/2008 Differential fee (Photocopy) of Rs.12,000/- submitted on 26/10/2017
	Composition	Each Sachet contains: Calcium Lactate Gluconate….1000mg Calcium Carbonate….327mg Vitamin C (Ascorbic Acid) ….500mg Vitamin D3….4mg Vitamin B6….10mg
	Pharmacological Group	Vitamin and mineral formulations

<table>
<tr><td>Type of Form</td><td>Form 5</td></tr>
<tr><td>Finished Product Specification</td><td>Manufacturer Specification</td></tr>
<tr><td>Pack Size & Demanded Price</td><td>As per S.R. O</td></tr>
<tr><td>Approval Status of Product in Reference Regulatory Authorities</td><td>…..</td></tr>
<tr><td>Me-too Status</td><td>CaC-1000 sachet by M/s. GSK OTC (Pvt.) Ltd. Petaro Road, Jamshoro</td></tr>
<tr><td>GMP Status</td><td>Last inspection report dated 09/11/2018, the panel recommended for the grant of GMP Certificate.</td></tr>
<tr><td>Remarks of the Evaluator.</td><td>1. Me Too (CaC-1000 Sachet) product mentioned by the firm in Form 5 is available with different composition.
2. Vitamin D3 used in the formulation is above UL, as the upper tolerable intake level of vitamin D is 10000IU (250mcg) while the used amount is 4000mcg same amount is used in me-too also.</td></tr>
<tr><td>Previous Decision of 295th meeting</td><td>Registration Board in its 295th meeting decided as under:
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.</td></tr>
<tr><td>Response of the firm along with Remarks of the Evaluator</td><td>Firm submitted the comparison table of composition of CaC-1000plus Effervescent Tablet and High C-D Sachet which is as under:
<table>
<tr><td>CaC-1000 Plus Effervescent Tablet</td><td>High C-D Sachet</td></tr>
<tr><td>Each Effervescent tablet contains:
Calcium Lactate Gluconate….1000mg
Calcium Carbonate….327mg
Vitamin C (Ascorbic Acid) ….500mg
Vitamin D3….400IU
Vitamin B6….10mg</td><td>Each Sachet contains:
Calcium Lactate Gluconate….1000mg
Calcium Carbonate….327mg
Vitamin C (Ascorbic Acid) ….500mg
Vitamin D3….4mg/400IU
Vitamin B6….10mg</td></tr>
</table>
It is submitted that firm compare two different pharmaceutical dosage form, which are not consider as pharmaceutical Equivalent.</td></tr>
<tr><td colspan="2"><u>Decision of 296th meeting:</u>
Deferred for submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. In case of new combination evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in 275th meeting is required.</td></tr>
<tr><td colspan="2">Remarks of the Evaluator: Densical sachet of Platinum pharma Karachi was registered with Reg No. 042153 dated 23-01-2006 and having following composition:
Each Sachet contains:
Calcium Lactate ….1000mg
Calcium Carbonate….327mg
Vitamin C ….500mg
Vitamin D….4mg
Vitamin B6….10mg
The applied formulation has Calcium Lactate Gluconate 1000mg while me too registered has Calcium Lactate 1000mg.</td></tr>
<tr><td colspan="2">Decision of 336th Meeting: Registration Board in line with vitamin-mineral policy discussed by Registration Board in its 291st and 295th meeting decided to Approve with innovator’s specification with following composition:
Each Sachet contains:
Calcium Lactate ….1000mg
Calcium Carbonate….327mg
Vitamin C ….500mg</td></tr>
</table>

	Vitamin D….4mg **Vitamin B6….10mg** **Firm shall submit fee of Rs:30000/- for revision of formulation before issuance of registration letter.**

Before issuance of registration letter, firm has submitted a request to issue registration letter with their applied formulation. Which is as under:

"Each Sachet contains:
Calcium Lactate Gluconate….1000mg
Calcium Carbonate……..327mg
Vitamin C (Ascorbic Acid) ….500mg
Vitamin D3….4mg
Vitamin B6….10mg"

As per record, list of already registered drug products in sachet dosage form containing Calcium Lactate Gluconate is as under;

Sr. No.	Reg. No.	Name of Drug and Composition	Name of Manufacturer
1.	084643	CaC-1000 Sachet Each 10gm contains Calcium Carbonate_ 327 mg Calcium Lactate Gluconate_ 1000 mg Vitamin C_ 500 mg	GlaxoSmithKline Consumer Health Care Pakistan Ltd [Formerly GSK OTC Pvt Ltd], Petaro Road , Jamshoro
2.	028235	Vitascot Sachets Each sachet contains Calcium Lactate Gluconate_ 1000 mg Vitamin C_ 500 mg Calcium Carbonate_ 327 mg	Scotmann Pharmaceuticals
3.	104534	Dewcal Sachet Each sachet of granules contains Calcium Lactate Gluconate_ 1000 mg Vitamin C_ 500 mg Calcium Carbonate_ 327 mg-	Jinnah Pharmaceuticals (Pvt) Ltd., 13-Km Lahore Road Multan., Multan
4.	025955	Calsol Powder in Sachet Each sachet contains Calcium Lactate Gluconate_ 1000 mg Vitamin C_ 500 mg Calcium Carbonate_ 327 mg	Shaigan Pharmaceuticals (Pvt) Ltd
5.	019198	Calvin-C 500 Each sachet contains Calcium Lactate Gluconate_ 1000 mg- Calcium Gluconate_ 578 mg- Calcium Lactate_ 422 mg- Vitamin C_ 500 mg- Calcium Carbonate_ 327 mg-	Bloom Pharmaceuticals (Pvt) Ltd.

Decision: Registration Board acceded to request of the firm and decided to grant registration of product as per following details;

Each Sachet contains:
Calcium Lactate Gluconate….1000mg
Calcium Carbonate….327mg
Vitamin C (Ascorbic Acid) ….500mg
Vitamin D3….4mg
Vitamin B6….10mg

Post Registration Variation-I Section

Case No. 01: Change Of Manufacturing Site From Bulk Import/Local Repacking To Local Manufacture Of Rivotril Drops 0.25% (Clonazepam) Reg No. 001047 By M/S Martin Dow Limited, Karachi.

1.	Name, address of Applicant / Marketing Authorization Holder	M/s Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area, Karachi
	Name, address of Manufacturing site.	M/s Martin Dow Limited, Plot no. 37, Sector 19, Korangi Industrial Area, Karachi
	Name of Previous Manufacturer	M/s Delpharm Milano S.R.L. via Carnevale 1 20090 Segrate-(MI), Italy
	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 28-04-2023
	Details of fee submitted	PKR 30,000/-: dated 04-03-2023
	The proposed proprietary name / brand name	**Rivotril Drops 0.25%**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Clonazepam ……. 2.5mg
	Pharmaceutical form of applied drug	Oral Drops
	Pharmacotherapeutic Group of (API)	Benzodiazepines
	Reference to Finished product specifications	Innovator's Specification
	Proposed Pack size	10ml
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	**Product name:** Rivotril clonazepam 2.5mg/mL oral liquid bottle **Status:** Approved **Regulatory Authority:** TGA
	For generic drugs (me-too status)	**Product Name:** Naze 0.25% Oral Drops **Company Name:** M/s. Schazoo Pharmaceuticals Pvt. Ltd. **Registration No.:** 053501
	GMP status of the Finished product manufacturer	GMP certificate issued on 03-09-2024 valid till 15-08-2027
	Name and address of API manufacturer.	**F.I.S. –Fabbrica Italiana Sintetici S.p.A.** *Site of Montecchio Maggiore* DUNS# 431189117 Viale Milano, 26 36075 Montecchio Maggiore (VI) –Italy
	Module-II (Quality Overall Summary)	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 ± 2°C / 75 ± 5% RH for 60 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batch No NPD-S-2235-S, NPD-S-2236-S NPD-S-2237-S
	Module-III (Drug Product):	The firm has submitted detail of manufacturer, description of manufacturing process and controls, impurities, specifications, analytical procedure and its validation studies, batch analysis, reference standard, container closure system and stability studies of drug product.
	Pharmaceutical equivalence and comparative dissolution profile	Pharmaceutical Equivalence have been established against: **Innovator Product**: Rivotril 2.5mg/ml oral drops **Batch no:** M1923 **Manufacturer:** Delpharm Milano S.R.L **Expiry Date:** April-2023 While CDP is not applicable.
	Analytical method validation/verification of product	Method Validation studies are submitted

STABILITY STUDY DATA

Manufacturer of API	**F.I.S. –Fabbrica Italiana Sintetici S.p.A.** Site of Montecchio Maggiore DUNS# 431189117 Viale Milano, 26 36075 Montecchio Maggiore (VI) –Italy		
API Lot No.	2207000074		
Description of Pack (Container closure system)	Amber Glass Bottles 10ml with plastic caps, seal and dropper. The bottle is packed in a 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: months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	NPD-S-2235-S	NPD-S-2236-S	NPD-S-2237-S
Batch Size	200 bottles	200 bottles	200 bottles
Manufacturing Date	29.12.2022	29.12.2022	29.12.2022
Date of Initiation	18.01.2023	18.01.2023	18.01.2023
No. of Batches	03		

Administrative Portion

7.	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 the 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.
8.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Copy of GMP Certificate No. NBF/43/2021/V Of F.I.S. –Fabbrica Italiana Sintetici S.p.A. Italy. Valid till Dec 2024.
9.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted Form-6 ''License to import Drugs for Trial Batch'' for Clonazepam import of 0.090 Kgs for trial purpose.
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: **1. Firm is granted approval of Licensed section namely Oral Drops (Psychotropic) section by the Central Licensing Board**		
Decision: Approved **a) 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.** **b) Manufacturer will perform process validation of first three batches as per the commitment submitted in the registration application.**		

Case.No. 2 **Application Of Change Of Market Authorization Holder And Change Of Manufacturing Site Of Xanax Tablet 0.25mg, 0.5mg & 1mg**

M/s OBS Pharma (Pvt) Ltd, 108-Quaid-e- Azam Industrial Estate Kot Lakhpat Lahore having DML No. 000243 (Formulation) has submitted request for change of Importer/Market Authorization Holder in Pakistan along with Change of Manufacturing Site of Drug Product from M/s Pfizer Pakistan Limited, B-2, S.I.T.E. Karachi to M/s OBS Pharma (Pvt) Ltd, 108-Quaid-e- Azam Industrial Estate Kot Lakhpat Lahore

NOC dated : 11th September, 2024 from M/s Pfizer Pakistan, Limited, Karachi regarding transfer of registration to M/s OBS Pakistan (Pvt) Ltd, Lahore is submitted.

Asset Purchase Agreement for trademark and marketing rights of Xanax is submitted.

NOC from the Ministry of Narcotics Control, Islamabad was issued to the firm on 07th May 2024.

The firm M/s OBS Pharma (Pvt) Ltd, 108-Quaid-e- Azam Industrial Estate Kot Lakhpat Lahore was allocated 79.194 gm of Alprazolam for Trial/Development & stability determination by the Drug Registration Board.

As per PRV Guidelines 2nd Edition, following documents are required for change of manufacturing Site MaV-3 :

Sr. No.	Documents required	Submission by the firm
1.	Application on Form 5F (CTD) for human drug products	The firm has submitted application on Form 5F
2.	Proof that the proposed site/ manufacturer is appropriately authorized for the pharmaceutical form concerned i.e., approval of manufacturing facility from Licensing Division and having valid GMP certificate.	The firm is authorized to manufacture psychotropic drug product vide Licensing Division letter No: F.1-43/85-Lic (Vol-IV) dated : **20th May 2024.**
3.	In case of contract manufacturing, contract	Not applicable

	agreement with proposed manufacturer as per requirements laid down in SRO 1347(I)/2021 and contract termination letter with previously approved manufacturer by the MA holder.	
4.	Comparative dissolution profile data of at least one production batch of the drug product manufactured in the previous approved and proposed manufacturing site for oral solid dosage forms.	The firm has manufactured three lab scale batches of Xanax 0.25mg. 0.5mg and 1mg tablets. **Stability studies for both accelerated and real time are conducted for 01 month (02 points stability data is submitted i.e. initial and 1 month time point).** Batch details are as under: **For Xanax IMG** Batch No. OBSRD 01-001 Batch No. OBSRD 01-002 Batch No. OBSRD 01-003 **For Xanax 0.25 MG** Batch No. OBSRD 03-001 Batch No. OBSRD 03-002 Batch No. OBSRD 03-003 **For Xanax 0.5 MG** Batch No. OBSRD 02-001 Batch No. OBSRD 01-002 Batch No. OBSRD 01-003 Comparative dissolution profile data of at least one production batch of the drug product manufactured in the previous approved and proposed manufacturing site for oral solid dosage forms is not provided
5.	Certificate of analysis and/or batch analysis data (in a comparative tabulated format) of drug product of at least two production batches from the proposed site and last three batches from the previous approved site.	The firm has submitted certificate of analysis in tabulated form of 03 lab scale batches manufactured at the proposed site and production batches of previously approved site.
6.	Revised drafts of the package insert and labeling incorporating the proposed variation (where applicable).	Revised drafts of the package insert and labeling incorporating the proposed variation are submitted

The cases submitted by the M/s OBS Pharma (Pvt) Ltd, 108-Quaid-e- Azam Industrial Estate Kot Lakhpat Lahore pertains to change of registration holder and change of manufacturing site from M/s Pfizer Pakistan Limited, B-2, S.I.T.E. Karachi to M/s OBS Pharma (Pvt) Ltd, 108-Quaid-e- Azam Industrial Estate Kot Lakhpat Lahore.

As the change in registration holder for locally applied products does not cover under the ambit of post registration variation guidelines as matter also pertain to the registration of a psychotropic drug i.e Alprazolam hence the matter is placed before the registration Board for consideration please.

Decision: The Registration Board deliberated the matter in length and considered that as per PRV guidelines, document No. PE&R/GL/PV/001, Version II, for change of manufacturing site of registered Product, comparative dissolution profile data of at least one production batch of the drug product manufactured in the previous approved and proposed manufacturing site for oral solid dosage forms is required. However, in the instant case, the firm is allocated limited

quantity of API (Psychotropic) i.e. Alprazolam for the purpose of trial and stability study therefore, development of Production batch at new manufacturing is not possible. After thread bare deliberation, the Registration Board decided to defer the case for submission of stability data as per WHO TRS 981,2013 (47th report, Annex 3).

Case. No. 3 REQUEST TO PRINT READABLE EXPIRY DATE ON TABLETS

A letter is received to DRAP with the requesting that Pharmaceutical Companies may be asked to print readable expiry date on tablets. Use of expired medicines can be dangerous and lead to serious health consequences.

02. Moreover, most of the companies just punch/emboss expiry date on tablets which are not visible to read. Like the example of Panadol, Carsel tablet etc.

03.Some companies are very clearly printing expiry dates on tablets. Like Loprin etc.

04. Pharmaceutical Companies may be asked to print readable expiry date on tablets.

It is pertinent to mention that in the light of "The Drugs (Labeling and Packing) Rules, 1986", the requirements for labelling of dosage forms are as under :

(3) Manner of Labeling : The following particulars **shall appear either in print or in writing in inedible ink in a conspicuous manner** on a label of the innermost container of drug and also on the packing in which such container is packed namely :-

(a) The registered name of the drug;

(b) If the registered name is a proprietary name, then immediately following the registered name, the international non-proprietary name, and if no such non-proprietary name is known the Pharmacopoeial name or any other name, if any, approved by the registration board for this purpose in conspicuous manner;

(c) The international non-proprietary name of the pharmacopoeial name of the generic name, and if no such name is known the chemical name of each active ingredient of a drug with weight. Added by SRC 1122 (i) 86 dated 23-12-1986 Manual of Drug Laws Or measures in metric system, or the number of units of activity as the cause may be, expressed :-

(i) In the case of oral liquid preparations in terms of contents per specified volume, the volume being indicated in militaries;

(ii) In the case of liquid parenteral preparations ready for administration in terms of militaries or percentage by volume or dose. Provided that in the case of a preparation contained in ampoule, it shall be sufficient if the ingredients are shown on the label or wrapper affixed to any package in which such ampoule is issued for sale.

(iii) In the case of drugs in solid form intended for parenteral administration in terms of weight or unitage per milligram or gram or per container.

(iv) In the case of tablets, capsules pill or other units as the case may be; and

(v) In the case of other preparations in terms of percentage by weight or volume or unitage per gram or milliliter as the case may be;

(d) The name and principal place of business of the manufacturer

(e) The drug manufacturing license number.

(f) The drug registration number.

(g) The date of expiry.

(h) Urdu version of the following namely;

(i) Name of drug

(ii) dosage; and

(iii) Instructions;

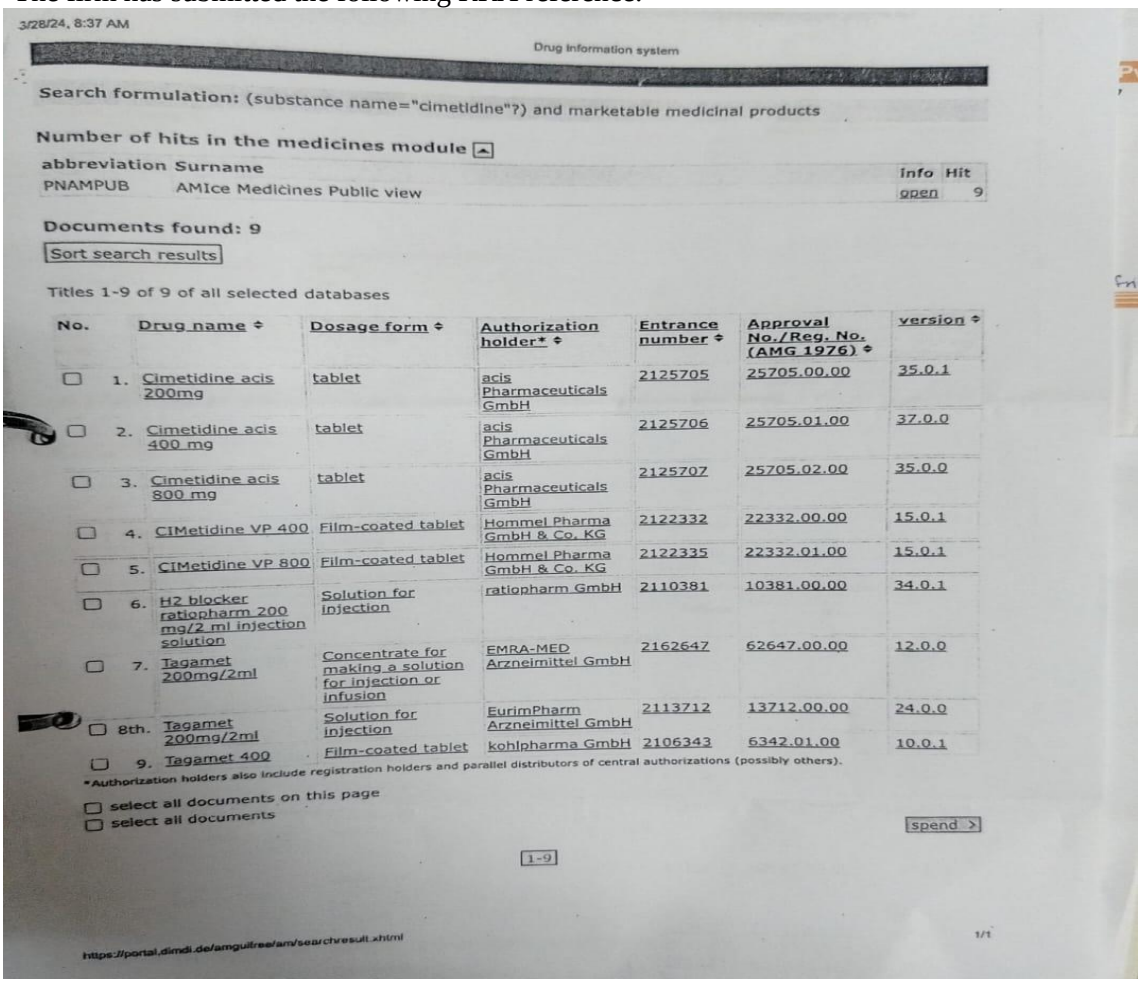
(i) The distinctive batch number date of manufacture and the maximum retail price;

Keeping the above mentioned legal requirements in view, it is proposed that an advisory may be issued to all Pharmaceutical companies that all the particulars (as mentioned under "The Drugs (Labeling and Packing) Rules, 1986", **shall appear either in print or in writing in inedible ink in a conspicuous manner** on a label of the innermost container of drug and also on the packing in which such container is packed.

Decision: Registration Board decided to issue an advisory to all pharmaceutical companies that all the particulars (as mentioned under "The Drugs (Labeling and Packing) Rules, 1986", shall appear either in print or in writing in inedible ink in a conspicuous manner on a label of the innermost container of drug and also on the packing in which such container is packed.

Case No. 01:- CHANGE IN SPECIFICATIONS

i.		M/s. Friends Pharma (Pvt) Ltd., 31-Km Ferozepur Road, Lahore.			
Sr. #	**Reg. No.**	**Existing Approved Name of drug with composition**	**Proposed Corrected Name of drug with composition**	**Date of Initial Reg. & Renewal**	**Application & Fee Details**
1.	074258	Frimet Injection Each 2ml contains: Cimetidine…..200mg (USP Specifications)	Frimet Injection Each 2ml contains: Cimetidine…..200mg (BP Specifications)	31-12-2012 24-11-2022	Fee Rs 10,000/- deposited slip No. 36599357 R&I TCS No 109756448 dated 28-03-2024
Decision of 121st PRVC:		*The Chairman Registration Board on recommendation of Committee deferred the request of the firm for RRA reference of applied formulation as submitted reference is of Cimetidine HCl.*			
Remarks:		*The firm submitted reply however RRA reference of applied formulation as submitted reference is of Cimetidine HCl was not provided and the firm was again advised to* ***submit application for standardization of formulation of above as per RRA in light of PRV Guidelines Ver. 2 along with fee for further processing of your application vide this office letter dated15-07-2024****.* *In response to the above letter, the firm submitted that the application for standardization is relevant only in case of a formulation change, specifically fro Cimetidine to Cimetidine HCl. Their product registration letter specifies Cimetidine Injection as Cimetidine 200mg, precisely aligned with the BP monograph. The pertains solely to a change in product specifications.* *Therefore the firm has requested to clarify which label claim they should opt for, considering the registration letter error and sought guidance on proper label claims and product specifications opted by them in future for Frimet Injection.*			
Decision of 128th PRVC:		*The Chairman Registration Board on recommendation of Committee deferred the request of the firm for RRA reference of applied formulation. If the firm fails to submit the RRA reference, then the case shall be placed before the Board for decision.*			
Remarks:		The firm has submitted the following RRA reference: -			



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Drug Information system

Search formulation: (substance name="cimetidine"?) and marketable medicinal products

Number of hits in the medicines module

abbreviation	Surname	Info	Hit
PNAMPUB	AMIce Medicines Public view	open	9

Documents found: 9

Sort search results

Titles 1-9 of 9 of all selected databases

No.	Drug name	Dosage form	Authorization holder*	Entrance number	Approval No./Reg. No. (AMG 1976)	version
1.	Cimetidine acis 200mg	tablet	acis Pharmaceuticals GmbH	2125705	25705.00.00	35.0.1
2.	Cimetidine acis 400 mg	tablet	acis Pharmaceuticals GmbH	2125706	25705.01.00	37.0.0
3.	Cimetidine acis 800 mg	tablet	acis Pharmaceuticals GmbH	2125707	25705.02.00	35.0.0
4.	CIMetidine VP 400	Film-coated tablet	Hommel Pharma GmbH & Co. KG	2122332	22332.00.00	15.0.1
5.	CIMetidine VP 800	Film-coated tablet	Hommel Pharma GmbH & Co. KG	2122335	22332.01.00	15.0.1
6.	H2 blocker ratiopharm 200 mg/2 ml injection solution	Solution for injection	ratiopharm GmbH	2110381	10381.00.00	34.0.1
7.	Tagamet 200mg/2ml	Concentrate for making a solution for injection or infusion	EMRA-MED Arzneimittel GmbH	2162647	62647.00.00	12.0.0
8th.	Tagamet 200mg/2ml	Solution for injection	EurimPharm Arzneimittel GmbH	2113712	13712.00.00	24.0.0
9.	Tagamet 400	Film-coated tablet	kohlpharma GmbH	2106343	6342.01.00	10.0.1

*Authorization holders also include registration holders and parallel distributors of central authorizations (possibly others).

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	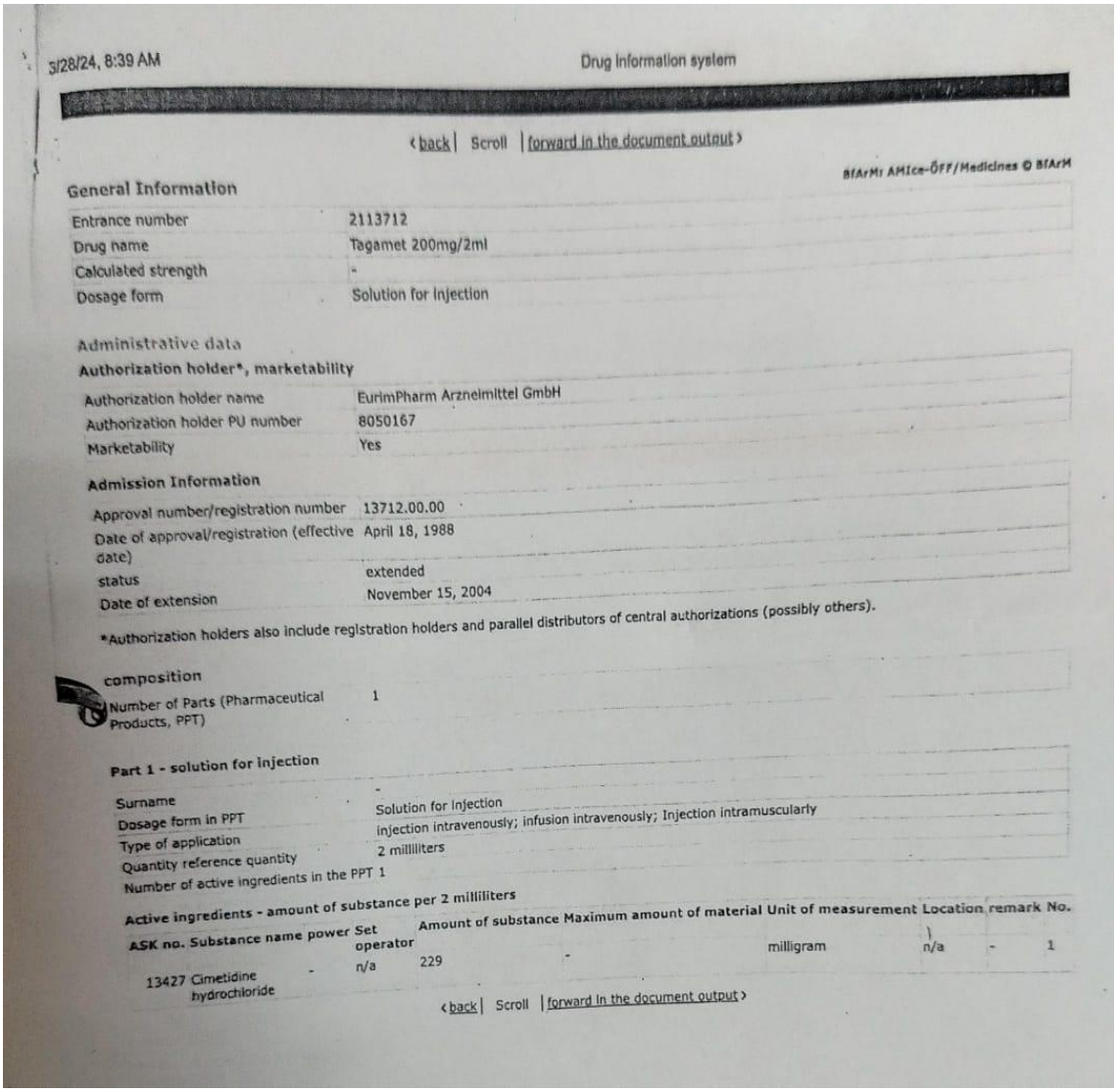

3/28/24, 8:39 AM Drug information system

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BfArM: AMIce-Öff/Medicines © BfArM

General Information

Entrance number	2113712
Drug name	Tagamet 200mg/2ml
Calculated strength	-
Dosage form	Solution for injection

Administrative data

Authorization holder*, marketability

Authorization holder name	EurimPharm Arzneimittel GmbH
Authorization holder PU number	8050167
Marketability	Yes

Admission Information

Approval number/registration number	13712.00.00
Date of approval/registration (effective date)	April 18, 1988
status	extended
Date of extension	November 15, 2004

*Authorization holders also include registration holders and parallel distributors of central authorizations (possibly others).

composition

Number of Parts (Pharmaceutical Products, PPT)	1

Part 1 - solution for injection

Surname	-
Dosage form in PPT	Solution for injection
Type of application	injection intravenously; infusion intravenously; Injection intramuscularly
Quantity reference quantity	2 milliliters
Number of active ingredients in the PPT 1	

Active ingredients - amount of substance per 2 milliliters

ASK no.	Substance name	power	Set operator	Amount of substance	Maximum amount of material	Unit of measurement	Location	remark	No.
13427	Cimetidine hydrochloride	-	n/a	229	-	milligram	n/a	-	1

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Remarks	The firm has multiple times be advised to standardize formulation from Cimetidine 200mg to Cimetidine as HCl 200mg. However, the firm is reluctant that their formulation is already standardized.
Decision:-	**Registration Board deferred the case for evidence of availability of formulation in RRAs other than Germany.**

Case No.02: <u>WORKING PAPER FOR GRANT OF ADDITIONAL PACK OF NON-ESSENTIAL MEDICINES.</u>

Federal Government vide S.R.O. 228(I)/2024, exempted all drugs and biological not included in the National Essential Medicines List, from price fixation.

Additional Packs of non-essential medicines were previously granted by Costing & Pricing Division. However, after notification of above SRO, the firms are submitting applications for grant of additional pack of Non-Essential Medicines in Post Registration Variation (PRV) Section. However, no guidelines are available in current version of PRV Guidelines for additional packs. Post Registration Variation (PRV) Section is of the view that following requirements may be implemented for grant of additional pack of Non Essential Medicines.

1. Application form as per Appendix I of PRV Guidelines Ver. 2 as Minor Variation.
2. Fee of **Rs. 9,000/-**, in accordance with Sr. No. 2 of S.R.O. 1324/2024, dated 30-08-2024 (Costing & Pricing Division) for each proposed pack.
3. Copy of Registration letter & renewal trail.
4. Evidence of availability of proposed pack in Pakistan or in RRAs. If proposed pack is neither available in Pakistan nor in RRAs then valid justification.

The application must be submitted through E-APP. In future, Chairman Registration Board may be authorized for grant of additional pack.

Decision:

Registration Board agreed to the above mentioned working paper and authorized its Chairman for approval of grant of additional pack of non-essential drugs. Registration Board further advised that all the applications for grant of additional pack of non-essential drugs shall only be received through E-App and for already applied cases, shortcomings shall be communicated to the firm in light of above working paper and these cases shall be processed through PRVC without waiting for finalization of Minutes.

Case No. 03:- RESEMBLANCE OF BRAND NAME CASE:

M/s. Wilshire Laboratories (Pvt) Ltd., Lahore submitted a request for resemblance of following products of M/s PharmEvo (Pvt.) Ltd., Karachi with their registered products. The details are given as below:-

Sr. No.	Reg. No.	Brand Name
1.	014331-EX	QSITA 50mg Tablet
2.	014337-EX	QSITA 100mg Tablet
3.	014489-EX	QSITA-M 50/500mg Tablet
4.	014490-EX	QSITA-M 50/500mg Tablet
5.	014342-EX	EMPA-Q 10mg Tablet
6.	014338-EX	EMPA-Q 25mg Tablet
7.	014340-EX	EMPA-M 12.5mg/500mg Tablets
8.	014341-EX	EMPA-M 12.5mg/1000mg Tablets
9.	014332-EX	ROSU-Q 5mg Tablet
10.	014335-EX	ROSU-Q 20mg Tablet
11.	014336-EX	ROSU-Q 10mg Tablet

The above mentioned brand names are similar to already registered following products of M/s. Wilshire Laboratories (Pvt.) Ltd., Lahore

Sr. No.	Reg. No.	Brand Name
1.	009776-EX	QSITA 50mg Tablet
2.	009777-EX	QSITA 100mg Tablet
3.	009661-EX	QSITA-M 50/100mg Tablet
4.	009662-EX	QSITA-M 50/1000mg Tablet
5.	009778-EX	EMPA-Q 10mg Tablet
6.	009779-EX	EMPA-Q 25mg Tablet
7.	009931-EX	EMPA-M 5/1000mg Tablet
8.	009176-EX	EMPA-M 5/500mg Tablet
9.	009932-EX	EMPA-M 12.5/500mg Tablet
10.	009933-EX	EMPA-M 12.5/1000mg Tablet
11.	009771-EX	ROSU-Q 5mg Tablet
12.	009772-EX	ROSU-Q 10mg Tablet
13.	009773-EX	ROSU-Q 20mg Tablet

Accordingly, brand name resemblance letter No. F-3-1/2024 (PR-II) dated 16-08-2024 was communicated to M/s Pharmevo (Pvt.) Ltd., Karachi wherein the firm through their legal consultant M/s Ali & Associates vide Dy. No. 9114 dated 02-09-2024 submitted the response which is reproduced below:-

We write upon the instructions of Pharmevo (Pvt.) Limited (herein after referred to as 'our client') and with reference to your with reference to your Letter dated 16/08/2024.

Please note that the subject letter and your directions contained therein to change the brand names Qsita, EMPA & Rosu (Brands), come as a cause of great concern to our client, since neither our client were intimated of any such complaint by Wilshire Private Limited, nor our client was given an opportunity of hearing on such complaint. Moreover, we note that Wilshire

Laboratories Private Limited (Wilshire Laboratories) has falsely claimed ownership of the said brands and withheld key information pertaining to the actual proprietorship of the Brands which vest with their former Principal/foreign Company and blatantly misrepresented the facts, in an attempt to mislead your good office.

In light of the above, we request you to provide us an extension till the 10th of September, 2024 to submit a comprehensive response on behalf of our client and highlight the information concealed by Wilshire Laboratories enabling you to take an informed decision.

Lastly, we would also like to bring to your attention that Wilshire Laboratories had also commenced a smear campaign against our client and threatened to cause disruption in our client's business by falsely claiming ownership over the said Brands. Therefore, being severely aggrieved by such actions, on behalf of our client we have filed a Suit bearing no. 7002 of 2024 before the Learned Intellectual Property Tribunal of Lahore and obtained a restraining order against the unlawful claims of Wilshire Laboratories and the same was intimated to your office vide our letter dated 23.08.2024. A copy of the said Letter along with the Order is attached herewith for your reference.

Meanwhile another reply was received in response to the same letter No. F-3-1/2024 (PR-II) dated 16-08-2024 from M/s Ali & Associates legal consultant of M/s Pharmevo (Pvt.) Ltd., Karachi vide Dy. No. 9549 dated 10-09-2024 which is reproduced below: -

We write upon instructions of PharmEvo (Pvt.) Limited ("our client") and further to our Letter dated 02.09.2024, wherein we requested for further time to respond to your subject letter 16/08/2024 directing our client to change the brand names of QSITA, QSITA-M EMPA-M, EMPA-Q, and ROSU-Q ("subject Brands"), as the same were registered in the name of Wilshire Laboratories Pvt. Ltd ("Wilshire Laboratories").

That by virtue of our Letter dated 02.09.2024, we informed your good office that Wilshire Laboratories is not the proprietor or owner of the subject Brands, as it was providing Contract Manufacturing services to a foreign company and we requested more time to provide you a

comprehensive response and supporting documents.

Thus, in addition to reiterating the contents of our earlier response, we would like to further submit as under;

1. *That the subject Brands are owned by Q Pharma Limited DMCC ("Q Pharma") and these were registered with DRAP in the name of Wilshire Laboratories to obtain the necessary licenses to manufacture and export these medicines/brands to Q Pharma, for sale in Kenya.*

2. *That subsequently, Q Pharma appointed our client for Contract manufacturing of the subject Brands and accordingly the Drug Registrations were obtained from your good offices. It is worth mentioning that these Drugs are only being exported to Q Pharma in Kenya, who holds the Marketing Authorization Holder of these drugs in Kenya, as such, there is no question of patient confusion arising in Pakistan or Kenya.*

3. *Moreover, as mentioned previously, Wilshire Laboratories is falsely claiming ownership of the subject Brands and in addition to our client seeking restraining orders dated 23.08.2024 in Suit 7002 of 2024, against Wilshire Laboratories from creating any disruption in their manufacture and supply of subject Brands to Q Pharma; we have also been informed that Q Pharma has also initiated action against Wilshire Laboratories baseless, false and groundless assertions over the subject Brands by filing a civil suit bearing no. 169 of 2024, before the Intellectual Property Tribunal of Lahore, which is the relevant forum to adjudicate disputes pertaining to Brand Names/ Trade Marks.*

4. *That we have also been informed that the premise of this action is to restrain Wilshire Laboratories from falsely claiming ownership of and from using the subject Brands, in any manner whatsoever and in acknowledgement of Q Pharma's proprietary rights, the*

Honorable Court has been pleased to restrain Wilshire Laboratories from claiming any proprietorship over the subject Brands vide Order dated 06.09.2024. The Order is attached herewith for your reference.

That in light of the above, we request your good office to dismiss Wilshire Laboratories baseless and unfounded assertions over the subject Brands, especially in light of the matter being sub-judice before the relevant forum i.e. the Intellectual Property Tribunal of Lahore.

Another letter was communicated to both the firms vide No. F-3-1/2024 (PR-II) dated 27-09-2024 dated 27-09-2024 wherein they were asked to provide updated status of registration of their products in the country of import. M/s Wilshire Laboratories (Pvt.) Ltd., Lahore has submitted the following response: -

Surprisingly, despite all the above, DRAP's letter dated 27.09.2024 seeks information from Wilshire Laboratories, the aggrieved party, regarding the status of registration of its pharmaceutical products in the country of import. It is submitted that this demand falls outside the purview of DRAP's and Registration Board's authority under the Drugs Aet, and there is no legal provision that empowers DRAP / Registration Board to seek such information from Wilshire Laboratories.

Wilshire Laboratories has consistently complied with all statutory requirements and applicable regulations, ensuring that its export-only products are not marketed or sold within Pakistan. The request for information regarding registration status in other countries does not pertain to DRAP's jurisdiction or responsibilities, and it in fact infringes upon the right conferred upon Wilshire Laboratories to market and sell its duly registered pharmaceutical products across the globe (other than Pakistan).

We therefore respectfully submit the following:

1. *DRAP should immediately cancel or suspend the fraudulent registrations obtained by Pharmevo (Private) Limited for the pharmaceutical products that infringe upon Wilshire's exclusive export-only licenses. Pharmevo's blatant fraud and disregard for regulatory instructions merit serious consequences.*

2. *DRAP should not impose unjustified demands on Wilshire Laboratories. especially as the aggrieved party in this matter. The requested information regarding foreign registrations is irrelevant to DRAP's mandate and should not be pursued.*

3. *DRAP should uphold its regulatory duty by taking prompt and decisive action against Pharmevo (Private) Limited. Wilshire Laboratories has cooperated fully with all regulatory requirements, and it expects the regulator to act justly in protecting its lawful rights.*

4. *DRAP should share and provide all and any correspondence, if any, undertaken by Pharmevo (Private) Limited with DRAP in respect of the subject matter and in case none has been undertaken as of this date. DRAP should share with us the steps taken by DRAP to safeguard the interests of Wilshire Laboratories conferred upon it by virtue of being the exclusive registered export-only license holder in respect of the aforesaid pharmaceutical products.*

5. *DRAP should ensure that until Pharmevo (Private) Limited complies with the direction issued to it vide Letter dated 16.08.2024 (to change the brand names), DRAP and its allied offices in provinces shall not issue any No-Objection Certificate (NOC) to Pharmevo (Private) Limited for the purposes of exporting such pharmaceutical products on the basis of alleged registration certificates obtained by it through fraud and misrepresentation.*

Failure to take appropriate action will leave Wilshire Laboratories with no option but to seek appropriate remedies, judicial or otherwise, to safeguard its rights and protect its valuable export-only licenses.

We trust that this matter will be given your immediate and serious attention to prevent further harm to Wilshire Laboratories' business operations and reputation.

Decision:

Registration Board deliberated the matter in detail and decided that the registrations of above mentioned brands shall be retained by that firm which will submit valid registration certificates of above mentioned products issued by Regulatory Authority of Kenya through Embassy of Kenya. The case shall be placed before Registration Board after submission of above information by the firm.

Case No. 04: CANCELLATION / DE-REGISTRATION OF DRUGS:

M/s. CCL Pharmaceuticals has submitted a request for cancellation / de-registration of drugs vide R&I Dy. No. 10782 dated 09-10-2024 which is reproduced below:-

We, M/s CCL Pharmaceuticals Pvt. Ltd. (DML No. 000052), located at 62 Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore, were granted drug registration vide letters no. F.3-11/2002-Reg-II (M-168) dated 14th February 2002 and no. F.3-8/2002-Reg-II (M-176) dated 10th February 2003 for following products (Copies of regn letters/renewals attached).

Sr. #	*Reg. No.*	*Product Name*
1.	*023985*	*Levocil Tablets 250mg (Levofloxacin)*
2.	*029542*	*Levocil Tablets 500mg (Levofloxacin)*

Since, we intend to shift the manufacturing of these products (tablet dosage form) to our PICS approved GMP plant i.e., M/s. CCL Pharmaceuticals (Pvt.) Limited, plot no. 710, Sundar Industrial Estate, Lahore (DML-000891); we would like to submit the request for deregistration of above said products for CCL Pharmaceuticals Pvt. Ltd., 62 Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore (DML-000052).

Further, we would like to inform that to cater the need of patients; we already had applied the registration of Levocil Tablets 250mg & 500mg (Levofloxacin) from our other plant and these products have already been approved in the 339th meeting of DRB for CCL Pharmaceuticals (Pvt) Ltd., Plot 710, Sundar Industrial Estate, Lahore (DML-000891) (copy from minutes attached for reference). Registration letter is waited. Further, the details of the other brands/products available in market is attached.

You are requested please to cancel registration of above said products at your earliest for issuance of registration of approved products at our other plant at Sundar Industrial Estate, Lahore.

Decision:

Registration Board acceded to the request of the firm for cancellation of registration of Levocil Tablet (Reg. No. 023985) and Levocil Tablet (Reg. No. 029542).

Case No. 05:- RESEMBLANCE OF COLOUR AND PATTERN OF ART WORK OF PRIMARY & SECONDARY LABEL & PACKING DUE TO SIMILARITY / RESEMBLANCE:

M/s Fynk Pharmaceuticals, Lahore submitted an application dated 01-12-2023 wherein the firm stated that colour & pattern of art work of primary & secondary label & packing of registered product **Voltex S.R. 100 Tablet (Reg. No. 060454)** of M/s Sapient Pharma, Lahore resembles with already registered product **Voveron SR 100mg Tablet (Reg. No. 036616)** of **M/s. Fynk Pharmaceuticals, 19-Km G.T. Road, Kalashah Kaku, Lahore.**

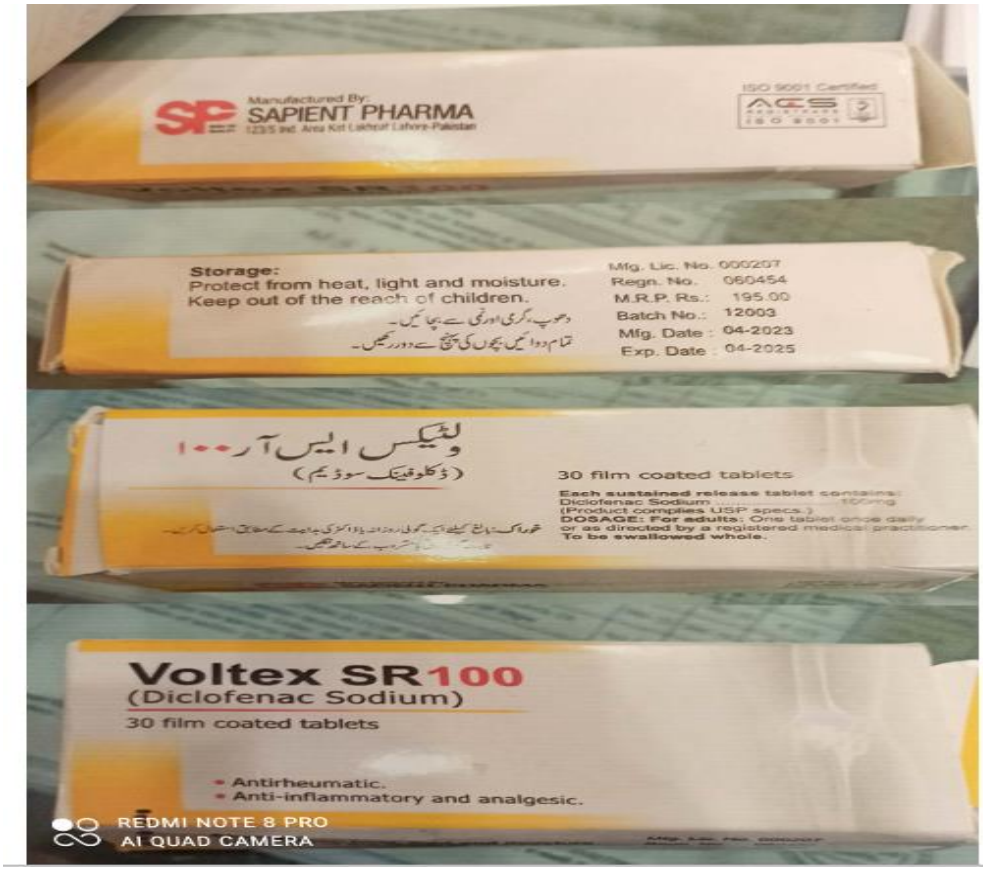
After evaluation of the application, a deficiency letter vide letter No. F. No. 3-1/2024 (PR-II) dated 22-01-2024 was communicated to the firm M/s. Fynk Pharmaceuticals, Lahore to provide evidence of resemblance i.e. outer pack of M/s Sapient Pharma's product. The firm submitted the following reply dated 31-01-2024 which is reproduced below:-

APPLICATION FOR CHANGE OF COLOUR AND PATTERN OF ART WORK OF PRIMARY AND SECONDARY LABEL AND PACKING OF VOLTEX S.R. 100 TABLET (REGN. NO. 060454)

Respected Sir,

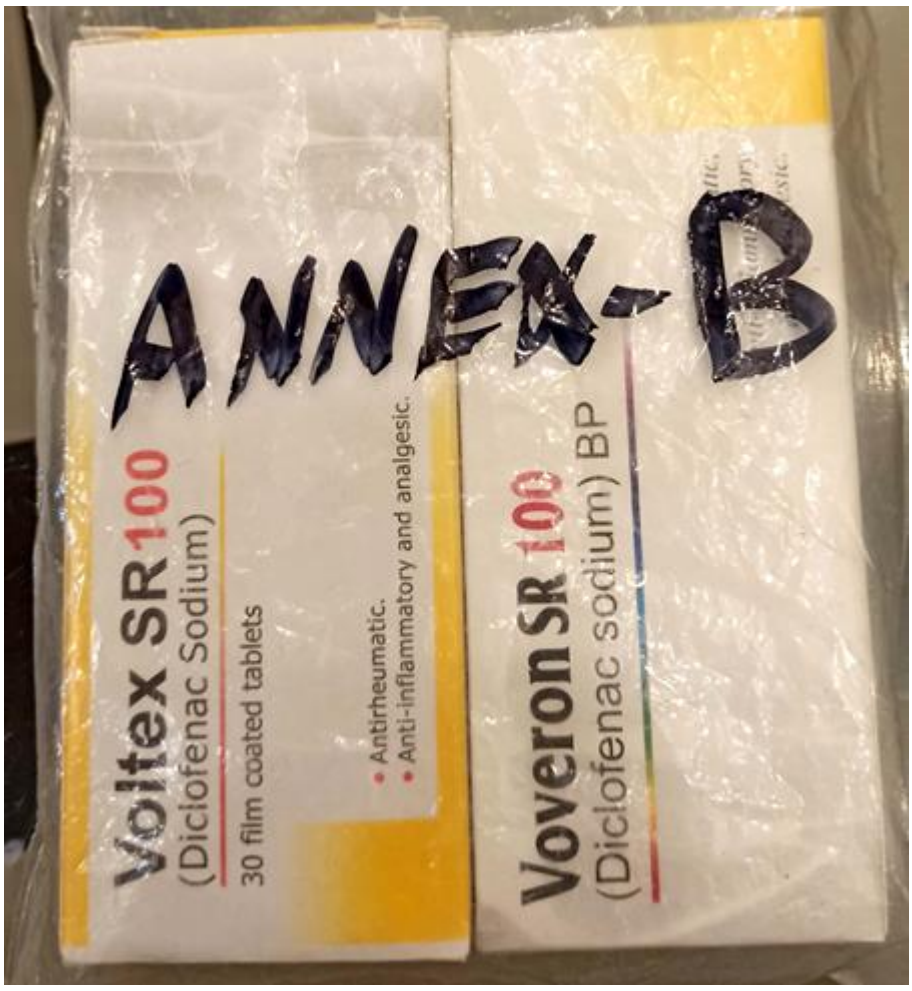
Reference to your letter No. F.No 3-1/2024(PR-II), Dated: 22-January-2024, we are pleased to submit the "Evidence of resemblance Le. outer pack of M/s Sapient Pharma's product Namely Voltex SR 100 Tablet under Registration No. 060454"

So you are humbly requested to cause M/s Sapient Pharma, Lahore with immediate effect the stoppage of sale of "Voltex S.R 100", 100", withdrawal of all sold batches of the said product from the market, and change of the color and pattern of the artwork of primary and secondary label and packing of the product "Voltex S.R 100" and till all aforesaid compliance, suspend the registration of the product "Voltex SR 100" in the best interest of justice.


Manufactured By:
SAPIENT PHARMA
ISO 9001 Certified
Storage:
Protect from heat, light and moisture.
Keep out of the reach of children.
Mfg. Lic. No. 000207
Regn. No. 060454
M.R.P. Rs.: 195.00
Batch No.: 12003
Mfg. Date : 04-2023
Exp. Date : 04-2025
30 film coated tablets
Voltex SR100
(Diclofenac Sodium)
30 film coated tablets
• Antirheumatic.
• Anti-inflammatory and analgesic.
REDMI NOTE 8 PRO
AI QUAD CAMERA

Voltex SR100
(Diclofenac Sodium)
Voveron SR 100
(Diclofenac sodium) BP

Voltex SR100
(Diclofenac Sodium)
30 film coated tablets
• Antirheumatic.
• Anti-inflammatory and analgesic.
Voveron SR 100
(Diclofenac sodium) BP
VOLTEX SR 100
(Diclofenac Sodium)
SAPIENT PHARMA
Voveron SR 100
(Diclofenac Sodium BP)


ANNEX-B
Voltex SR100
(Diclofenac Sodium)
30 film coated tablets
• Antirheumatic.
• Anti-inflammatory and analgesic.
Voveron SR 100
(Diclofenac sodium) BP

Accordingly, resemblance letter vide letter No. F-3-1/2024 (PR-II) dated 17-10-2024 was issued to M/s Sapient Pharma, Lahore for change of colour and pattern of art work of primary & secondary label & packing. M/s Sapient Pharma submitted the following reply dated 29-10-2024 which is reproduced below:-

Reply to Letter dated 17th October, 2024 BY M/s Sapient Pharma, CHANGE OF COLOUR AND PATTERN OF ART WORD OF PRIMARY & SECONDARY LABEL & PACKING DUE TO SIMILARITY/RESEMBLANCE.

Respectfully Submitted:

With reference to your letter and subject mentioned above, under M/s Sapient Pharma, Lahore, would like to explain as under.

That as alleged by your kind self in your letter that our product VOLTEX SR 100 Tablet (Registration No.060454) which was registered on 02nd October, 2009, have resemblance / similarity of colour & pattern of art work of primary & secondary label & packing with one product namely VOVERON SR 100mg which is manufactured by M/s FYNK Pharma, Kala shah Kaku.

It is submitted that the answering respondent did not copy the color & pattern of Art work of primary & secondary label & packing from one product namely VOVERON SR 100mg which is manufactured by M/s FYNK Pharma, Kala shah Kaku and if we suppose the said M/s FYNK Pharma copies our color & pattern of art work of primary & secondary label & packing then they should ask to change their label & packing.

In the above mentioned circumstances, which are alleged in your letter, it is respectfully submitted that there are 4 aspects which had to be ascertained, which are submitted as hereinafter,

1. *Date of registration of both products, for which kindly provide registration certificate of other product i/e Voveron SR 100mg manufactured by M/s FYNK Pharma, Kala Shah Kaku.*

2. *Comparison of labels of both products, for which kindly provide primary and secondary labels of other product i/e Voveron SR 100mg manufactured by M/s FYNK Pharma, Kala Shah Kaku which is alleged by your kind self has resemblance / similarity of colour & pattern of Art work of primary & secondary label & packing.*

3. *And if there was resemblance / similarity of colour & pattern of Art work of primary & secondary label & packing between both product then why this objection was not raised at the time of registration when the art work of the primary and secondary label of our product was attached with the application of registration.*

4. *That it is also hereby submitted that we are manufacturing and selling this product since from the last 15 years, till then neither DRAP nor M/s FYNK Pharma raised any objection, which at this belated stage has arise which cause damage and loss to our reputation and huge quantity of already printed primary and secondary labels of our product.*

Under the circumstances explained above it is most respectfully prayed that kindly provide the above referred documents / labels to conclude and resolve the issue once for all.

It is further submitted that the answering respondent is hereby assures and ready to fully comply with in accordance with law and the rules, if any.

Decision:

Registration Board advised to refer the case to QA & LT Division for thorough assessment and for presenting the assessment report in Registration Board. The Board further advised that in future all such cases will be referred to QA & LT Division and assessment report will be presented before Registration Board for cosnideration.

Case No. 06:- **REQUEST FOR CANCELLATION / DE-REGISTRATION OF LEUKOZOLE 100MG CAPSULE (REG. NO. 012043-EX) REGISTERED FOR EXPORT PURPOSE.**

M/s. CCL Pharmaceuticals (Pvt.) Ltd, Lahore submitted an online application vide Tracking ID: 18J-3LD-LDJS wherein the firm requested for change in title of MAH/ Manufacturer to M/s CCL Pharmaceuticals (Pvt.) Ltd., Plot No.710, Sunder Industrial Estate, Lahore for the export product "Leukozole 100mg Capsule (Reg. No. 012043-EX). The case was discussed in 132nd Meeting of PRVC and the case was approved subject to submission of Application Form as per Appendix I of PRV Guidelines Ver. 2 and differential fee of Rs. 45000/-.

Accordingly, deficiency letters were communicated to the firm vide letter no. No. F-132-PRVC/2024 (PR-II) dated 10-10-2024 & 10-10-2024. The firm submitted a request for cancellation/de-registration of drug registered for export purpose vide R&I Dy. No. 11762 dated 01-11-2024 which is reproduced below:-

This refers to your letter no. F.132-PRVC/2024 (PR-II) dated 10-10-2024 (copy attached for reference).

Sr. #	***Registration No.***	***Product Name***
1.	*012043-EX*	*Leukozole 100mg Capsule* *Each capsule contains:* *Fluconazole….200mg*

Since, we are no more interested to manufacture said product due to no demand in export, we would like to submit the request for deregistration of above said product.
You are requested please to cancel registration of above said product registered for export purpose for M/s. CCL Pharmaceuticals (Pvt.) Limited (formerly M/s. Dynatis Pakistan), Plot No. 710, Sundar Industrial Estate, Lahore (DML-000891).

Decision:

Registration Board acceded to the request of the firm for cancellation of registration of Leukazole 100mg Capsule (Reg. No. 012043-EX).

Case No. 07: Change of registration status from previous manufacturing site i.e M/s Gray's Pharmaceuticals Plot No 442, Street No. 7, Sector I-9/2, Industrial Area Islamabad to new manufacturing site i.e M/s Gray's Pharmaceuticals Plot No. 02 Street No 03 National Industrial Zone, Rawat (DML No. 517) deferred in 313th meeting of Registration Board.

Sr. No	Reg. No.	Brand Name & Composition	Initial date of Registration PRV (If any)	Date of application (R&I) Fee submitted	RRA status	Decision of 313th DRB
	1	II	III	IV	V	VII
1.	063317	Escit Dispersible Tablet 10mg Each dispersible tablet contains: Escitalopram (as Oxalate) … 10mg (Gray's Specs)	02-06-2010	1806 -(R&I) dated 07.05.2012 Rs. 8000/- 191-(R&I) dated 13-01-2016 Rs. 12000/- **16.06.2020** Rs. 10000/-	Not confirmed	Deferred for following: i) Differential fee Rs. 15,000/- as renewal application for year 2020 is submitted after due date but within 60 days. **ii)** Deferred for confirmation of approval

						of formulation in RRA.
2.	068663	Duloxet 20mg Capsule Each capsule contains:- Coated Pelllets of Duloxetine eq. to Duloxetine… 20mg (Grays Specs) **Source of Pellets**: M/s. R.A Chempharma, Ltd., 6-3-1239/2 Amar House, 4th Floor Raj Bhawan Road, Somajiguda, Hyderabad 500082-India	29-01-2011	1466 -(R&I) dated 03.05.2016 Rs. 20000/- **28.01.2021** Rs. 10000/-	To be standardized as "Enteric coated pellets of duloxetine eq to duloxetine	Deferred for submission of differential fee for the year 2016 & 2021 being imported source of pellets.
3.	068664	Duloxet 40mg Capsule Each capsule contains:- Coated Pelllets of Duloxetine eq. to Duloxetine… 40mg (Grays Specs) **Source of Pellets**: M/s. R.A Chempharma, Ltd., 6-3-1239/2 Amar House, 4th Floor Raj Bhawan Road, Somajiguda, Hyderabad 500082-India	29-01-2011	33 -(R&I) dated 11.01.2016 Rs. 20000/- **28.01.2021** Rs. 10000/-	To be standardized as "Enteric coated pellets of duloxetine eq to duloxetine"	Deferred for submission of differential fee for the year 2016 & 2021 being imported source of pellets.

Remarks:

For sr. no. 1:

The firm has submitted differential fee of Rs. 15000/-. For already registered formulations which are not available in RRAs, DRAP Authority in its 179th meeting decided that PE&R shall verify the following:

- The product/ formulation has never been withdrawn/ deregistered/ unlicensed on safety reasons by any RRA/ML4 NRA.
- The manufacturer has established pharmacovigilance verified by the Division of Pharmacy Services of DRAP according to the procedures/ guidelines of DRAP.
- The international pharmacovigilance data of subject product/ formulation do not show any critical ADR reports according to the UPSALA database.
- The product maintains the characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies.

For sr. no. 2 & 3:

The firm has submitted differential fee of Rs. 10000/- for each product for renewal application year 2016 and differential fee of Rs. 15000/- for renewal application of year 2021. Moreover, the firm has also requested to change the source of pellets from M/s. R.A Chempharma, Ltd., 6-3-1239/2 Amar House, 4th Floor Raj Bhawan Road, Somajiguda, Hyderabad 500082-India to M/s Vision Pharmaceutical (Pvt.) Ltd., Plot No. 22-23, Industrial Triangle, kahuta Road, Islamabad.

Decision:

Registration Board decided as follows:

- **Deferred the request of firm for product at sr. no. 1 for evidence of availability of formulation in RRAs.**
- **Acceded to request of firm for products at S.No 2 and 3 for change in registration status from previous manufacturing site i.e. M/s Gray's Pharmaceuticals Plot No 442, Street No. 7, Sector I-9/2, Industrial Area Islamabad to new manufacturing site i.e. M/s Gray's Pharmaceuticals Plot No. 02 Street No 03 National Industrial Zone, Rawat (DML No. 517) along with change in source of pellets from M/s. R.A Chempharma, Ltd., 6-3-1239/2 Amar House, 4th Floor Raj Bhawan Road, Somajiguda, Hyderabad 500082-India to M/s Vision Pharmaceutical (Pvt.) Ltd., Plot No. 22-23, Industrial Triangle, kahuta Road, Islamabad.**

Export Facilitation Desk

Case No. 01: Registration of Drug (s) of M/s Indus Pharma (Pvt.) Ltd, Plot No. 26-27, 63-67, Sector-27, Korangi Industrial Area, Karachi, for export purposes only approved in 107th PRVC.

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; (Pages. 494-540/C)
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML.	Copy of DML provided (Page- 504 /C). Approval of relevant section verified from letter No. F 2-13/85-Lic dated 03-06-2022 (Page 505/C).
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 17-12-2021 (Page 507/C).
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 (Pages. 508-541/C)

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.	Lacosa-Q 50mg Tablet Each film coated tablet contains: Lacosamide.....50mg	Lalap 50mg tablet by M/s Genix	Dy. No.1028/23 (12.09.2023) Rs.30,000/- (29.08.2023)
2.	Lacosa-Q 100mg Tablet Each film coated tablet contains: Lacosamide.....100mg	Lalap 100mg tablet by M/s Genix	Dy. No.1029/23 (12.09.2023) Rs.30,000/- (29.08.2023)

Decision of 107th PRVC:

The Chairman Registration Board on recommendation of Committee acceded to request of the firm for registration of products at sr. no. 72-73 for Export Purpose Only subject to submission of more brand names.

Updated Status: The applied brand names are already registered in name of M/s CCL for Export registrations vide registration number 012975-EX & 012975-EX. M/s CCL Pharmaceuticals have provided NOC in name of M/s Indus Pharma. However, CCL Pharmaceuticals have not applied for change of brand name for its registered products.

Decision:

Registration Board advised M/s CCL Pharmaceuticals to provide alternate brand names for their registered products as they have provided the NOC in name of M/s Indus Pharma. Registration Board further advised that if the firm provides alternate names, then Chairman Registration Board is authorized for deciding the case.

Case Referred 138-PRVC

Case No.02: Registration of Drug (s) of M/s Amros Pharmaceuticals, Plot No. A-96, S.I.T.E. 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; (Pages.46-50/C)
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 (Page-51/C). Approval of relevant section verified from letter No. F 2-8/93-Lic dated 27-06-2019 (Page 52/C).
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 13-10-2020 (Page 53/C).
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 (Pages. 54/C)

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.	Layrik Capsule 300mg Each capsule contains: Pregabalin.....300mg	Gabica 300mg capsule by M/s Getz	Dy. No. 8260/22 (21.09.2022) Rs.30,000/- (13.09.2022) Brand name resemble with innovator brand LYRICA by M/s PFIZER
2.	Layrik Capsule 150mg Each capsule contains: Pregabalin.....150mg	Gabica 150mg capsule by M/s Getz	Dy. No. 8261/22 (21.09.2022) Rs.30,000/- (13.09.2022) Brand name resemble with innovator brand LYRICA by M/s PFIZER

Decision of 87th PRVC:

The Committee considered the case and deferred the request for more brand names.

Updated Status:

The proposed brand name resembles with already registered brand name Lyrica of M/s Pfizer Pakistan. The firm again requested for the same brand name. However, as per practice the firm was advised to provide evidence of approval of proposed brand name in country of Import. Now, the firm has submitted that the brand name will be approved in country of import after grant of registration from Pakistan.

Decision of 138th PRVC:

Referred to Registration Board.

Decision:

Registration Board advised the firm to provide more brand names and if the firm provides alternate names, then there will be no need to again present the case before Registration Board and Chairman Registration Board is authorized for further processing

Case No. 03: Registration of Zolip 10mg Tablet granted exclusively for Export Purpose in name of M/s Himark Laboratories Pvt. Ltd., Lahore.

Chairman Registration Board in 119th meeting of Post Registration Variation Committee approved following product and registration for Export purpose exclusively was granted as per following details:

Sr. No.	Reg. No.	Name of Drug (s) & Composition	Letter No. and Date of Issuance
1.	015623-EX	Zolip 10mg Film Coated Tablet Each Film Coated Tablet Contains: Zolpidem Tartrate……..10mg	No. F. 119-PR-II/2024-EFD Dated: 15-05-2024

The aforementioned drug is included in the list of Psychotropic substances and Licensing Division of DRAP has confirmed that firm does not have the approved Psychotropic Tablet Manufacturing Facility (the same was not informed by them at the time of submission of application). The said scenario provokes the provisions of Section 7 (11) (a, d) and 42 of the Drug Act, 1976 & Rule 24 (17) of Drugs (Licensing, Registering & Advertising) Rules, 1976.

Accordingly, the firm was advised to appear in person before Registration Board to explain their position as to why not the registration of aforesaid product be cancelled with immediate effect. The firm vide its letter dated 04-12-2024 submitted that they decided to cancel the registration of said product as they don't have Psychotropic Section.

Decision:

Registration Board decided to cancel the registration of Zolpip 10mg Tablet (Reg. No. 015623-EX).

Import & Vet Section

Case No.01 REQUEST OF M/S RA HEALTH CARE (SMC-PVT.) LTD FOR EXEMPTION FROM LOCAL LABELING FOR HOSPITAL USE PRODUCT (SEVOFLURANE LIQUID FOR INHALATION).

M/s RA Health Care (SMC-Pvt.) Ltd, 2nd Floor Building No. 50 Mir Arcade, Mini Commercial Phase 7, Bahria Town, Rawalpindi has stated with a fee of Rs.10,000/- that to meet local labeling Laws, our global manufacturing and supply chain setups require adjustments in manufacturing flow which will take a considerably long time due to the company's operational complexity. Detail of product is as under:-

Details of Product:

S. No.	Reg. No.	Name of Product	Remarks
1.	115751	Sevoflurane Liquid For Inhalation Each aluminium bottle contains:- Sevoflurane……. 250ml (USP Specification)*	E-application No. Reg. Letter date 16th February, 2024
Product License Holder:		M/s Baxter Healthcare Corporation, 1 Baxter Parkway, Deerfield, IL 60015, United States of America.	
Manufacturer:-		M/s Baxter Healthcare Corporation, Route 3-Km 144.2, Guayama, Puerto, Rico 00784, United States of America	

Firm requested for exemption from local labeling for a period of 03 years as product is for hospital use only and will be directly used by qualified anesthesiologists / health care professionals in surgical theater within hospital settings.

Further firm inform that we requested for exemption from local labeling as our product is for hospital use only and will be directly used by qualified anesthesiologists / health care professionals in surgical theater within hospital settings.

Due to quality issues, it is not possible to get the product locally labeled, for the safety of patients we request you to give us exemption from local label requirements for a period of 3 years. It is requested to please accept our request at your earliest convenience, so we can make the product available for the patient.

Decision M-339

The Registration Board advised the firm to reapply with a local agreement with a DML holder to comply with the Drugs (Labelling & Packing) Rules, 1986.

Reply by firm as under:

We are writing to follow-up on our application for exemption from local labeling for our registered product SEVOFLURANE (Reg # 115751), which was reviewed in 339th DRB meeting.

In view of DRB decision, we are obliged for your consideration by grating us the flexibility to perform local labelling however anesthesia inhaled gases are highly sensitive products with regards to its manufacturing, quality control and hazardous standards protection is strongly prohibited to carry manufacturing activities and re-opening the pack in other premises once its formally released by principal quality division.

Further, Global Product License Holder advises against relabeling finished product in Pakistan due to high risk associated with poor handling potentially compromising the quality of Baxter's Sevoflurane.

Specifically, leakage of anesthesia gas since the Aluminum bottle is sealed with screw-on caps under quality surveillance with special protocols.

Therefore, we have re-evaluated all the possibilities to ensure compliance with labeling requirements and conducting assessment with Global Manufacturer to supply Sevoflurane with following details (Registration number, MRP & Urdu) in accordance with Drugs (Labelling & Packing) Rules, 1986.

We are fully committed to abide local laws in its best sprit however, the same SKUs are being supplied across middle east and Africa markets with the same label and identical product knowing that having shared labels across multiple countries will enhance the supply chain and improve the product availability in Pakistan and the other courtiers. Hence, change in the label would impact all markets in scope along securing re-approvals which will lead to a possible implementation within next 9 months as the manufacturing planning to supply multiple markets scheduled in advance due to high demand of bulk quantities and the change control procedure will require minimum 9 months period to implement new label.

Firm requested for 6-9 months grace period for 12,000 units to be imported in international label in 4 divided consignments, supplied to Military Hospitals for critical surgical procedures.

Proceeding of 343rd Meeting:

Jam Muhammad Aslam representative eof Law Divison opined that as per Rule 3 of Drugs (Labelling & Packing) Rules, 1986, the Registration Baord may allow relaxtion any of the condition mentin aforementioned Rules. Members of Rsgitration Baord were of the opinion that other brands of the sevoflorane are available and can be supplied to the institution and instant provision may be used in extraordinary situations. Moreover, in such situation the Board has also allowed import of such products in international packs with local printing as per the Drugs (Labelling & Packing) Rules, 1986. However, Mr. Syed Adnan Rizvi Director DTL, Govt. of Sindh, Karachi was of the opinion that the firm's request may kindly be acceded to import for 12,000 units of sevoflurane in international packing as the product is highly needed in Military and other tertiary care hospitals to avoid spread of spurious and illegal import of life-saving drugs like Iso and sevoflurane in the market.

Decision: The Registration Board has decided to acced to the request subject to the submission of letter from the concerned Military Hospitals stating that they have no objection to the supply of Sevoflurane from M/s Baxter Healthcare Corporation, 1 Baxter Parkway, Deerfield, IL 60015, United States of America, in international packaging without mentioning of registration number, Urdu version of the (i) Name of drug (ii) Dosage and (iii) Instructions, the distinctive batch number, date of manufacture and the maximum retail price along with Marketing Authorization Holder in Pakistan.

Case.No.02. <u>REQUEST OF M/S AL QASIM ENTERPRISES, RAWALPINDI FOR REGISTRATION OF "SEVOPRANE INHALATION SOLUTION" TOTHEIR NAME FROM M/S MUKHTAR ENTERPRISES ALONGWITH CHANGE OF NAME OF MANUFACTURER.</u>

Subject case discussed in 340th meeting of registration Board as under:

M/s Al Qasim Enterprises, Lower Portion House No.134-E, Street No.1, Sabzazar Range Road, Rawalpindi has submitted an application for Registration of following already registered product from M/s Mukhtar Enterprises, Lower Portion, 151-C Block, Faisal Town, Lahore to their name. Detail of each proposed product is as under: -

Product: Sevoprane Inhalation Solution (Reg. No. 110584)			
S. No.	**Name / Detail of Documents**	**Documents / information provided by firm**	
1.	Product Name/ Composition	**As per Reg. No.** Sevoprane Inhalation Solution Each bottle contains: Sevoflurane…… 100% (As per Innovator's Specification)*	**As per CoPP (No.2024-A1-478)** Sevoprane Inhalation Solution Each bottle contains: Sevoflurane…… 100%
	Reg. date / renewal	25th August, 2022	

	Name and address of Applicant(Transferee)	M/s Al Qasim Enterprises, Lower Portion House No.134-E, Street No.1, Sabzazar Range Road, Rawalpindi.	
	Name of Transferor	M/s Mukhtar Enterprises, Lower Portion, 151-C Block, Faisal Town, Lahore.	
	Detail of Drug Sale License	**DSL No. 01-374-0176-039416D (valid upto 07-03-2028)** **Address:** M/s Al Qasim Enterprises, Lower Portion House No.134-E, Street No.1, Sabzazar Range Road, Rawalpindi.	
	Name and address of Manufacturer / Product License Holder	**As per Reg. Letter.** **Product License Holder & Manufacturer:** M/s Ilsung Pharmaceuticals Co. Ltd, 349, Sandan-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea	**As per CoPP (No.2024-A1-478).** **Product License Holder &** **Manufacturer:** M/s IL Sung IS Co., Ltd, (Excluding Building B. excluding parts of building D) 349, Sandan-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea
	Exporting Country	Korea	
	Diary No. & Date of R& I	Dy. No. 9293 Dated 04/09/2024.	
	Finished Product Specification	As per Innovator's Specifications	
	Shelf life	36 Months	
	MRP/Pack Size	250ml Bottle	

The firm has submitted the following supporting documents / information for approval of above transfer of registrations: -

a) Application with a fee of Rs.300,000/-.
b) Copy of Reg. letter issued on 25th August, 2022.
c) Original & Legalized CoPP issued by Korea.
d) Original Legalized of Letter of authorization in the name of M/s Al Qasim Enterprises,Lower Portion House No.134-E, Street No.1, Sabzazar Range Road, Rawalpindi.
e) Original Legalized Termination letter from Product License Holder in the name of M/s Mukhtar Enterprises, Lower Portion, 151-C Block, Faisal Town, Lahore.
f) Original NOC for transfer of registration from M/s Mukhtar Enterprises, Lower Portion,151-C Block, Faisal Town, Lahore **(issued on 13-08-2024).**
g) Undertaking.

Decision M-340:
Registration Board considered and decided to call personal hearing to M/s Mukhtar Enterprises, Lower Portion, 151-C Block, Faisal Town, Lahore, to appear before theRegistration Board.

Proceeding:
CEO of Mukhtar enterprises, Hafiz Farooq Ahmad, appeared before the Board and confirmed that they have issued NOC for registration of Sevoprane Inhalation Solution Registration in the name of M/s Al Qasim Enterprises,Lower Portion House No.134-E, Street No.1, Sabzazar Range Road, Rawalpindi.

Decision:
Keeping in view the above position, Registration Board decided to approve the change of importer/ MA Holder in Pakistan for Sevoprane Inhalation Solution(Reg.No. 110584) from the name of M/s Mukhtar Enterprises, Lower Portion, 151-C Block, Faisal Town, Lahore to the name of M/s Al Qasim Enterprises, Lower Portion House No.134-E, Street No.1, Sabzazar Range Road, Rawalpindi as per policy for imported finished drug registration (in accordance with details of composition and manufacturer as per CoPP). Registration Board authorized its chairman for approval of change of Marketing authorization holder (Both for Imported and locally manufactured products). Furthermore, NOC shall be verified before issuance of letter. The pending cases shall be processed without waiting for finalization of minutes.

Case No.03. **REQUEST OF M/S MARTIN DOW LIMITED, KARACHI FOR REGISTRATION OF FEMFERTIL CAPSULE 200MG & 100MG TO THEIR NAME FROM M/S ACUMEN PHARMA (PVT) LTD, RAWALPINDI.**

Subject case discussed in 339th meeting of registration Board as under:

M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi has submitted an application for Registration of following already registered product from M/s Acumen Pharma (Pvt) Ltd, Plot No.39&40, Street No.S-2, RCCI, Industrial Estate, Rawat to their name. Detail of each proposed product is as under: -

Product: Femfertil Capsule 200mg (approved in 258th RB)			
S. No.	**Name / Detail of Documents**	**Documents / information provided by firm**	
1.	Product Name/ Composition	**As per approval** Fertigest Capsule 200mg. Each soft gelatin capsule contains:- Progesterone …..200mg	**As per CoPP/LOA:** Femfertil Capsule 200mg. Each soft gelatin capsule contains:- Progesterone …..200mg
	Reg. date / renewal status	approved in 258th RB	
	Name and address of Applicant(Transferee)	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.	
	Name of Transferor	M/s Acumen Pharma (Pvt) Ltd, Plot No.39&40, Street No.S-2, RCCI, Industrial Estate, Rawat	
	Detail of Drug Sale License	**DSL No. DHOKK/(drugs)-69/2024 (valid upto 16-06-2029)** **Address:** M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi. **Godown addresses:** Plot No.32, Sector 16 K.I.A., Karachi. 1st Floor, Plot NO.211 Sector 23 K.I.A., Karachi. Plot No.116, Sector 15 K.I.A., Karachi	
	Name and address of Manufacturer / Product License Holder	**As per Minutes 258 RB.** **Product License Holder & Manufacturer:** M/s Laboratorios Leon Farma, C/La Vallina s/n, P.INavatejera, 24008 Villaquilambre (Leon) Spain	**As per CoPP (No.36918/2023).** **Product License Holder & Manufacturer:** M/s Laboratorios Leon Farma, S.A. C/La Vallina s/n, Poligono Industrial Navatejera Villaquilambre, 24008 Leon, Spain.
	Name of exporting Country	Spain	
	Diary No. & Date of R& I	Dy. No. 5734 Dated 03/06/2024.	
	Finished Product Specification	As per Innovator's Specifications	
	Shelf life	24 Months	
	MRP/Pack Size	As per DPC, Pack size 15's (as per CTD Doc)	
Product: Femfertil Capsule 100mg (approved in 258th RB)			
S. No.	**Name / Detail of Documents**	**Documents / information provided by firm**	
2.	Product Name/ Composition	**As per approval** Fertigest Capsule 100mg. Each soft gelatin capsule contains:- Progesterone …..100mg	**As per CoPP/LOA:** Femfertil Capsule100mg. Each soft gelatin capsule contains:- Progesterone …..100mg
	Reg. date / renewal status	approved in 258th RB	
	Name and address of Applicant(Transferee)	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.	
	Name of Transferor	M/s Acumen Pharma (Pvt) Ltd, Plot No.39&40, Street No.S-2, RCCI, Industrial Estate, Rawat	

	Detail of Drug Sale License	**DSL No. DHOKK/(drugs)-69/2024 (valid upto 16-06-2029)** **Address:** M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi. **Godown addresses:** Plot No.32, Sector 16 K.I.A., Karachi. 1st Floor, Plot NO.211 Sector 23 K.I.A., Karachi. Plot No.116, Sector 15 K.I.A., Karachi	
	Name and address of Manufacturer / Product License Holder	**As per Minutes 258 RB.** **Product License Holder & Manufacturer:** M/s Laboratorios Leon Farma, C/La Vallina s/n, P.INavatejera, 24008 Villaquilambre (Leon) Spain	**As per CoPP (No.36934/2023).** **Product License Holder & Manufacturer:** M/s Laboratorios Leon Farma, S.A. C/La Vallina s/n, Poligono Industrial Navatejera Villaquilambre, 24008 Leon, Spain.
	Name of exporting Country	Spain	
	Diary No. & Date of R& I	Dy. No. 5735 Dated 03/06/2024.	
	Finished Product Specification	As per Innovator's Specifications	
	Shelf life	24 Months	
	MRP/Pack Size	As per DPC, Pack size 30's (as per CTD Doc)	

The firm has submitted the following supporting documents / information for approval of above transfer of registrations: -

a) Application with a fee of Rs.300,000/- for each product.
b) Copy of extract of minutes M-258.
c) Original & Legalized CoPP issued by Spain.
d) Original Legalized of Letter of authorization in the name of M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.
e) Original Legalized Termination letter from Product License Holder in the name of M/s Acumen Pharma (Pvt) Ltd, Plot No.39&40, Street No.S-2, RCCI, Industrial Estate, Rawat.
f) Original NOC for transfer of registrations from M/s Acumen Pharma (Pvt) Ltd, Plot No.39&40, Street No.S-2, RCCI, Industrial Estate, Rawat **(issued on 23-01-2024).**
g) Undertaking.

Decision: -

The Registration Board deferred the case for personal hearing of M/s Acumen Pharma (Pvt) Ltd, Plot No.39&40, Street No.S-2, RCCI, Industrial Estate, Rawat along with records.

Proceeding:

Manager Operation of M/s Acumen Pharma (Pvt) Ltd, Plot No.39&40, Street No.S-2, RCCI, Industrial Estate, Rawat Rehan Ullah, appear before the Board and confirmed that they have issued NOC for registration of Fertigest Capsule 100mg & Fertigest Capsule 200mg in the name of M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.

Decision:

Keeping in view the above position, Registration Board decided to approve the change of importer/ MA Holder in Pakistan for Fertigest Capsule 100mg & Fertigest Capsule 200mg M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi as per policy for imported finished drug registration (in accordance with details of composition and manufacturer as per CoPP)

Case No.03. <u>REQUEST OF M/S AMGOMED (DISTRIBUTOR), ISLAMABAD FOR REGISTRATION OF LETRASAN 2.5MG TABLETS TO THEIR NAME FROM M/S THE SEARLE COMPANY Ltd, KARACHI.</u>

M/s Amgomed (Distributor), Islamabad has submitted an application for transfer of Registration of following already registered product from M/s The Searle Company Ltd, F-319, SITE, Karachi to their name. Detail of each proposed product is as under: -

Product: Letrasan 2.5mg Tablets (Reg. No.087519)			
S. No.	**Name / Detail of Documents**	**Documents / information provided by firm**	
1.	Product Name/ Composition	**As per Reg. Letter** Letrasan 2.5mg Tablets Each Film Coated Tablet Contains: Letrozole……. 2.5MG	**As per CoPP:** Letrasan 2.5mg Film Coated Tablets Each Film Coated Tablet Contains: Letrozole……. 2.5mg
	Reg. date / renewal status	Reg. Letter issued on 06-04-2018 Renewal submit on	
	Name and address of Applicant(Transferee)	M/s Amgomed (Distributor), Office No. 4, 1st Floor, Ghousia Plaza, Jinnah Avenue Blue Area, Islamabad.	
	Name of Transferor	M/s The Searle Company Ltd, F-319, SITE, Karachi	
	Detail of Drug Sale License	**DSL No. DHO-ISB-1881 (valid upto 21-03-2026)** **Address:** M/s Amgomed (Distributor), Office No. 4, 1st Floor, Ghousia Plaza, Jinnah Avenue Blue Area, Islamabad. **Godown addresses:** Office No.5 1st Floor Rose-1, Plaza, I-8, Markaz, Islamabad	
	Name and address of Manufacturer / Product License Holder	**As per Reg. Letter.** **Manufacturer:** M/s. Deva Holding A.S., Cerkezkoy Organize Sanayi Bolgesi, Karaagac MAH., Fatih Bulvari, no: 26 Kapakh/ Tekirdag/ Turkey. **Product License Holder:** M/S. Deva Holding A.S., Halkali Merkez MAH. Basin Ekspres Cad. No:1 34303, kucukcekmece - Istanbul/ Turkey.	**As per CoPP (No.2024/1510) Dated 08-05-2024** **Manufacturer:** M/s. Deva Holding A.S., Cerkezkoy Organize Sanayi Bolgesi, Karaagac MAH., Fatih Bulvari, No: 26 Kapakh/ Tekirdag/ Turkey. **Product License Holder:** M/S. Deva Holding A.S., Halkali Merkez MAH. Basin Ekspres Cad. No:1 34303, kucukcekmece - Istanbul/ Turkey.
	Name of exporting Country	Turkey	
	Diary No. & Date of R& I	Dy. No./ID- W2V-4LU-3GR1	
	Finished Product Specification	(USP Specification)	
	Shelf life	36 Months	
	MRP/Pack Size	Rs.6000/30's (as per Reg. Letter)	

The firm has submitted the following supporting documents / information for approval of above transfer of registrations: -

a) Application with a fee of Rs.65,000/-.
b) Copy of Reg. letter / last renewal.
c) Original & Legalized CoPP.
d) Original Legalized of Letter of authorization.
e) Original Legalized Termination letter.
f) Original NOC for transfer of registrations **(issued on 06-05-2024).**
g) Undertaking.

Decision:

Keeping in view the above position, Registration Board decided to approve the change of MA Holder in Pakistan for Letrasan 2.5mg Tablets (Reg. No. 087519) from the name of M/s The Searle Company Ltd, F-319, SITE, Karachi to the name of M/s Amgomed (Distributor), Office No. 4, 1st Floor, Ghousia Plaza, Jinnah Avenue Blue Area, Islamabad as per policy for imported finished drug registration (in accordance with details of composition and manufacturer as per CoPP). Furthermore, NOC shall be verified before issuance of letter.

I & V-I SECTION/VET

Case. No.01:- **REQUEST OF M/S. CHAKWAL PHARMA INTERNATIONAL, LAHORE CANTT FOR REGISTRATION OF VALCYTE 450MG TABLETS TO THEIR NAME FROM M/S BIO VISION CORPORATION, LAHORE.**

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 has submitted an application for Registration of following already registered products from M/s. Bio Vision Corporation, 88-A, Punjab Cooperative Housing Society (PCHS), Defence Ghazi Road, Lahore (Godown: Basement 543/10-E PCHS Defence Ghazi Road Cantt. Lahore) to their name. Detail of each proposed product is as under: -

Product:		**Doxipan 20 Water Soluble Powder (Reg.No. 093609)**	
S. No.	**Name / Detail of Documents**	**Documents / information provided by firm**	
1.	Product Name/ Composition	**As per Reg. Letter** Doxipan 20 Water Soluble Powder Each gram contains:- Doxycycline Hydrochloride….200mg (USP Specifications)	**As per CoPP:** Doxipan 200 mg/g Oral Soluble Powder (named Doxipan 20 in the importing country), Doxycycline hydrochloride (as Hyclate), 800mg/g
	Reg. date / renewal status	Reg. Letter issued on 08-11-2018 Renewal due date 07-11-2023	
	Name and address of Applicant(Transferee)	M/s. Chakwal Pharma International, Suit # 6, First Floor, Board Plaza, Tufail Road, Lahore Cantt	
	Name of Transferor	M/s Bio Vision Corporation, 88-A, Punjab Cooperative Housing Society (PCHS), Defence Ghazi Road, Lahore (Godown: Basement 543/10-E PCHS Defence Ghazi Road Cantt. Lahore)	
	Detail of Drug Sale License	**DSL No. 05-352-0066-023933D (valid upto 13-11-2023)** **Address:** 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.	
	Name and address of Manufacturer / Product License Holder	**As per Reg. Letter.** **Product License Holder.** M/s. Industria Italiana Integratori TREI S.p.A. –Viale Corassori, 62 - 41124 Modena - Italy. **Manufacturer**: M/s. Industria Italiana Integratori TREI via Affarosa, 4-42010 Rio Saliceto (RE) Italy.	**As per CoPP (157/2023/C):** **Product License Holder.** M/s. Industria Italiana Integratori TREI S.p.A. –Viale Corassori, 62 - 41124 Modena - Italy. **Manufacturer:** M/s. Industrial Italiana Integratori TREI S.p.A. Via Affarosa, 4 - 42010 Rio Saliceto (RE).
	Name of exporting Country	Italy	
	Diary No. & Date of R& I	Dy. No. 25178 Dated 16/10/2023.	
	Finished Product Specification	USP Specifications approved on 08-11-2018.	
	Shelf life	02 Years	
	MRP/Pack Size	De-controlled (as per Reg. Letter)	
Product:		**Trimethosulfa Orale Oral Solution (Reg.No. 093228)**	
S. No.	**Name / Detail of Documents**	**Documents / information provided by firm**	
2.	Product Name/ Composition	**As per Reg. Letter** Trimethosulfa Orale Oral Solution Each ml Oral Solution contains:-	**As per CoPP:** Trimethosulfa Orale Oral Solution

		Sulphadiazine……..200mg Trimethoprim……..40mg	Each ml Oral Solution contains:- Sulphadiazine……..200mg Trimethoprim……..40mg
	Reg. date / renewal status	Reg. Letter issued on 24-10-2018 Renewal due date 23-10-2023	
	Name and address of Applicant(Transferee)	M/s. Chakwal Pharma International, Suit # 6, First Floor, Board Plaza, Tufail Road, Lahore Cantt	
	Name of Transferor	M/s. Bio Vision Corporation, 88-A, Punjab Cooperative Housing Society (PCHS), Defence Ghazi Road, Lahore (Godown: Basement 543/10-E PCHS Defence Ghazi Road Cantt. Lahore)	
	Detail of Drug Sale License	**DSL No. 05-352-0066-023933D (valid upto 13-11-2023)** **Address:** 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.	
	Name and address of Manufacturer / Product License Holder	**As per Reg. Letter.** **Product License Holder.** M/s. Industria Italiana Integratori TREI S.p.A. –Viale Corassori, 62 - 41124 Modena - Italy. **Manufacturer**: M/s. Industria Italiana Integratori TREI via Affarosa, 4-42010 Rio Saliceto (RE) Italy.	**As per CoPP (157/2023/C):** **Product License Holder.** M/s. Industria Italiana Integratori TREI S.p.A. –Viale Corassori, 62 - 41124 Modena - Italy. **Manufacturer:** M/s. Industrial Italiana Integratori TREI S.p.A. Via Affarosa, 4 - 42010 Rio Saliceto (RE).
	Name of exporting Country	Italy	
	Diary No. & Date of R& I	Dy. No. 25180 Dated 16/10/2023.	
	Finished Product Specification	As per Innovator's Specifications approved on 24-10-2018.	
	Shelf life	03 Years	
	MRP/Pack Size	De-controlled (as per Reg. Letter)	
Product:	**AMOXID Water Soluble Powder (Oral Water Soluble Powder) (Reg.No. 093229)**		
S. No.	**Name / Detail of Documents**	**Documents / information provided by firm**	
3.	Product Name/ Composition	**As per Reg. Letter** AMOXID Water Soluble Powder Oral Water Soluble Powder Each gram contains:- Amoxicillin Trihydrate….800mg (eq. to Amoxicillin base 696.8mg) (USP Specifications)	**As per CoPP:** AMOXID Water Soluble Powder, Amoxicillin trihydrate, 800 mg/g, equal to Amoxicillin base 696.8 mg/g
	Reg. date / renewal status	Reg. Letter issued on 24-10-2018 Renewal due date 23-10-2023	
	Name and address of Applicant(Transferee)	M/s. Chakwal Pharma International, Suit # 6, First Floor, Board Plaza, Tufail Road, Lahore Cantt	
	Name of Transferor	M/s. Bio Vision Corporation, 88-A, Punjab Cooperative Housing Society (PCHS), Defence Ghazi Road, Lahore (Godown: Basement 543/10-E PCHS Defence Ghazi Road Cantt. Lahore)	
	Detail of Drug Sale License	**DSL No. 05-352-0066-023933D (valid upto 13-11-2023)** **Address:** 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.	

	Name and address of Manufacturer / Product License Holder	**As per Reg. Letter.** **Product License Holder.** M/s. Industria Italiana Integratori TREI S.p.A. –Viale Corassori, 62 - 41124 Modena - Italy. **Manufacturer**: M/s. Industria Italiana Integratori TREI via Affarosa, 4-42010 Rio Saliceto (RE) Italy.	**As per CoPP (157/2023/C):** **Product License Holder.** M/s. Industria Italiana Integratori TREI S.p.A. –Viale Corassori, 62 - 41124 Modena - Italy. **Manufacturer:** M/s. Industrial Italiana Integratori TREI S.p.A. Via Affarosa, 4 - 42010 Rio Saliceto (RE).
	Name of exporting Country	Italy	
	Diary No. & Date of R& I	Dy. No. 25179 Dated 16/10/2023.	
	Finished Product Specification	As per Innovator's Specifications approved on 24-10-2018.	
	Shelf life	02 Years	
	MRP/Pack Size	De-controlled (as per Reg. Letter)	

The firm has submitted the following supporting documents / information for approval of above transfer of registrations: -

a) Application with a fee of Rs.150,000/-per product.
b) Copy of Registration letter as mentioned above table.
c) Original & Legalized CoPP issued by Italy.
d) Original Legalized of Letter of authorization in the name of 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 from Product License Holder.
e) Original Legalized Termination letter from Product License Holder in the name of M/s Bio Vision Corporation, 88-A, Punjab Cooperative Housing Society (PCHS), Defence Ghazi Road, Lahore (Godown: Basement 543/10-E PCHS Defence Ghazi Road Cantt. Lahore).
f) Undertaking.

Remarks of Evaluation:
Copy of Last renewal.

Composition of Doxipan as per initial registration letter and CoPP is not same, clarify.

The case was discussed in its 336th of Registration Board considered the case and decided to issue show cause notice to the M/s. Bio Vision Corporation, 88-A, Punjab Cooperative Housing Society (PCHS), Defence Ghazi Road, Lahore that why not the registrations in your name be cancelled as MAH aboard has terminated the sole agency agreement with your firm.

Accordingly show cause notice issued to M/s. Bio Vision Corporation, 88-A, Punjab Cooperative Housing Society (PCHS), Defence Ghazi Road, Lahore. In response the firm has informed are as under:-

With deep veneration and extreme regards, it is submitted that;

1. That the subject Show Cause Notice was issued to M/s. Bio Vision Corporation, Lahore which is received to me on dated 28.09.2024 about the cancellation of registration of imported veterinary drugs mentioned in the show cause notice as per Section 7 (11) (b-c) & Section 42 of Drugs Act 1976 & Rule 24 (17) of Drugs (Licensing, Registering, Advertising) Rules, 1976.

My humble submission in this regard are as under:-

1. The termination letter of the Distribution Agreement between M/s. Livisto, Industria Italiana Integration TRIE SP-A Viale Corasson n' 62-41124 Medena Italy and M/s. Bio Vision Corporation, Lahore issued without adopting the proper procedure mentioned in the Distribution Agreement between the parties by ignoring the terms and condition of the agreement with the collusiveness of M/s. Chakwal Pharma International Raiwind Road, Lahore who malafidely

entered into the agreement with the above said M/s. Livisto, Industria Italiana Company to damage the business as well as good will of the M/s. Bio Vision Corporation, Lahore.

2. The termination letter dated 29.05.2024 issued malafidely on the wrong information and trapping by the M/s.Chakwal Pharma International, Lahore on the allegation ofof under performance which is absolutely wrong because our firm Bio Vision Corporation, Lahore doing the business with due diligence and efficiently even in Corona days and fulfill the target of M/s. Livisto, Industria Italiana Company. As evident the letter /email dated 03.03-2023 just issued before 03 months prior about asking the Bio Vision Corporation, Lahore for renewal the registration of products (drugs) mentioned in the show cause notice under reply "If Bio Vision Corporation do work under performance target or against the agreement, why the M/s. Livisto, Industria Italiana Company send about said letter/email for renewal the registration of drugs mentioned in the show cause notice under reply". The said email is attached for your kind perusal.
3. The sudden termination, without adopting the proper and ethical ways, caused me a big economical loss. I did a huge investment for publicity and marketing these products. There is a huge investment in the form of credits in the market. There is a big infrastructure investment. No accounts settlement has been done as yet.

   As the documents shows that the termination of the above mentioned agreement is done malafidely and without adopting proper ways, I humbly request that DRAP should protect a Pakistani ruined by the foreign supplier by rejecting their application.
4. That the Bio Vision Corporation on the above said behavior and malafidely issuing the termination letter dated 29.05.2024 by M/s. Livisto, Industria Italiana Company, challenged in Declaratory suit before the court of learned Senior Civil Judge Lahore titled "Saif Ur Rehman Tahir Vs Chakwal Pharma International etc" with the prayer that "Declaring the termination letter dated 29.05.2023 illegal, unlawful and void ab-initio and permanently restrained to you office proceed on the above mentioned termination letter"

   So, I hope the learned Civil Court passed the degree in favour of our Bio Vision Corporation, Lahore by declaring the termination letter dated 29.05.2023 being illegal, unlawful and void ab-initio. In the above circumstances, I may be requested to your honour please postponed the proceeding of cancellation the registration of Bio Vision Corporation, Lahore till the decision of civil suit pending adjudication in the Civil Court Lahore, and withdrawal the show cause notice under reply in the best interest of justice and law of equity.

   Under current circumstances, the section 7 (11) (b,c) and 42 of the Drugs Act, 1976 & Rule 24 (17) of Drugs (Licensing, Registering & Advertising) Rules, 1976 as mentioned in Show Cause Notice are not applicable to us.

Decision:

Registration Board considered the case and decided to issue show cause notice/personal hearing to the M/s. Bio Vision Corporation, 88-A, Punjab Cooperative Housing Society (PCHS), Defence Ghazi Road, Lahore that why not the registrations in your name be cancelled as MAH aboard has terminated the sole agency agreement with your firm.

Case. No.02:- **INFORMATION FOR LISTING THIRD COUNTRIES-COMMISSION DELEGATED REGULATION (EU) 2023/905.**

FR received from Dr. Muhammad Shahjahan Zafar RO Epidemiology, ministry of National Food Security and Research and stated as under:

The undersigned is directed to refer to DRAP letter No.6-6/2023-QA dated 01-12-2023 above subject and to state that EU has inquired an update regarding the status of the deregistration process for amantadine used in veterinary medicine.

Amantadine has been classified by the EU among antibiotics reserved veterinary purposes may consequently lead to EU ban on the export of livestock products from Pakistan. Such de-registration in Pakistan holds particular significance, safeguarding the livestock trade interests and aligning with international standards.

DRAP, kindly requested to provide an update on the status of the deregistration of amantadine used in combination formulations and single amantadine formulations for veterinary use. If deregistration has not yet been completed, an anticipated timeline for the process's completion would be appreciated.

Decision: Registration Board decided to refer the case to sub-committee on veterinary drugs.

Case. No.03:-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 331: - Registration Board deliberated the matter and decided as under:

i. 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 for approval by Federal Government. So, in order to avoid pendency/delay in processing of issues relating to veterinary drugs requiring input/recommendation of pertinent veterinary expert, the Board under Rule 24 (4) of the Drugs (L, R&A) Rules, 1976 decided to constitute sub-committee on Veterinary Drugs having following composition: -

2.	Dr. Qurban Ali, Co-opted Member Registration Board Ex-Director General, National Veterinary Laboratory, Islamabad.	Chairman
3.	Director QA/LT, Drug Regulatory Authority of Pakistan, Islamabad.	Member
4.	Mst. Najia Saleem, Deputy Director (PE&R), DRAP	Evaluator
5.	Assistant Director (I&V-I), DRAP	Secretary
6.	Any Co-opt member with the consent of Chairman/Secretary Registration Board	Member

ii. In order to in time disposal of applied dossiers, the sub-committee on Veterinary Drugs will place its input/recommendations on the registration applications of veterinary drugs, including review of existing/new veterinary drug formulations for consideration/decision by the Registration Board.

Decision: - Registration Board deliberated the matter and decided as under:

i. **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 for approval by Federal Government. So, in order to avoid pendency/delay in processing of issues relating to veterinary drugs requiring recommendations of pertinent veterinary expert, the Board under Rule 24 (4) of the Drugs (L, R&A) Rules, 1976 decided to constitute sub-committee on Veterinary Drugs having following composition: -**

1.	**Dr. Syed Asad Ali Shah Member Registration Board Livestock & Dairy Development Department Khyber Pakhtunkhwa**	**Chairman**
2.	**Director QA&LT or its Representative Drug Regulatory Authority of Pakistan, Islamabad**	**Member**
3.	**Dr. Qurban Ali, Ex-Director General, National Veterinary Laboratory, Islamabad.**	**Member**
4.	**Animal Husbandry Commissioner or its Representative M/o National Food Security & Research, Islamabad**	**Member**
5.	**Mst. Najia Saleem, Deputy Director (PE&R), DRAP**	**Evaluator**
6.	**Deputy Director (I&V-I), DRAP**	**Secretary**
7.	**Any Co-opt member with the consent of Chairman/Secretary Registration Board**	**Member**

ii. The sub-committee will evaluate matters related to veterinary drugs and submit its recommendations for consideration of Registration Board.

iii. Registration Board directed PE&R Division to issue notification of sub-committee without waiting for finalization of minutes.

RRR Section

Case No.01. M/s. Pacific Pharmaceuticals Ltd., 30th Km Multan Road, Lahore.

1.	Brand Name + Dosage Form and Strength	Fido Wobenzym Tablets
	Composition	Each Tablet Contains: Pancreatin ….. 100 mg Papain ….. 60 mg Rutosid ….. 50 mg Bromelain ….. 45 mg Trypsin ….. 24 mg Chymotrypsin ..... 1 mg
	Dairy No. date of R &I fee	Dy No.11026 Dated:17.10.2024 Rs.30000/- & Dy No.12056 Dated:11.11.2024 Rs.7000/-
	Type of Form	Form - 5
	Finished Product Specifications	In-house Specifications
	Pack Size and Demand Price	40’s, As per SRO
	GMP Status	
	Remark of the Renewal section	Registration of Fido Wobenzym Tablets (062799) due to non-submission of renewal of 2020 in prescribed time period. RRA not confirmed.

	Decision: Registration Board deferred the product for confirmation of approval status in Reference Regulatory Authorities.	
2.	Brand Name + Dosage Form and Strength	Flamil Cream
	Composition	Each 100 gm Contains: Silver Sulfadiazine ….. 1% w/w
	Dairy No. date of R &I fee	Dy No.11027 Dated:17.10.2024 Rs.30000/- & Dy No.12056 Dated:11.11.2024 Rs.7000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP Specifications
	Pack Size and Demand Price	50 gm, As per SRO
	GMP Status	
	Remark of the Renewal section	Registration of Flamil Cream (067972) due to non-submission of renewal of 2020 in prescribed time period.
	Decision:- Approved	
3.	Brand Name + Dosage Form and Strength	Medritis 1 mg Tablets
	Composition	Each Tablet Contains: Glimepiride ….. 1 mg
	Dairy No. date of R &I fee	Dy No.11025 Dated:17.10.2024 Rs.30000/- & Dy No.12056 Dated:11.11.2024 Rs.7000/-
	Type of Form	Form - 5
	Finished Product Specifications	BP Specifications
	Pack Size and Demand Price	2x10's, As per SRO
	GMP Status	
	Remark of the Renewal section	Registration of Medritis 1 mg Tablets (038353) due to non-submission of renewal of 2020 in prescribed time period.
	Decision:- Approved	
4.	Brand Name + Dosage Form and Strength	Plasil Drops
	Composition	Each 1 ml Contains: Metoclopramide HCl BP eq. to 4 mg of Anhydrous Substance
	Dairy No. date of R &I fee	Dy No.11028 Dated:17.10.2024 Rs.30000/- & Dy No.12056 Dated:11.11.2024 Rs.7000/-
	Type of Form	Form - 5
	Finished Product Specifications	BP Specifications
	Pack Size and Demand Price	20 ml, As per SRO
	GMP Status	
	Remark of the Renewal section	Registration of Plasil Drops (003633) due to non-submission of renewal of 2020 in prescribed time period. RRA not confirmed.
	Decision: Registration Board deferred the product for confirmation of approval status in Reference Regulatory Authorities.	

5.	Brand Name + Dosage Form and Strength	Plasil Syrup
	Composition	Each 1 ml Contains: Metoclopramide HCl BP eq. to 4 mg of Anhydrous Substance
	Dairy No. date of R &I fee	Dy No.11031 Dated:17.10.2024 Rs.30000/- & Dy No.12056 Dated:11.11.2024 Rs.7000/-
	Type of Form	Form - 5
	Finished Product Specifications	BP Specifications
	Pack Size and Demand Price	50 ml, 100 ml, As per SRO
	GMP Status	
	Remark of the Renewal section	Registration of Plasil Syrup (003630) due to non-submission of renewal of 2020 in prescribed time period. RRA not confirmed.
	Decision: Registration Board deferred the product for confirmation of approval status in Reference Regulatory Authorities.	
6.	Brand Name + Dosage Form and Strength	Plasil Tablet
	Composition	Each Tablet Contains: Metoclopramide HCl BP eq. to 10 mg of Anhydrous Substance
	Dairy No. date of R &I fee	Dy No.11032 Dated:17.10.2024 Rs.30000/- & Dy No.12056 Dated:11.11.2024 Rs.7000/-
	Type of Form	Form - 5
	Finished Product Specifications	BP Specifications
	Pack Size and Demand Price	20's, 100's, 500's, As per SRO
	GMP Status	
	Remark of the Renewal section	Registration of Plasil Tablet (003631) due to non-submission of renewal of 2020 in prescribed time period. Product is available in MHRA.
	Decision:- Approved	
7.	Brand Name + Dosage Form and Strength	Repanide 1 mg Tablet
	Composition	Each Tablet Contains: Repaglinide ….. 1 mg
	Dairy No. date of R &I fee	Dy No.11029 Dated:17.10.2024 Rs.30000/- & Dy No.12056 Dated:11.11.2024 Rs.7000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP Specifications
	Pack Size and Demand Price	3 x 10's, As per SRO
	GMP Status	
	Remark of the Renewal section	Registration of Repanide 1 mg Tablet (040921) due to non-submission of renewal of 2010 in prescribed time period.
	Decision:- Approved	

8.	Brand Name + Dosage Form and Strength	Repanide 2 mg Tablet
	Composition	Each Tablet Contains: Repaglinide ….. 2 mg
	Dairy No. date of R &I fee	Dy No.11030 Dated:17.10.2024 Rs.30000/- & Dy No.12056 Dated:11.11.2024 Rs.7000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP Specifications
	Pack Size and Demand Price	3 x 10's, As per SRO
	GMP Status	
	Remark of the Renewal section	Registration of Repanide 2 mg Tablet (040922) due to non-submission of renewal of 2010 in prescribed time period.
	Decision:- Approved	
9.	Brand Name + Dosage Form and Strength	Rifinah 150 mg Tablet
	Composition	Each Film Coated Tablet Contains: Rifampicin ….. 150 mg Isoniazid ….. 100 mg
	Dairy No. date of R &I fee	Dy No.11024 Dated:17.10.2024 Rs.30000/- & Dy No.12056 Dated:11.11.2024 Rs.7000/-
	Type of Form	Form - 5
	Finished Product Specifications	Ph. Int. Specifications
	Pack Size and Demand Price	48's, 100's, 500's, As per SRO
	GMP Status	
	Remark of the Renewal section	Registration of Rifinah 150 mg Tablet (002657) due to non-submission of renewal of 2020 in prescribed time period.
	RRA of instant strength not confirmed	
	Decision: Registration Board deferred for standardization of formulation as per WHO approved formulations.	
10.	Brand Name + Dosage Form and Strength	Cermion 30 mg Tablets
	Composition	Each Tablet Contains: Nicergoline ….. 30 mg
	Dairy No. date of R &I fee	Dy No.11034 Dated:17.10.2024 Rs.30000/- & Dy No.12056 Dated:11.11.2024 Rs.7000/-
	Type of Form	Form - 5
	Finished Product Specifications	In-house Specifications
	Pack Size and Demand Price	30's, As per SRO
	GMP Status	
	Remark of the Renewal section	Registration of Cermion 30 mg Tablets (012430) due to non-submission of renewal of 1996 in prescribed time period.
	RRA Status not confirmed	
	Decision: Registration Board deferred the product for confirmation of approval status in Reference Regulatory Authorities.	
11.	Brand Name + Dosage Form and Strength	Cermion 10 mg Tablets

	Composition	Each Tablet Contains: Nicergoline ….. 10 mg
	Dairy No. date of R &I fee	Dy No.11033 Dated:17.10.2024 Rs.30000/- & Dy No.12056 Dated:11.11.2024 Rs.7000/-
	Type of Form	Form - 5
	Finished Product Specifications	In-house Specifications
	Pack Size and Demand Price	30's, As per SRO
	GMP Status	
	Remark of the Renewal section	Registration of Cermion 10 mg Tablets (012431) due to non-submission of renewal of 1996 in prescribed time period.
	RRA Status not confirmed	
	Decision: Registration Board deferred the product for confirmation of approval status in Reference Regulatory Authorities.	

Case No.02. M/s. Medisave Pharmaceuticals, Plot No.578-579 Sundar Industrial Estate Lahore.(DML No.000681).

1.	**Brand Name + Dosage Form and Strength**	Terac tablet 400mg
	Composition	Each Tablet Contains: Pefloxacin……..400mg
	Dairy No. date of R &I fee	Dy No.11187 Dated:21.10.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP Specifications
	Pack Size and Demand Price	1x10s, As per SRO
	GMP Status	GMP certificate dated 08.11.2023
	Remark of the Renewal section	Registration of Fido Terac tablet 400mg (062571) due to non-submission of renewal of 2020 in prescribed time period.
	Decision:- Approved	
2.	**Brand Name + Dosage Form and Strength**	Gap-50 tablet
	Composition	Each Tablet Contains: Levosulpride……..50mg
	Dairy No. date of R &I fee	Dy No.11186 Dated:21.10.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	As per innovator Specifications
	Pack Size and Demand Price	2x10s, As per SRO
	GMP Status	GMP certificate dated 08.11.2023
	Remark of the Renewal section	Registration of Fido Gap-50 tablet (074161) due to non-submission of renewal of 2020 in prescribed time period.
	Decision:- Approved	
3.	**Brand Name + Dosage Form and Strength**	Asept Suspension
	Composition	Each 5ml Contains: Nalidixic Acid
	Dairy No. date of R &I fee	Dy No.11185 Dated: 21.10.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP Specifications

	Pack Size and Demand Price	60ml, As per SRO
	GMP Status	
	Remark of the Renewal section	Registration of Asept Suspension (038353) due to non-submission of renewal of 2020 in prescribed time period.
	Decision:- Approved	

Case No.03.M/s. Uni-Tiech Pharmaceuticals Pvt Limited, Plot No. 4/116-119, Sector 21, Korangi Industrial Area, Karachi.

1.	**Brand Name + Dosage Form and Strength**	Uni-Prima 500mg Dry Powder Injections
	Composition	Each Vial contains: Cefpirome (as Sulphate)…. 500mg
	Dairy No. date of R &I fee	Dy No.12258 Dated: 15.11.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	Innovator's Specification.
	Pack size and Demand Price	1's, As per SRO
	GMP Status	**GMP inspection report dated 11.06.2024 and GMP indicating the compliance good.**
	Remark of the Renewal section	Registration of Uni-Prima 500mg Dry Powder Injections (047474) applied for fresh registration as per direction of Registration Board in 336th meeting due to non-submission of renewal application.
	Decision:- Approved	
2.	**Brand Name + Dosage Form and Strength**	Uni-Prima 1gm Dry Powder Injections
	Composition	Each Vial contains: Cefpirome (as Sulphate)…. 1gm
	Dairy No. date of R &I fee	Dy No.12260 Dated: 15.11.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	Innovator's Specs.
	Pack size and Demand Price	1's, As per SRO
	GMP Status	**GMP inspection report dated 11.06.2024 and GMP indicating the compliance good.**
	Remark of the Renewal section	Registration of Uni-Prima 1gm Dry Powder Injections (047475) applied for fresh registration as per direction of Registration Board in 336th meeting due to non-submission of renewal application.
	Decision:- Approved	
3.	**Brand Name + Dosage Form and Strength**	Unistrip
	Composition	Each Lozenges Contains: Dybenal…….1.2mg Amylmetacresol……0.6mg
	Dairy No. date of R &I fee	Dy No.12263 Dated: 15.11.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	Innovator's Specification.
	Pack size and Demand Price	25x10's, As per SRO

	GMP Status	**GMP inspection report dated 11.06.2024 and GMP indicating the compliance good.**
	Remark of the Renewal section	Registration of Unistrip (048668) applied for fresh registration as per direction of Registration Board in 336th meeting due to non-submission of renewal application..
	Decision: Registration Board deferred the product for confirmation of RRA status whether its being regulated either as health Product or Pharmaceutical product.	
4.	**Brand Name + Dosage Form and Strength**	Unigastic 0.3mg Injection
	Composition	Each ml Contains: Buprenorphine (as HCL) ……0.3mg
	Dairy No. date of R &I fee	Dy No.12270 Dated: 15.11.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	BP Specification.
	Pack size and Demand Price	5'sx1ml, As per SRO
	GMP Status	**GMP inspection report dated 11.06.2024 and GMP indicating the compliance good.**
	Remark of the Renewal section	Registration of Unigastic 0.3mg Injection (050516) applied for fresh registration as per direction of Registration Board in 336th meeting due to non-submission of renewal application..
	Psychotropic section approval not submitted	
	Decision: Registration Board deferred the product for confirmation of approval of Psychotropic section by the Central Licensing Board.	
5.	**Brand Name + Dosage Form and Strength**	Sosetiech 30mg Injection
	Composition	Each ml Contains: Pentazocine (as Lactate)…….30mg
	Dairy No. date of R &I fee	Dy No.12271 Dated: 15.11.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	USP Specification.
	Pack size and Demand Price	5'sx1ml, As per SRO
	GMP Status	**GMP inspection report dated 11.06.2024 and GMP indicating the compliance good.**
	Remark of the Renewal section	Registration of Sosetiech 30mg Injection (050517) applied for fresh registration as per direction of Registration Board in 336th meeting due to non-submission of renewal application..
	Decision:- Approved	
6.	**Brand Name + Dosage Form and Strength**	Alprazolam 1mg Tablet
	Composition	Each Tablet contains: Alprazolam …….1mg
	Dairy No. date of R &I fee	Dy no. 12269 dated 15.11.2024 Rs.37,000/-
	Type of form	Fom-5
	Finished product specifications	USP Specification.
	Pack size and Demand Price	30's,As per SRO
	GMP Status	**GMP inspection report dated 11.06.2024 and GMP indicating the compliance good.**

	Remark of the Renewal section	Registration of Alprazolam 1mg Tablet (053353) applied for fresh registration as per direction of Registration Board in 336th meeting due to non-submission of renewal application..
	Psychotropic section approval not submitted	
	Decision: Registration Board deferred the product for confirmation of approval of Psychotropic section by the Central Licensing Board.	
7.	**Brand Name + Dosage Form and Strength**	Sodacarbol 50ml Injection
	Composition	Each ml contains: Sodium Bicarbonate….8.4%
	Dairy No. date of R &I fee	Dy no. 12269 dated 15.11.2024 Rs.37,000/-
	Type of form	Fom-5
	Finished product specifications	USP Specification.
	Pack size and Demand Price	50ml, As per SRO
	GMP Status	**GMP inspection report dated 11.06.2024 and GMP indicating the compliance good.**
	Remark of the Renewal section	Registration of Sodacarbol 50ml Injection (067298) cancelled vide DRAP letter No. 3-9/2023-RRR (M-329) dated 10.09.2023 due to non-submission of renewal in prescribed time period.
	Decision:- Approved	
8.	**Brand Name + Dosage Form and Strength**	Pyriclo Tablet
	Composition	Each Tablet contains: Meclozine HCl….25mg, Pyridoxine HCl….50mg(USP Specifications)
	Dairy No. date of R &I fee	Dy No.12261 Dated: 15.11.2024 Rs.30,000/-
	Type of form	Fom-5
	Finished product specifications	Innovator's Specification.
	Pack size and Demand Price	10x10's, As per SRO
	GMP Status	**GMP inspection report dated 11.06.2024 and GMP indicating the compliance good.**
	Remark of the Renewal section	Registration of Pyriclo Tablet (048655) cancelled vide DRAP letter No. 3-9/2023-RRR (M-329) dated 10.09.2023 due to non-submission of renewal in prescribed time period.
	RRA not confirmed	
	Decision: Registration Board deferred the product for confirmation of approval status in reference regulatory authorities.	
9.	**Brand Name + Dosage Form and Strength**	Zemtiech 30mg Tablet
	Composition	Each tablet contains: Diltiazem…..30mg (BP Specifications)
	Dairy No. date of R &I fee	Dy No.12258 Dated: 15.11.2024 Rs.37,000/-
	Type of form	Fom-5
	Finished product specifications	BP Specification.
	Pack size and Demand Price	100's, As per SRO
	GMP Status	**GMP inspection report dated 11.06.2024 and GMP indicating the compliance good.**

	Remark of the Renewal section	Registration of Zemtiech 30mg Tablet (067308) cancelled vide DRAP letter No. 3-9/2023-RRR (M-329) dated 10.09.2023 due to non-submission of renewal in prescribed time period.
	Decision:- Approved	
10.	**Brand Name + Dosage Form and Strength**	Unidrine 30mg Tablet
	Composition	Each tablet contains: Ephedrine HCl…...30mg (Manufacturer Specifications)
	Dairy No. date of R &I fee	Dy No.12259 Dated: 15.11.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	BP Specification.
	Pack size and Demand Price	100's, As per SRO
	GMP Status	**GMP inspection report dated 11.06.2024 and GMP indicating the compliance good.**
	Remark of the Renewal section	Registration of Unidrine 30mg Tablet (061260) cancelled vide DRAP letter No. 3-9/2023-RRR (M-329) dated 10.09.2023 due to non-submission of renewal in prescribed time period.
	Decision: Registration Board deferred the product for confirmation of approval of Psychotropic section by the Central Licensing Board.	
11.	**Brand Name + Dosage Form and Strength**	Bon- Tech 0.25mcg Tablet
	Composition	Each Tablet contains: Alfacalcidol…0.25mcg (USP Specifications)
	Dairy No. date of R &I fee	Dy No.12262 Dated: 15.11.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	Innovator's Specification.
	Pack size and Demand Price	10's, As per SRO
	GMP Status	**GMP inspection report dated 11.06.2024 and GMP indicating the compliance good.**
	Remark of the Renewal section	Registration of Bon- Tech 0.25mcg Tablet (048656) cancelled vide DRAP letter No. 3-9/2023-RRR (M-329) dated 10.09.2023 due to non-submission of renewal in prescribed time period.
	Decision:- Approved	
12.	**Brand Name + Dosage Form and Strength**	Muskodine 2mg Tablet
	Composition	Each tablet contains: Tizanidine…...2mg (USP Specifications)
	Dairy No. date of R &I fee	Dy No.12272 Dated: 15.11.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	USP Specification.
	Pack size and Demand Price	10's, As per SRO
	GMP Status	**GMP inspection report dated 11.06.2024 and GMP indicating the compliance good.**
	Remark of the Renewal section	Registration of Muskodine 2mg Tablet (067295) cancelled vide DRAP letter No. 3-9/2023-RRR (M-329) dated 10.09.2023 due to non-submission of renewal in prescribed time period.

	Decision:- Approved	
13.	**Brand Name + Dosage Form and Strength**	Unizem 10mg Tablet
	Composition	Each Tablet contains: Diazepam…….10mg (USP Specifications)
	Dairy No. date of R &I fee	Dy no. 12264 dated 15.11.2024 Rs.37,000/-
	Type of form	Fom-5
	Finished product specifications	USP Specification.
	Pack size and Demand Price	3X10's, As per SRO
	GMP Status	**GMP inspection report dated 11.06.2024 and GMP indicating the compliance good.**
	Remark of the Renewal section	Registration of Unizem 10mg Tablet (061046) cancelled vide DRAP letter No. 3-9/2023-RRR (M-329) dated 10.09.2023 due to non-submission of renewal in prescribed time period.
	Psychotropic section approval not submitted	
	Decision: Registration Board deferred the product for confirmation of approval of Psychotropic section by the Central Licensing Board.	
14.	**Brand Name + Dosage Form and Strength**	U-A1 0.5mg Tablets
	Composition	Each Tablet Contains: Alprazolam ……0.5mg
	Dairy No. date of R &I fee	Dy no. 12268 dated 15.11.2024 Rs.37,000/-
	Type of form	Fom-5
	Finished product specifications	USP Specification.
	Pack size and Demand Price	30's, As per SRO
	GMP Status	**GMP inspection report dated 11.06.2024 and GMP indicating the compliance good.**
	Remark of the Renewal section	Registration of U-A1 0.5mg Tablets (047200) cancelled vide DRAP letter No. 3-7/2022-RRR (M-316) dated 27.05.2022 due to non-submission of renewal in prescribed time period.
	Psychotropic section approval not submitted	
	Decision: Registration Board deferred the product for confirmation of approval of Psychotropic section by the Central Licensing Board.	
15.	**Brand Name + Dosage Form and Strength**	BPM 3mg Tablets
	Composition	Each Tablet Contains: Bromazepam …3mg
	Dairy No. date of R &I fee	Dy no. 12265 dated 15.11.2024 Rs.37,000/-
	Type of form	Fom-5
	Finished product specifications	Innovator's Specification.
	Pack size and Demand Price	30's, As per SRO
	GMP Status	**GMP inspection report dated 11.06.2024 and GMP indicating the compliance good.**
	Remark of the Renewal section	Registration of BPM 3mg Tablets (047201) cancelled vide DRAP letter No. 3-7/2022-RRR (M-316) dated 27.05.2022 due to non-submission of renewal in prescribed time period..
	Psychotropic section approval not submitted	
	Decision: Registration Board deferred the product for confirmation of approval of	

	Psychotropic section by the Central Licensing Board.	
16.	**Brand Name + Dosage Form and Strength**	Unigastic 0.2mg Tablets
	Composition	Each Tablet Contains: Buprenorphine HCl Eq. to Buprenorphine……0.2mg
	Dairy No. date of R &I fee	Dy no. 12266 dated 15.11.2024 Rs.37,000/-
	Type of form	Fom-5
	Finished product specifications	BP Specification.
	Pack size and Demand Price	50's, As per SRO
	GMP Status	**GMP inspection report dated 11.06.2024 and GMP indicating the compliance good.**
	Remark of the Renewal section	Registration of Unigastic 0.2mg Tablets (047202) cancelled vide DRAP letter No. 3-7/2022-RRR (M-316) dated 27.05.2022 due to non-submission of renewal in prescribed time period.
	Psychotropic section approval not submitted	
	Decision: Registration Board deferred the product for confirmation of approval of Psychotropic section by the Central Licensing Board.	

Case No.04. M/s. Reign Pharmaceuticals PCSIR – KLC (Pvt.) Ltd , TBIC Building 1, PCSIR Laboratories Complex, Shahrah-e-Dr. Salim-uz-Zaman Siddiqui, Off University Road, Karachi, 75280, Pakistan.

1.	**Brand Name + Dosage Form and Strength**	Besulex Tablet 5mg
	Composition	Each sugar and enteric coated tablet contains: Bisacodyl……5mg
	Diary No. , Date of R&I Fee	Dy. No.11685 dated:31.10.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	BP specifications
	Pack Size and Demand Price	As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Besulex Tablet 5mg (007640-Ex) due to non-submission of renewal of 2023 in prescribed time period MHRA Approved product.
	Decision:- Approved	
2.	**Brand Name + Dosage Form and Strength**	C-Throcin 125mg/5ml Dry Powder Suspension
	Composition	Each 5ml contains: Clarithromycin……..125mg
	Diary No. , Date of R&I Fee	Dy. No.11824 dated:04.11.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP specifications
	Pack Size and Demand Price	60ml, As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of C-Throcin 125mg/5ml Dry Powder Suspension (60ml) (073800) due to non-submission of renewal of 2023 in prescribed time period
	Decision: Registration Board approved the product as per following details: **Each 5ml contains:** **Clarithromycin as taste masked micro pellets … 125mg**	

	Firm shall submit fee for correction in label claim along with source of pellets before issuance of registration letter.	
3.	**Brand Name + Dosage Form and Strength**	Diraxim Tablet 550mg
	Composition	Each film coated tablet contains: Rifaximin…….550mg
	Diary No. , Date of R&I Fee	Dy. No.11684 dated:31.10.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	BP specifications
	Pack Size and Demand Price	10's , As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Diraxim Tablet 550mg (091043) due to non-submission of renewal of 2023 in prescribed time period
	Decision: Approved	
4.	**Brand Name + Dosage Form and Strength**	Ephabol Syrup
	Composition	Each 5ml contains: Pyritinol HCl…….80.5mg
	Diary No. , Date of R&I Fee	Dy. No.11675 dated:31.10.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	Reign specifications
	Pack Size and Demand Price	As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Ephabol Syrup (007641-Ex) due to non-submission of renewal of 2023 in prescribed time period
	RRA status not confirmed	
	Decision: Registration Board deferred the product for confirmation of approval status in reference regulatory authorities.	
5.	**Brand Name + Dosage Form and Strength**	Gnate 15mg/90mg Dry Powder Suspension
	Composition	Each 5ml contains: Artemether……15mg Lumefantrine……90mg
	Diary No. , Date of R&I Fee	Dy. No.11829 dated:04.11.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP specifications
	Pack Size and Demand Price	60ml , As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Gnate 15mg/90mg Dry Powder Suspension (073798) due to non-submission of renewal of 2023 in prescribed time period
	Decision:- Approved	
6.	**Brand Name + Dosage Form and Strength**	Gnate 30mg/180mg DS Dry Powder Suspension
	Composition	Each 5ml contains: Artemether……..30mg Lumefantrine…….180mg
	Diary No. , Date of R&I Fee	Dy. No.11678 dated:31.10.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP specifications
	Pack Size and Demand Price	60ml , As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.

	Remark of Renewal Section	Registration of Gnate 30mg/180mg DS Dry Powder Suspension (073799) due to non-submission of renewal of 2023 in prescribed time period.
	RRA status not confirmed	
	Decision: Registration Board deferred the product for confirmation of approval status in reference regulatory authorities.	
7.	**Brand Name + Dosage Form and Strength**	Gnate DS 80mg/480mg Tablet
	Composition	Each tablet contains: Artemether……80mg Lumefantrine…….480mg
	Diary No. , Date of R&I Fee	Dy. No.1162 dated:31.10.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP specifications
	Pack Size and Demand Price	4's , As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Gnate DS 80mg/480mg Tablet (073795) due to non-submission of renewal of 2023 in prescribed time period
	Decision: Approved	
8.	**Brand Name + Dosage Form and Strength**	Gnate 40mg/240mg tablet
	Composition	Each tablet contains: Artemether……..40mg Lumefantrine……240mg
	Diary No. , Date of R&I Fee	Dy. No.11831 dated:04.11.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP specifications
	Pack Size and Demand Price	8's, 10's, As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Gnate 40mg/240mg tablet (073794) due to non-submission of renewal of 2023 in prescribed time period
	Decision:- Approved	
9.	**Brand Name + Dosage Form and Strength**	Largimox 400mg Tablet
	Composition	Each film coated tablet contains: Moxifloxacin……..400mg
	Diary No. , Date of R&I Fee	Dy. No.11683 dated:31.10.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP specifications
	Pack Size and Demand Price	5's , As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Largimox 400mg Tablet (073791) due to non-submission of renewal of 2023 in prescribed time period
	Decision:- Approved	
10.	**Brand Name + Dosage Form and Strength**	Lesil 500mg Film Coated Tablet
	Composition	Each film coated tablet contains: Levofloxacin as hemihydrate…….500mg
	Diary No. , Date of R&I Fee	Dy. No.11822 dated:04.11.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP specifications
	Pack Size and Demand Price	10's , As per SRO

	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Lesil 500mg Film Coated Tablet (073793) due to non-submission of renewal of 2023 in prescribed time period
	Decision:- Approved	
11.	**Brand Name + Dosage Form and Strength**	Loczol 150mg Capsule
	Composition	Each capsule contains: Fluconazole……..150mg
	Diary No. , Date of R&I Fee	Dy. No.11830 dated:04.11.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	JP specifications
	Pack Size and Demand Price	1's , As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Loczol 150mg Capsule (073797) due to non-submission of renewal of 2023 in prescribed time period
	Decision:- Approved	
12.	**Brand Name + Dosage Form and Strength**	Nutrilyte Sachet
	Composition	Each sachet contains: Sodium chloride……..2.6g Glucose , anhydrous…….13.5g Potassium chloride…….1.5g Trisodium citrate, dehydrate……2.9g
	Diary No. , Date of R&I Fee	Dy. No.11671 dated:31.10.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	BP specifications
	Pack Size and Demand Price	20's , As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Nutrilyte Sachet (073805) due to non-submission of renewal of 2023 in prescribed time period
	Decision:- Approved	
13.	**Brand Name + Dosage Form and Strength**	Nutrizin 20mg/5ml Syrup
	Composition	Each 5ml contains: Zinc Sulphate Monohydrate eq. to Elemental Zinc……...…….20mg
	Diary No. , Date of R&I Fee	Dy. No.11674 dated:31.10.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP specifications
	Pack Size and Demand Price	60ml , 100ml , 120ml , As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Nutrizin 20mg/5ml Syrup (073806) due to non-submission of renewal of 2023 in prescribed time period
	Decision:- Approved	
14.	**Brand Name + Dosage Form and Strength**	Ofloren 200mg Film Coated Tablet
	Composition	Each film coated tablet contains: Ofloxacin……200mg
	Diary No. , Date of R&I Fee	Dy. No.11832 dated:04.11.2024

		Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP specifications
	Pack Size and Demand Price	As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Ofloren 200mg Film coated tablet (007642-Ex) due to non-submission of renewal of 2023 in prescribed time period
	Decision:- Approved	
15.	**Brand Name + Dosage Form and Strength**	OM-R 20mg Capsule
	Composition	Each capsule contains: Omeprazole enteric coated pellets eq. to Omeprazole…….20mg
	Diary No. , Date of R&I Fee	Dy. No.11687 dated:31.10.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP specifications
	Pack Size and Demand Price	14's , As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of OM-R 20mg Capsule (076746) due to non-submission of renewal of 2023 in prescribed time period
	Decision:- Approved. Firm shall submit source of pellets before issuance of registration letter.	
16.	**Brand Name + Dosage Form and Strength**	OM-R Capsule 40mg
	Composition	Each capsule contains: Omeprazole enteric coated pellets eq. to Omeprazole……40mg
	Diary No. , Date of R&I Fee	Dy. No.11826 dated:04.11.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP specifications
	Pack Size and Demand Price	14's, As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of OM-R 40mg Capsule (076745) due to non-submission of renewal of 2023 in prescribed time period
	Decision:- Approved. Firm shall submit source of pellets before issuance of registration letter.	
17.	**Brand Name + Dosage Form and Strength**	Openate 20 Sachet
	Composition	Each sachet contains: Omeprazole…….. 20mg Sodium Bicarbonate…….1680mg
	Diary No. , Date of R&I Fee	Dy. No.11672 dated:31.10.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	Reign specifications
	Pack Size and Demand Price	7's , As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Openate 20 Sachet (086651) due to non-submission of renewal of 2023 in prescribed time period
	Decision:- Approved	
18.	**Brand Name + Dosage Form and Strength**	Openate 40 Sachet
	Composition	Each sachet contains:

		Omeprazole…….40mg Sodium bicarbonate…… 1680mg
	Diary No. , Date of R&I Fee	Dy. No.11829 dated:04.11.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	Reign specifications
	Pack Size and Demand Price	7's , As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Openate 40 Sachet (086652) due to non-submission of renewal of 2023 in prescribed time period
	Decision:- Approved	
19.	**Brand Name + Dosage Form and Strength**	Ortalidan Tablet
	Composition	Each tablet contains: Propyphenazone……175mg Caffeine…….. 25mg
	Diary No. , Date of R&I Fee	Dy. No.11823 dated:04.11.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	In house specifications
	Pack Size and Demand Price	As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Ortalidan Tablet (007639-EX) due to non-submission of renewal of 2023 in prescribed time period
	Decision: Registration Board deferred the product for confirmation of approval status in reference regulatory authorities.	
20.	**Brand Name + Dosage Form and Strength**	Pisacta 20mg Capsule
	Composition	Each capsule contains: Piroxicam as Beta Cyclodextrin……..20mg
	Diary No. , Date of R&I Fee	Dy. No.11686 dated:31.10.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	BP specifications
	Pack Size and Demand Price	20's , As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Pisacta 20mg Capsule (073796) due to non-submission of renewal of 2023 in prescribed time period
	Decision:- Registration	
21.	**Brand Name + Dosage Form and Strength**	Reftox 250mg I.V Injection
	Composition	Each vial contains: Cefotaxime sodium eq. to Cefotaxime……250mg
	Diary No. , Date of R&I Fee	Dy. No.11838 dated:04.11.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP specifications
	Pack Size and Demand Price	1's , As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Reftox 250mg I.V Injection (088951) due to non-submission of renewal of 2023 in prescribed time period
	Decision:- Registration Board deferred the product for confirmation of approval of	

	Dry Powder Injection (Cephalosporin) section by Central Licensing Board.	
22.	**Brand Name + Dosage Form and Strength**	Reftox 500mg IV Injection
	Composition	Each vial contains: Cefotaxime (as sodium)…….500mg
	Diary No. , Date of R&I Fee	Dy. No.11839 dated:04.11.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP specifications
	Pack Size and Demand Price	1's , As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Reftox 500mg IV Injection (088950) due to non-submission of renewal of 2023 in prescribed time period
	Decision:- Registration Board deferred the product for confirmation of approval of Dry Powder Injection (Cephalosporin) section by Central Licensing Board.	
23.	**Brand Name + Dosage Form and Strength**	Reftox 1000mg IV Injection
	Composition	Each vial contains: Cefotaxime sodium equivalent to Cefotaxime…….....1000mg
	Diary No. , Date of R&I Fee	Dy. No.11670 dated:31.10.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP specifications
	Pack Size and Demand Price	1's , As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Reftox 1000mg IV Injection (088955) due to non-submission of renewal of 2023 in prescribed time period
	Decision:- Registration Board deferred the product for confirmation of approval of Dry Powder Injection (Cephalosporin) section by Central Licensing Board.	
24.	**Brand Name + Dosage Form and Strength**	Ren-C 1000 sachet
	Composition	Each sachet contains: Ascorbic acid……500mg Calcium carbonate……..327mg Calcium lactate……..…….422mg Calcium gluconate……..……...578mg
	Diary No. , Date of R&I Fee	Dy. No.11673 dated:31.10.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	BP specifications
	Pack Size and Demand Price	10's , As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Ren-C 1000 sachet (073804) due to non-submission of renewal of 2023 in prescribed time period
	Decision:- Approved	
25.	**Brand Name + Dosage Form and Strength**	Renflox 125mg/5ml Dry powder suspension
	Composition	Each 5ml contains: Ciprofloxacin……..125 mg
	Diary No. , Date of R&I Fee	Rs. 37,030/-
	Type of Form	Form - 5
	Finished Product Specifications	USP specifications

	Pack Size and Demand Price	60ml , As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Renflox 125mg/5ml Dry powder suspension (073802) due to non-submission of renewal of 2023 in prescribed time period
	Decision: Registration Board approved the product as per following details: **Each 5ml contains:** **Ciprofloxacin as taste masked micro pellets … 125mg** **Firm shall submit full fee for correction in label claim along with source of pellets before issuance of registration letter.**	
26.	**Brand Name + Dosage Form and Strength**	Renflox 500mg Film coated tablet
	Composition	Each film coated tablet contains: Ciprofloxacin as HCl ……500mg
	Diary No. , Date of R&I Fee	Dy. No.11834 dated:04.11.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP specifications
	Pack Size and Demand Price	10's , As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Renflox 500mg Film coated tablet (073792) due to non-submission of renewal of 2023 in prescribed time period
	Decision: Registration Board approved the product as per following details: **Each 5ml contains:** **Ciprofloxacin as taste masked micro pellets … 250mg** **Firm shall submit full fee for correction in label claim along with source of pellets before issuance of registration letter.**	
27.	**Brand Name + Dosage Form and Strength**	Renlyte Syrup (300ml, 500ml, 600ml)
	Composition	Each 100ml contains: Sodium Chloride ……0.26g Trisodium Citrate Dihydrate……0.29g Potassium Chloride……...0.15g Glucose……..1.35g
	Diary No. , Date of R&I Fee	Dy. No.11825 dated:04.11.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP specifications
	Pack Size and Demand Price	300ml , 500ml, 600ml, As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Renlyte Syrup (300ml, 500ml, 600ml) (080779) due to non-submission of renewal of 2023 in prescribed time period
	Decision:- Approved	
28.	**Brand Name + Dosage Form and Strength**	Renosar Plus 50/12.5mg Film Coated Tablet
	Composition	Each film coated tablet contains: Losartan Potassium……..50mg Hydrochlorothiazide……12.5mg
	Diary No. , Date of R&I Fee	Dy. No.11832 dated:04.11.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP Specifications
	Pack Size and Demand Price	As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.

	Remark of Renewal Section	Registration of Renosar Plus 50/12.5mg Film Coated Tablet (007643-Ex) due to non-submission of renewal of 2023 in prescribed time period
	Decision:- Approved	
29.	**Brand Name + Dosage Form and Strength**	Renplex-F Syrup
	Composition	Each 5ml contains: Iron (III) hydroxide polymaltose complex eq. to elemental iron……...….50mg Folic acid……0.35mg
	Diary No. , Date of R&I Fee	Dy. No.11677 dated:31.10.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	Reign specifications
	Pack Size and Demand Price	60ml , 120ml , As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Renplex-F Syrup Pack size 60ml & 120ml (079694) due to non-submission of renewal of 2023 in prescribed time period
	Decision:- Approved	
30.	**Brand Name + Dosage Form and Strength**	Rensita 50mg Film Coated Tablet
	Composition	Each film coated tablet contains: Sitagliptin phosphate monohydrate equivalent to sitagliptin……..……50mg
	Diary No. , Date of R&I Fee	Dy. No.11836 dated:04.11.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP specifications
	Pack Size and Demand Price	As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Rensita 50mg Film Coated Tablet (007373-Ex) due to non-submission of renewal of 2023 in prescribed time period
	Decision:- Approved	
31.	**Brand Name + Dosage Form and Strength**	Rensita 100mg Film coated Tablet
	Composition	Each film coated tablet contains: Sitagliptin phosphate monohydrate eq. to sitagliptin……..100mg
	Diary No. , Date of R&I Fee	Dy. No.11837 dated:04.11.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP specification
	Pack Size and Demand Price	As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Rensita 100mg Film coated Tablet (007374-Ex) due to non-submission of renewal of 2023 in prescribed time period
	Decision:- Approved	
32.	**Brand Name + Dosage Form and Strength**	Rensitamet Tablet 50mg + 1000mg
	Composition	Each film coated tablet contains: Sitagliptin phosphate monohydrate eq. to Sitagliptin……50mg

		Metformin Hydrochloride……..1000mg
	Diary No. , Date of R&I Fee	Dy. No.11681 dated:31.10.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	BP specifications
	Pack Size and Demand Price	As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Rensitamet Tablet 50mg + 1000mg (007372-Ex) due to non-submission of renewal of 2023 in prescribed time period
	Decision:- Approved	
33.	**Brand Name + Dosage Form and Strength**	Renzith 200mg/5ml Dry Powder Suspension
	Composition	Each 5ml contains: Azithromycin as dihydrate…….200mg
	Diary No. , Date of R&I Fee	Dy. No.11828 dated:04.11.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP specifications
	Pack Size and Demand Price	15ml , As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Renzith 200mg/5ml Dry Powder Suspension (073801) due to non-submission of renewal of 2023 in prescribed time period
	Decision:- Approved	
34.	**Brand Name + Dosage Form and Strength**	Renzole 20mg Capsule
	Composition	Each Capsule contains: Esomeprazole enteric coated pellets eq. to esomeprazole…….20mg
	Diary No. , Date of R&I Fee	Dy. No.11688 dated:31.10.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP specifications
	Pack Size and Demand Price	14's , As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Renzole 20mg Capsule (073807) due to non-submission of renewal of 2023 in prescribed time period
	Source of pellets not submitted	
	Decision:- Approved. Firm shall submit source of pellets before issuance of registration letter.	
35.	**Brand Name + Dosage Form and Strength**	Renzole 40mg Capsule
	Composition	Each capsule contains: Esomeprazole enteric coated pellets eq. to Esomeprazole…….40mg
	Diary No. , Date of R&I Fee	Dy. No.11679dated:31.10.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP specifications
	Pack Size and Demand Price	14's , As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Renzole 40mg Capsule (073808) due to non-submission of renewal of 2023 in prescribed time period
	Source of pellets not submitted	

	Decision:- Approved. Firm shall submit source of pellets before issuance of registration letter.	
36.	**Brand Name + Dosage Form and Strength**	Rontilate 2gm Sachet
	Composition	Each sachet contains: Strontium Ranelate……2gm
	Diary No. , Date of R&I Fee	Dy. No.11833 dated:04.11.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	Reign specifications
	Pack Size and Demand Price	7's , As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Rontilate 2gm Sachet (073803) due to non-submission of renewal of 2023 in prescribed time period
	Decision:- Approved	
37.	**Brand Name + Dosage Form and Strength**	Rymol Suspension 250mg/5ml
	Composition	Each 5ml contains: Paracetamol…….250mg
	Diary No. , Date of R&I Fee	Dy. No.11827 dated:04.11.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP specifications
	Pack Size and Demand Price	As per SRO
	GMP Status	GMP Certificate issued on 31st December, 2021.
	Remark of Renewal Section	Registration of Rymol Suspension 250mg/5ml (007317-Ex) due to non-submission of renewal of 2023 in prescribed time period
	Decision:- Approved	
38.	**Brand Name + Dosage Form and Strength**	Seravi DS 10mg Tablet
	Composition	Each enteric coated tablet contain: Serratiopeptidase……10mg
	Diary No. , Date of R&I Fee	Dy. No.11680 dated:31.10.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	Reign specifications
	Pack Size and Demand Price	As per SRO
	GMP Status	
	Remark of Renewal Section	Registration of Seravi DS 10mg Tablet (007644-Ex) due to non-submission of renewal of 2023 in prescribed time period
	RRA status not confirmed	
	Decision: Registration Board deferred the product as product is under review by grey area committee of the Authority.	

Case No.05. M/s. Alen Pharmaceuticals Pvt Ltd. Plot No.138 Nowshera Industrial Estate, Riasalpur Pakistan.

1.	**Brand Name + Dosage Form and Strength**	I-Mec Tablet
	Composition	Each film coated tablet contains: Ivermectin BP……..6mg
	Diary No. , Date of R&I Fee	Dy. No.11292 dated:23.10.2024 Rs.37000/-
	Type of Form	Form - 5
	Finished Product Specifications	USP specifications
	Pack Size and Demand Price	10's As per SRO

	GMP Status	DML Inspection report dated 14.04.2022.
	Remark of Renewal Section	Registration of I-Mec Tablet (078421) due to non-submission of renewal of 2018 in prescribed time period.
Decision:- Approved		

Case No.06.M/s. Panacea Pharmaceuticals, Plot # 04, Street # S-6, National Industrial Zone Rawat, Islamabad.

1.	**Brand Name + Dosage Form and Strength**	Pcef 250mg Capsule
	Composition	Each capsule contains:- Cefradine …..… 250mg.
	Dairy No. date of R &I fee	Dy No.10404 dated 27.09.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	BP Specifications
	Pack size and Demand Price	5x10,s.As per SRO
	GMP Status	GMP certificate issued based upon evaluation conducted on 24-11-2022
	Remark of the Renewal section	Registration of Pcef Capsule 250mg (046181) due to non-submission of renewal of 2022 in prescribed time period.
	Decision:- Approved	
2.	**Brand Name + Dosage Form and Strength**	Pcef 500mg Capsule
	Composition	Each capsule contains:- Cefradine …..… 500mg.
	Dairy No. date of R &I fee	Dy No.10405 dated 27.09.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	BP Specifications
	Pack size and Demand Price	2x6's, As per SRO
	GMP Status	
	Remark of the Renewal section	Registration of Pcef Capsule 500mg (046182) due to non-submission of renewal of 2022 in prescribed time period.
	Decision:- Approved	
3.	**Brand Name + Dosage Form and Strength**	Pcef 125mg/5mL powder for Oral Suspension
	Composition	After reconstitution each 5mL contains:- Cefradine …..… 125mg.
	Dairy No. date of R &I fee	Dy No.10402 dated 27.09.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	BP Specifications
	Pack size and Demand Price	As per SRO
	GMP Status	
	Remark of the Renewal section	Registration of Pcef 125mg/5mL powder for Oral Suspension (046189) due to non-submission of renewal of 2022 in prescribed time period.
	Decision: Registration Board deferred the product for confirmation of approval status in Reference Regulatory Authorities.	
4.	**Brand Name + Dosage Form and Strength**	Pcef 250mg/5mL powder for Oral Suspension
	Composition	After reconstitution each 5mL contains:-

		Cefradine …..… 250mg.
	Dairy No. date of R &I fee	Dy No.10403 dated 27.09.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	BP Specifications
	Pack size and Demand Price	As per SRO
	GMP Status	
	Remark of the Renewal section	Registration of Pcef 250mg/5mL powder for Oral Suspension (046190) due to non-submission of renewal of 2022 in prescribed time period.
	Decision:- Approved	
5.	**Brand Name + Dosage Form and Strength**	Weldrox 500mg Capsule
	Composition	Each capsule contains:- Cefadroxil as Monohydrate …..… 500mg.
	Dairy No. date of R &I fee	Dy No.10401 dated 27.09.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	GMP Status	
	Remark of the Renewal section	Registration of Weldrox Capsule 500mg (046178) due to non-submission of renewal of 2022 in prescribed time period.
	Decision:- Approved	
6.	**Brand Name + Dosage Form and Strength**	Weldrox 125mg/5mL powder for Oral Suspension
	Composition	After reconstitution each 5mL contains:- Cefadroxil as Monohydrate …..… 125mg.
	Dairy No. date of R &I fee	Dy No.10399 dated 27.09.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	GMP Status	
	Remark of the Renewal section	Registration of Weldrox 125mg/5mL powder for Oral Suspension (046185) due to non-submission of renewal of 2022 in prescribed time period.
	Decision:- Approved	
7.	**Brand Name + Dosage Form and Strength**	Weldrox 250mg/5mL powder for Oral Suspension
	Composition	After reconstitution each 5mL contains:- Cefadroxil as Monohydrate …..… 250mg.
	Dairy No. date of R &I fee	Dy No.10400 dated 27.09.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	GMP Status	
	Remark of the Renewal section	Registration of Weldrox 250mg/5mL powder for Oral Suspension (046186) due to non-submission of renewal of 2022 in prescribed time period.
	Decision:- Approved	
8.	**Brand Name + Dosage Form and Strength**	P-Dox 100mg Capsule

	Composition	Each capsule contains:- Doxycycline as Hyclate …..… 100mg.
	Dairy No. date of R &I fee	Dy No.10396 dated 27.09.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	USP Specifications
	Pack size and Demand Price	As per SRO
	GMP Status	
	Remark of the Renewal section	Registration of P-Dox Capsule 100mg (046481) due to non-submission of renewal of 2022 in prescribed time period.
	Decision:- Approved	
9.	**Brand Name + Dosage Form and Strength**	Vclean 500mg Tablet
	Composition	Each vaginal tablet contains:- Clotrimazole …..… 500mg.
	Dairy No. date of R &I fee	Dy No.10397 dated 27.09.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	BP Specifications
	Pack size and Demand Price	As per SRO
	GMP Status	
	Remark of the Renewal section	Registration of Vclean Tablet 500mg (050184) due to non-submission of renewal of 2023 in prescribed time period.
	Decision:- Approved	
10.	**Brand Name + Dosage Form and Strength**	Silset 200mg Tablet
	Composition	Each film coated tablet contains:- Silymarin …..… 200mg.
	Dairy No. date of R &I fee	Dy No.10398 dated 27.09.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	Innovator's Specifications
	Pack size and Demand Price	As per SRO
	GMP Status	
	Remark of the Renewal section	Registration of Silset Tablet 200mg (048308) due to non-submission of renewal of 2023 in prescribed time period.
	Decision:- Registration Board deferred the product for confirmation of status of product in reference regulatory authorities as Drug or otherwise.	

Case No.07.M/s. Medicraft Pharmaceuticals, Pvt Ltd, Plot # 126-B Industrial Estate Hyatabad, Peshawar.

1.	**Brand Name + Dosage Form and Strength**	Ranmic Capsule 500mg
	Composition	Each capsule contains:- Tranexamic Acid …..… 500mg.
	Dairy No. date of R &I fee	Dy No.10068 dated 20.09.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	USP
	Pack size and Demand Price	2x10,s.As per SRO
	GMP Status	Inspection report dated on 10-05-2022
	Remark of the Renewal section	Registration of Panmic Capsule 500mg (036373) due

		to non-submission of renewal in prescribed time period.
	Remarks of evaluator: Product is available in JP. **Decision:- Approved with JP Specifications. Firm shall submit fee for correction in specifications before issuance registration letter.**	
2.	**Brand Name + Dosage Form and Strength**	Hepamed Injection
	Composition	Each 5ml contains:- L-Ornithine L-aspartate …..… 500mg.
	Dairy No. date of R &I fee	Dy No.10072 dated 20.09.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	Manufacture's Specifications
	Pack size and Demand Price	2x6's, As per SRO
	GMP Status	Inspection report dated on 10-05-2022
	Remark of the Renewal section	Registration of Hepamed Injection (064079) due to non-submission of renewal in prescribed time period.
	Decision:- Registration Board deferred the product for confirmation of approval status in reference regulatory authorities.	
3.	**Brand Name + Dosage Form and Strength**	Nabupin 10mg Injection
	Composition	Each ml contains:- Nalbuphine Hydrochloride …..… 10mg.
	Dairy No. date of R &I fee	Dy No.10069 dated 20.09.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	Manufacture's Specifications
	Pack size and Demand Price	1mlx10's, As per SRO
	GMP Status	
	Remark of the Renewal section	Registration of Nabupin 10mg Injection (064478) due to non-submission of renewal in prescribed time period.
	Decision:- Approved	
4.	**Brand Name + Dosage Form and Strength**	Acniclear Capsule
	Composition	Each capsule contains:- Isotretinoin…..… 10mg.
	Dairy No. date of R &I fee	Dy No.10070 dated 20.09.2024 Rs.37000/-
	Type of form	Fom-5
	Finished product specifications	BP Specifications
	Pack size and Demand Price	10's, As per SRO
	GMP Status	
	Remark of the Renewal section	Registration of Acniclear Capsule (051093) due to non-submission of renewal in prescribed time period.
	Decision:- Registration Board deferred the product for confirmation of product whether Hard Gel Capsule or Soft Gel.	
5.	**Brand Name + Dosage Form and Strength**	Vetomed Syrup
	Composition	Each 5ml contains: Salbutamol (as sulphate) BP……..2mg
	Dairy No. date of R &I fee	Dy No.10071 dated 20.09.2024 Rs.37000/-

	Type of form	Fom-5
	Finished product specifications	BP Specifications
	Pack size and Demand Price	60ml, As per SRO
	GMP Status	
	Remark of the Renewal section	Registration of Vetomed Syrup (041897) due to non-submission of renewal in prescribed time period.
	Decision:- Approved	

Case No. 8 M/s. Wilshire Laboratories (Pvt) Ltd .,124/1 Industial Estate Kot Lakhpat Lahore. (DML No.000232)

Sr.No.	Reg. No.	Brand Name & Composition	Date of Reg. PRV (If any)	Date of application (R&I) Fee submitted	Remarks	Validity
1.	029400	Dermaan Tab Each tablet contains Paracetamol …. 500mg codeine Phosphate …. 30mg	19.02.2003	Dy No.798 Rs. 165000/- 12.01.2024	Fee of Rs.15000/- to be submitted	**Renewal is granted w.e.f. 19.02.2023 to 18.02.2028**
2.	076977	Vorato 100mg Injection Each injection contains Suxamethonium Chloride.100mg (B.P Specifications)	30.09.2013	Dy No.798 Rs. 60,000/- 12.01.2024	Fee of Rs.15000/- to be submitted	**Renewal is granted w.e.f. 30.09.2023 to 29.09.2028**
3.	076978	Vorato 200mg Injection Each injection contains Suxamethonium Chloride …. 200mg (B.P Specifications)	30.09.2013	Dy No.798 Rs. 60,000/- 12.01.2024	Fee of Rs.15000/- to be submitted	**Renewal is granted w.e.f. 30.09.2023 to 29.09.2028**
4.	076976	Vorato 500mg injection Each injection contains Suxamethonium Chloride.500mg (B.P Specifications)	30.09.2013	Dy No.798 Rs. 60,000/- 12.01.2024	Fee of Rs.15000/- to be submitted	**Renewal is granted w.e.f. 30.09.2023 to 29.09.2028**
5.	086300	Pizoto 50mg Injection Each ml contains: Pethidine hydrochloride..50mg (As per innovator Specifications)	16.01.2018	Dy No.798 Rs. 180,000/- 12.01.2024	Fee of Rs.15000/- to be submitted	**Renewal is granted w.e.f. 16.01.2023 to 15.01.2028**

Remarks:
Firm has submitted differential fee as renewal applications submitted after due date but within one year as per SRO.1005/(i)/2017. Now the firm has requested for regularization for above mentioned product.

Decision:- Registration Board regularized the renewal of registration of above products and granted validity of products as mentioned against each subject to submission of differential fee of Rs.15000/- for each product before issuance of renewal letter.

Case No. 09 M/s. DeMont Research Laboratories (Pvt) Ltd. 20Km Lahore Sharikpur Road, Lahore

Sr.No.	Reg. No.	Brand Name & Composition	Date of Reg. PRV (If any)	Date of application (R&I) Fee submitted	Validity granted by Board

1.	85175	Flowset SR 0.4mg capsules Each capsule contains: Tamsulosin hydrochloride sustained release pellets eq to tamsulosin……0.4mg (As per innovators Specifications)	18.09.2017	Dy No.28351 Rs.15000/- Dated:05.10.2022 & Dy No.26218 Rs.15000/- Dated:30.10.2023	**Renewal is granted w.e.f.18.09.2022 to 17.09.2027**
2.	85174	Bexol 40mg Tablet Each film coated tablet contains Febuxostat……40mg (As per innovators Specifications)	18.09.2017	Dy No.28351 Rs.15000/- Dated:05.10.2022 & Dy No.26218 Rs.15000/- Dated:30.10.2023	**Renewal is granted w.e.f.18.09.2022 to 17.09.2027**
3.	85173	Bexol 80mg Tablet Each film coated tablet contains Febuxostat……80mg (As per innovators Specifications)	18.09.2017	Dy No.28351 Rs.15000/- Dated:05.10.2022 & Dy No.26218 Rs.15000/- Dated:30.10.2023	**Renewal is granted w.e.f.18.09.2022 to 17.09.2027**
4.	84895	Nexa 40mg Capsule Each capsule contains Esomeprazole magnesium Trihydrate enteric coated pellets eq. to Esomeprazole…..40mg (USP Specifications)	15.09.2017	Dy No.28351 Rs.15000/- Dated:05.10.2022 & Dy No.26218 Rs.15000/- Dated:30.10.2023	**Renewal is granted w.e.f.15.09.2022 to 16.09.2027**
5.	84894	Itrazil 100mg Capsule Each capsule contains Itraconazole……..100mg (USP Specifications)	15.09.2017	Dy No.28351 Rs.15000/- Dated:05.10.2022 & Dy No.26218 Rs.15000/- Dated:30.10.2023	**Renewal is granted w.e.f.15.09.2022 to 16.09.2027**

Remarks:
Firm has submitted differential fee as renewal applications submitted after due date but within sixty days as per SRO.1005/(i)/2017. Now the firm has requested for regularization for above mentioned product.

Decision:- Registration Board regularized the renewal of registration of above products and granted validity of products as mentioned against each case.

Case No. 10 M/s. Dyson Research Laboratories (Pvt) Ltd. 28Km Ferozepur Road, Lahore

Sr.No.	Reg. No.	Brand Name & Composition	Date of Reg. PRV (If any)	Traking ID	Validity granted by Board
1.	055344	Dysozole Capsule 20mg. Each Capsule contains:- Omeprazole as enteric coated Pellet…..20mg. (USP Specifications) **Source of pellets:-**	05/03/2009	WLG-5R1-2NQH Dated:15.03.2024 Rs.30000/-	**Renewal is granted w.e.f.05.03.2024 to 04.03.2029**

		M/s. Smilax Laboratories Ltd plot no.88/A Flat no 401 Sarala Nivas street #1 sagar society road #. 2 Banjara hills Hyderabad 34 india and then local encapsulation			
2.	055349	Magicap Capsule 20mg. Each capsule contains:- Fluoxetine as HCl ……20mg. (USP Specifications)	05/03/2009	2Y9-G98-ASNE Dated:15.03.2024 Rs.30000/-	**Renewal is granted w.e.f.05.03.2024 to 04.03.2029**
3.	055350	Zyson Capsule 250mg. Each Capsule contains:- Azithromycin as dihydrate ……...250mg. (USP Specifications)	05/03/2009	2BP-961-6UNS Dated:15.03.2024 Rs.30000/-	**Renewal is granted w.e.f.05.03.2024 to 04.03.2029**
4.	055351	Achedec Tablets 50mg. Each enteric coated tablet contains:- Diclofenac Sodium …50mg. (USP Specifications)	05/03/2009	6BA-WRW-51EM Dated:15.03.2024 Rs.30000/-	**Renewal is granted w.e.f.05.03.2024 to 04.03.2029**
5.	055352	Gofung Capsules 50mg. Each Capsule contains:- Fluconazole……..50mg. (BP Specifications)	05/03/2009	YV5-P8V-2J63 Dated:15.03.2024 Rs.30000/-	**Renewal is granted w.e.f.05.03.2024 to 04.03.2029**
6.	055353	Gofung Capsules 150mg. Each Capsule contains:- Fluconazole……150mg. (BP Specifications)	05/03/2009	DQM-ZME-QHYR Dated:15.03.2024 Rs.30000/-	**Renewal is granted w.e.f.05.03.2024 to 04.03.2029**
7.	055354	Clariquen Tablets 250mg. E ach film coated Tablet contains:- Clarithromycin ……250mg (USP Specifications)	05/03/2009	Z58-Q3M-XGN4 Dated:15.03.2024 Rs.30000/-	**Renewal is granted w.e.f.05.03.2024 to 04.03.2029**
8.	055355	Clariquen Tablets 500mg. Each film coated Tablet contains:- Clarithromycin ……500mg. (USP Specifications)	05/03/2009	E1X-81N-XNPZ Dated:15.03.2024 Rs.30000/-	**Renewal is granted w.e.f.05.03.2024 to 04.03.2029**
9.	055356	Mukil Capsule 100mg. Each capsule contains:- Itraconazole ……100mg. (Dyson's Specifications)	05/03/2009	1L2-24Y-BUVM Dated:15.03.2024 Rs.30000/-	**Renewal is granted w.e.f.05.03.2024 to 04.03.2029**
10.	069342	G Active Tablet Each film coated tablet contains:- Gemifloxacin (as Mesylate)… 320mg	01/04/2011	Dy No.12731 Rs.20000/- Dated 29.04.2021	**Renewal is granted w.e.f.01.04.2021 to 31.03.2025**

Remarks:
Firm has submitted differential fee as renewal applications submitted after due date but within sixty days as per SRO.1005/(i)/2017. Now the firm has requested for regularization for above mentioned product.

Decision:- Registration Board regularized the renewal of registration of above products and granted validity of products as mentioned against each case.

Case No. 11 M/s. Danas Pharmaceuticals (Pvt) Ltd. 312-Industrial Triangle Kahuta Road, Islamabad

Sr.No.	Reg. No.	Brand Name & Composition	Date of Reg.	Date of application (R&I) Fee submitted	Validity granted by Board

			PRV (If any)		
1.	079440	Gabfast Capsule 300mg Each capsule contains:- Pregabalin … 300mg	07/04/2015	Dy No. 15559 Rs.20000/- Dated 01.07.2020 & Dy No. 10474 Rs.10000/- Dated 30.09.2024	**Renewal is granted w.e.f.07.04.2020 to 06.04.2025**
2.	079441	Gabfast Capsule 75mg Each capsule contains:- Pregabalin … 75mg	07/04/2015	Dy No. 15559 Rs.20000/- Dated 01.07.2020 & Dy No. 10474 Rs.10000/- Dated 30.09.2024	**Renewal is granted w.e.f.07.04.2020 to 06.04.2025**
3.	079442	Gabfast Capsule 150mg Each capsule contains:- Pregabalin … 150mg	07/04/2015	Dy No. 15559 Rs.20000/- Dated 01.07.2020 & Dy No. 10474 Rs.10000/- Dated 30.09.2024	**Renewal is granted w.e.f.07.04.2020 to 06.04.2025**

Remarks:
The Renewal application for year 2020 was submitted late but within 60 days. Now the firm has requested for regularization for above mentioned products.

Decision:- Registration Board regularized the renewal of registration of above products and granted validity of products as mentioned against each case.

Item No. III Division of Quality Assurance & Laboratory Testing

S. No.	Case Title
1.	**Delegation of Functions/ Powers**
2.	**Substandard SN ZOR Powder for Oral Suspension Batch No. 342, Manufactured by M/s S.N.B pharma (Pvt) Ltd. Peshawar**
3.	**Misbranded Oxarise Liquid Oral Drench Reg. No. 109971 Batch # OX-008 Manufactured by M/s Biorise Pharmaceuticals, Multan**
4.	**Manufacture & Sale of Substandard Molimax Oral Suspension, Batch No. L2165, Manufactured by M/s. Alliance Pharmaceuticals (Pvt) Limited, Peshawar.**
5.	**Substandard Novarise Syrup B. No#113 Reg No.040306 Manufactured by M/s. Shrooq Pharmaceuticals (Pvt.) Ltd., Lahore.**
6.	**Adulterated & Substandard Paracet 1g Infusion by M/s Standpharm (Pvt). Ltd, Lahore.**
7.	**Manufacturing & Sale of Sub-Standard Water For Injection, Batch No. 440 Manufactured by M/s. Karachi Pharmaceutical Laboratories, Karachi.**
8.	**Manufacture/Sale of Substandard Drug Namely Famila Injection (Reg. No. 015615) Batch No. 083 Manufactured by M/s. Zafa Pharmaceutical Laboratories (Pvt) Ltd. Karachi.**
9.	**Sub-Standard Glycerin by M/s Opal Laboratories, Karachi**
10.	**Comparison of Counterfeits of "Pyodine Solution" in Compliance With Directions of Registration Board.**

CASE NO.1: DELEGATION OF FUNCTIONS/ POWER

The Registration Board in its 309th meeting delegated its powers to Chairman Registration Board under Rule 24 (10) of the Drugs (Licensing, Registering & Advertising) rules, 1976 in order to facilitate timely disposal of routine and day to day business of Registration Board.

Decision of 309th meeting of Registration Board:

Registration Board deliberated and delegated following functions to its Chairman under Rule 24 (10) Of Drugs (Licensing, Registering and Advertising) Rules, 1976:

i. Issuance of Show cause notices as per section 7(11) of the Drugs Act, 1976.

ii. To continue the custody of the seized stocks by the FID till decision of case.

iii. To extend the period of "not to dispose off" for three months.

iv. Grant of extension in the time of testing to Federal Government Analyst

The Board further deliberated matter regarding issuance of letter on behalf of Registration Board and directed to proceed as per Rule 24(12) of Drugs (Licensing, Registering and Advertising) Rules, 1976

The Chairman Registration Board, in order to facilitate timely disposal of routine and day to day business, has advised to place following agenda before the Registration Board to delegate following functions / powers to Director, Quality Assurance & Laboratory Testing Division, under Rule 24 (10) of the Drugs (Licensing, Registering & Advertising) Rules, 1976:

S. No.	Functions / Powers	Function / Power Delegated to
1.	Issuance of Show cause notices as per section 7(11) of the Drugs Act, 1976.	Director Quality Assurance and Laboratory Testing
2.	To continue the period of "not to dispose-of stocks orders passed by FID" for three months under Section 18(1) (i) of the Drugs Act, 1976.	Director Quality Assurance and Laboratory Testing
3.	To continue custody of the seized stocks by the FID under Section 18(1)(f) of the Drugs Act, 1976,	Director Quality Assurance and Laboratory Testing
4.	To grant approval for sending Board's portion of drug samples to the Appellate Laboratory as per section 22(5) of the Drugs Act, 1976,	Director Quality Assurance and Laboratory Testing
5.	Grant of extension in the time of testing to Federal Government Analyst under section 22(2) of the Drugs Act, 1976.	Director Quality Assurance and Laboratory Testing
6.	Issuance of Show Cause Notices/Personal hearing letters/Communication of Minutes/Decisions/Directions of the Board to the Concerned Quarters Quality Control matters on behalf of Secretary Registration Board. The letter shall be issued with Name & Designation of the officer.	Assistant Director (QA&LT) / Deputy Director (QA&LT)

Proceedings and Decision of 343rd Meeting of Registration Board

On the recommendation of the Chairman of the Registration Board, an agenda item was presented to address the efficient and timely disposal of routine matters involving contraventions of various provisions of the Drugs Act, 1976. The Board deliberated on the necessity of delegating specific powers to streamline the handling of such matters.

After deliberation, the Board decided to delegate the following functions / powers to the Director of Quality Assurance & Laboratory Testing (QA&LT). This delegation is authorized in accordance with Rule 24(10) of the Drugs (Licensing, Registering & Advertising) Rules, 1976.

S. No.	Functions / Powers	Functions / Powers Delegated to
1.	Approval for issuance of Show cause notices as per section 7(11) of the Drugs Act, 1976.	Director Quality Assurance and Laboratory Testing
2.	To continue the period of *"not to dispose-of stocks orders passed by FID"* for three months under Section 18(1) (i) of the Drugs Act, 1976.	Director Quality Assurance and Laboratory Testing
3.	To continue custody of the seized stocks by the FID under Section 18(1)(f) of the Drugs Act, 1976,	Director Quality Assurance and Laboratory Testing
4.	Grant of extension in the time of testing to Federal Government Analyst under section 22(2) of the Drugs Act, 1976.	Director Quality Assurance and Laboratory Testing
5.	Issuance of Show Cause Notices/Personal hearing letters/Communication of Minutes/Decisions/Directions of the Registration Board to the Concerned Quarters / Quality Control matters on behalf of Secretary Registration Board. The letter shall be issued with Name & Designation of the officer.	Assistant Director (QA&LT) / Deputy Director (QA&LT)

CASE NO. 2: <u>SUBSTANDARD SN ZOR POWDER FOR ORAL SUSPENSION BATCH NO. 342, MANUFACTURED BY M/S. S.N.B PHARMA (PVT) LTD. PESHAWAR.</u>

The Federal Inspector of Drugs, DRAP, Quetta during inspection of M/s Satellite Medicine Agency, Satellite Town, Quetta dated 08th November,2023 took samples of the SN Zor Powder for Oral Suspension on Form-3 and sent to the Federal Government Analyst, CDL Karachi for test/analysis on Form-4.

2. Federal Government Analyst, CDL Karachi vide test report No. KQ-11-23-000154 dated 22-02-2024, declared the batch 342 of product SN Zor Powder for Oral Suspension manufactured by M/s. S.N.B Pharma (Pvt) Ltd. Peshawar as of *"Substandard Quality"*. Details of CDL test report are as under.

Name of Product	Manufactured by	Reg. No.	Batch No.	Mfg. Date	Expiry Date	CDL Report
SN Zor powder for oral suspension (Azithromycin)	M/S. S.N.B Pharma (PVT) LTD. Peshawar	074547	342	082-2023	08-2025	Sub-Standard On the Basis of Assay. Azithromycin (88.33%) Limit (90-110%)

3. Firm was ordered to recall the defected batch of the product in question and Federal Inspector of Drugs Quetta was directed to investigate the matter and submit a comprehensive report in the matter.

4. Area FID DRAP, Quetta, vide letter No. DK-40-41/2023-FID-QTA 99 dated 14th May, 2024, concluded that firm was involved in violation under Section 23(1)(a)(v) of the Drugs Act, 1976 and rules framed thereunder and that a complete case was being submitted under Section 19(7) of the Drugs Act, 1976 for necessary action.

5. FID DRAP, Quetta had also submitted the request of the company for appellate testing of their product from the appellate laboratory vide letter No. SN/FIDQ/0705/2024 dated 07th May, 2024, from the company after receiving the letter from the Federal Inspector of DRAP, Quetta, along with the CDL report on the 04th March, 2024 (which FID sent on 1st March, 2024) under Section 22(4) of the Drugs Act, 1976.

6. Under Section 22(4) of The Drugs Act 1976, the person from whom the sample was taken has to notify in writing within thirty days of the receipt of a copy of the report that he intends to adduce evidence in contravention of the report.

7. The request of the company for testing of the sample of the drug lying with the Registration Board from the appellate laboratory specified for the purpose by the Federal Government under Section 22(5) of the Drugs Act 1976 is being presented before the Board, ***as thirty days have passed since the receipt of a copy of the report.***

8. Proceedings and Decision of 343rd Meeting of Registration Board

The Board, after considering the facts of the case and thorough deliberations, decided as follows:

i. ***Not to accede the firm's request for retesting of sample from Appellate Laboratory under section 22 (5) of the Drugs Act, 1976.***

ii. ***To issue show cause notice to M/S. S.N.B Pharma (PVT) LTD. Peshawar under Section 42 of the Drugs Act, 1976 and call the representatives of the firm for personal hearing before Registration Board in its forthcoming meeting.***

CASE NO.3: MISBRANDED OXARISE LIQUID ORAL DRENCH REG. NO. 109971 BATCH#OX-008 MANUFACTURED BY M/S BIORISE PHARMACEUTICALS, MULTAN

The Federal Inspector of Drugs, DRAP, Lahore during inspection dated 27-11-2023 took samples of Oxarise Oral Liquid Drench on Form-3 and Portion of sample was sent to the Federal Government Analyst, CDL Karachi for test/analysis on Form-4 bearing No.3585/2023-DRAP (L-IV) dated: 2-11-2023.

2. Federal Government Analyst, CDL Karachi vide test report No. LHR-12-23-000057 declared the batch OX-008 of product Oxarise Oral Liquid Drench manufactured by M/s Biorise Pharmaceuticals, Multan as of Misbranded (The information regarding Batch Number, Date of manufacturing, Date of expiry and retile Price on the outer Label is not written or printed in indelible ink). Details of CDL test report are as under.

S.	Product	Manufactured by	B. No.	Manufactured / Expiry	CDL Test Result
01	Oxarise Oral Liquid Drench	M/s Biorise Pharmaceuticals, Multan	OX-008	Mfg: 04-2023 Exp: 04-2025	Sample has been declared as "Misbranded" under section 3(s) (i) of the Drugs Act, 1976. *"The information regarding Batch Number, Date of manufacturing, Date of expiry and retile Price on the outer Label is not written or printed in indelible ink"*

3. Firm was ordered to recall the defected batch of the product in question and Federal Inspector of Drugs Lahore was directed to investigate the matter and submit a comprehensive report in the matter.

4. FID Lahore has replied through letter No.2118/2024-DRAP (L-IV) dated 15-08-2024 wherein he has intimated that a copy of the Test Report was supplied to the manufacturer with the direction to immediately stop manufacturing / distribution of the same batch, recall the said drug and explain their position in this regard, vide this office letter No.834/2024-DRAP (L-IV) dated 19-03-2024. FID Lahore has further stated that the manufacturer has submitted his replies vide letters No. Nil, dated 06-04- 24 and 30-04-2024, which is self-explanatory (they have circulated the recall letter to their Distributor/Wholesaler/Retailer and they conveyed that stock has already consumed. Moreover, they said issues was observed with the old printer, and they purchase and switch to the new printer for batch printing. Copy of new printer Invoice and printed label/outer carton is attached).

5. FID has further stated that he has also visited the premises of M/s. Biorise Multan on 07-06-2024, to check and verify the corrective measures which has been taken by the firm regarding proper batch number, date of manufacturing, date of expiry and printing of their MRP. The firm has purchased

inkjet printer for the proper in-house printing of batch number, date of manufacturing, date of expiry and their MRP. After taking these measures case of indelible ink and misbranding of their product in question may be considered as compliant. The remaining tests performed and reported by CDL Karachi vide its report No. LHR.12-23-000057 dated 06-03-2024 were found compliant.

6. **Decisions and Proceedings of 340th Meeting of Registration Board:**

The Board, after considering the facts of the matter and after thorough deliberations, concluded that the firm will submit the following:

i. *SOP's for reviewing the printed materials as per Drugs (Labelling and Packing) Rules,1986.*

ii. Annual product Quality review of Oxarise Oral Liquid Drench (109971) for last 02 years

7. **Reply of Firm:**

i. Firm submitted SOP for sampling and release of packing materials

The standard operating procedure outline the procedure for analyzing and releasing packaging materials.

ii. Annual product Quality review of Oxarise Oral Liquid Drench

Firm submitted Annual Product Quality review of Oxarise Oral Liquid Drech for 2 years

- In 2023 total number of batches reviewed were: 04

Detail of batches is as follows

S.No	Batch	Batch Size	Manufacturing Date	Expiry date
1.	OX-008	600 Liters	04-2023	04-2025
2.	OX-009	1000 Liters	06-2023	06-2025
3.	OX-010	1000 Liters	10-2023	10-2025
4.	OX-011	1000 Liters	12-2023	12-2025

CONCLUSION:

Our product Oxarise (Oxfendazole) Oral Drench has been reviewed in Jan-2024 which includes all the batches manufactured in year 2022. The statistical evaluation and trend analysis data obtained shows that the result complies with the specifications thus no revalidation of product is required.

- In 2022 total number of batches reviewed were: 07

Detail of batches is as follows

S.No	Batch	Batch Size	Manufacturing Date	Expiry date
1.	OX-001	250 Liters	03-2022	03-2024
2.	OX-002	500 Liters	03-2022	03-2024
3.	OX-003	1500 Liters	05-2022	05-2024
4.	OX-004	1500 Liters	05-2022	05-2024
5.	OX-005	1000 Liters	06-2022	06-2024
6.	OX-006	1500 Liters	07-2022	07-2024
7.	OX-007	1000 Liters	07-2022	07-2024

CONCLUSION:

Our product Oxarise (Oxfendazole) Oral Drench has been reviewed in Jan-2023 which includes all the batches manufactured in year 2022. The statistical evaluation and trend analysis data obtained shows that the result complies with the specifications thus no revalidation of product is required.

The Board after considering the facts of the case and thorough deliberations has decided to issue advisory to the firm M/s Biorise Pharmaceuticals, Multan to be careful in future.

CASE NO.4: MANUFACTURING & SALE OF SUBSTANDARD MOLIMAX ORAL SUSPENSION, BATCH NO. L2165, MANUFACTURED BY M/S. ALLIANCE PHARMACEUTICALS (PVT) LIMITED, PESHAWAR.

The Federal Inspector of Drug, DRAP, Peshawar inspected M/s Alliance Pharmaceuticals Pvt Limited wherein following sample 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	Expiry Date	CDL Remarks
Molimax Oral Suspension (Domperidone)	M/s. Alliance Pharmaceuticals (Pvt) Ltd., Peshawar.	044548	L2165	01/022	12/023	Sub-Standard on the basis of Assay. Domperidone (83.18%) Limits (90-110%).

2.The Federal Government Analyst, Central Drugs Laboratory, Karachi declared the above said sample as "Sub-Standard" quality vide test report No. IP-4-22-00078 dated 20-06-2022. 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	Specification	Result	Reference
1	Description	White to off-white suspension which is free from black particles filled in amber colored plastic bottle.	Complies.	Mfg. Specs.
2	Identification	The identification test must identify Domperidone.	Complies	Mfg. Specs.
3	pH	4.0 to 6.0	4.78-Complies	Mfg. Specs.
4	**Assay** Domperidone (Label claim 5mg/5ml)	90.0% to 110.0%	**83.18%** **Does not comply.**	Mfg. Specs.

Remarks: The sample is of **"Sub-Standard"** quality under the Drugs Act, 1976.

3. FID, DRAP, Peshawar informed that the firm has requested for retesting.

4. 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.

5. Ms. Alliance Pharmaceuticals Pvt Limited submitted their reply that Domperidone suspension is not included in any pharmacopeia and product is of internal specifications and both UV and HPLC methods are used. Assay was performed by UV method by CDL, Karachi. They requested for appellate testing with HPLC method.

6. FGA, CDL submitted that mentioned test method is UV instead of HPLC and corrigendum in connection is issued.

7. Firm submitted recall log, Area FID has been requested for verification of recalled stock, reply awaited.

8. **Technical Evaluation of OOS Investigation:**

i. The product was declared as sub-standard on the basis of assay.

ii. There may be issues during manufacturing processes, quality of API, and instability of product.

iii. Firm submitted that CDL, Karachi performed assay on HPLC but the product is non-pharmacopeial.

iv. FGA, CDL has clarified that they have tested by UV method and product is out of specification.

9. **Decisions and Proceedings of 331st Meeting of Registration Board:**

Out of Specification (OOS) investigations and testing records submitted by Ms. Alliance Pharmaceuticals Pvt Limited Peshawar and CDL, DRAP Karachi was presented before Registration Board.

10**. Decision:**

The Board deliberated the case in detail and decided to accede to the request of appellate testing.

11. The Registration Board portion was sent to the Appellate laboratory for resting under Section 22(5) of the Drug Act 1976. Appellate laboratory vides letter No No.F.03-35/2022-QC dated 04-12-2023.

12. The appellate laboratory declared the sample as substandard vide report No. F. 1-20/01-M/2023-DC&TMD dated 22nd December, 2023. [Sub-Standard on the basis of Assay. Domperidone (83.18%) Limits (90-110%)]

13. In the light of Appellate report show cause notice vide office No F.03-35/2022-QC dated 5th November, 2024 and corrigendum date 19th November, 2024 under Section 42 of the Drugs Act 1976 was issued to the firm.

14. Division of QA&LT issued a notice of personal hearing vide letter F.03-46/2024-QALT (342-RB) dated 28th November, 2024 under Section 42 of the Drug Act 1976

Proceedings and Decision of 343rd Meeting of Registration Board

Mr. Shahid Mehboob QC Manager and Mr. Waseem Ghulam QA Manager of M/s. Alliance Pharmaceuticals (Pvt) Ltd., Peshawar appeared before the Board and apprised that product was tested near to expiry date. They added that there is absence of peak area, concentration values, chromatograms and raw data to substantiate the finding of Appellate Laboratory. They further added that same product has already been declared as standard by DTL, Multan.

The Board after considering the facts of the case and thorough deliberations decided to:

i. ***Suspend Registration of Molimax Oral Suspension, Registration No. 044548 manufactured by M/s. Alliance Pharmaceuticals (Pvt) Ltd., Peshawar under section 42 of the Drugs Act, 1976 and rules framed thereunder, for a period of 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.***

ii. ***Submission of RCA and CAPA by the firm.***

iii. ***Product Specific Inspection including verification of RCA and CAPA by panel of Inspectors / experts to be nominated by Director QA&LT.***

CASE NO.5: **SUBSTANDARD NOVARISE SYRUP B#113 REG NO.040306 MANUFACTURED BY M/S SHROOQ PHARMACEUTICALS (PVT.) LTD., LAHORE.**

Federal Government Analyst, CDL Karachi vide test report No. LHR-1-24-0000021 declared the batch 113 of product Novarise Syrup manufactured by M/s. Shrooq Pharmaceuticals (Pvt.) Ltd., Lahore as of substandard quality. Details of CDL test report are as under:

S.No	Product	Manufactured by	B. No.	Manufactured/ . / Expiry	CDL Test Result
01	Novarise Syrup	M/s. Shrooq Pharmaceuticals (Pvt.) Ltd., Lahore.	113	Mfg: 07-2023 Exp: 06-2025	Substandard on the basis of presence of Ethylene Glycol impurity. **Ethylene Glycol Content: 0.7818%** **Does not comply with the**

2. Firm was ordered to recall the defected batch of the product in question and Federal Inspector of Drugs-IV Lahore was directed to investigate the matter and submit a comprehensive report in the matter. FID-IV Lahore vide letter Ref. No. 1427/2024-DRAP (L-IV) dated 30-05-2024 informed that the firm was ordered to stop the sale of product in question and recall the stocks. Moreover, FID-IV Lahore has submitted the request of firm for appellate testing of their product vide letter No. DRAP/0524/001 dated 09th May, 2024 after receiving the letter from Federal Inspector on 22nd April,2024 (which FID sent on 9th April, 2024) under Section 22(4) of the Drugs Act, 1976.

3. In this regard it is submitted that the Registration Board in its 313th meeting decided as under:

"Proceedings and Decision of 313th Meeting of Registration Board.
The Board after thorough deliberations and considering the facts of the case decided as:
i. The firm will provide OOS investigation and complete testing record of the concerned batch along with scientific justifications/grounds with the request of Appellate testing under section 22(4) of the Drugs Act 1976.
ii. Federal Government Analyst, Karachi will provide OOS investigation and complete testing record of such reports.
iii. Registration Board advised QA&LT Division to present all cases of Appellate Testing with these both set of documents along with technical report of the case."

4. In the light of above-mentioned decision of the Board, the division of QA&LT vide letter F. No. 03-14/2024-QC requested the Federal Government Analyst CDL Karachi and M/s. Shrooq Pharmaceuticals (Pvt.) Ltd., Lahore for the submission of OOS investigation as directed by the Board.

5. Summary of evaluation of OOS investigation by the division of QA&LT is given as under:

Summary of OOS investigation submitted by Central Drugs Laboratory, Karachi:
Federal Government Analyst, CDL Karachi has submitted OOS investigation and has ruled out any possibility of error in the method of test/analysis, equipment and/or any operator or analyst related error.
Summary of OOS investigation submitted by M/s. Sharooq Pharmaceuticals (Pvt.) Ltd., Lahore:
M/s. Sharooq Pharmaceuticals (Pvt.) Ltd., Lahore in their reply has provided OOS investigation at laboratory and manufacturing level and has provided following findings:
i) The firm has reviewed complete batch manufacturing record of batch in question, all the processes i.e. dispensing and manufacturing were found as per manufacturing process as mentioned in BMR of respective batch.
ii) The firm did not found any deviation regarding the manufacturing and testing of batch on each stage.
iii) The assay results were well within the limit on each test point.
iv) Propylene Glycol lot used for manufacturing of batch under question was also used in 2 other products:

Sr. No.	*Product*	*Batch #*	*CDL Testing*

1.	*Novarise Syrup 120ml*	*113*	***Substandard***
2.	*Levtral Oral Solution*	*035*	*Standard Quality*
3.	*Citalax Oral Drops*	*013*	*Standard Quality*

Testing of all 03 products were performed by the CDL, Karachi. 02 products were declared as standard quality whereas 01 product was declared as substandard.

v) The ratio of Propylene Glycol to total batch volume used in manufacturing of batches as provided in para above are:

Sr. No.	***Product***	***Batch #***	***PG Ratio to Batch Volume***
1.	*Novarise Syrup 120ml*	*113*	*1.5%*
2.	*Levtral Oral Solution*	*035*	*0.1%*
3.	*Citalax Oral Drops*	*013*	*8.0%*

The product with high ratio i.e. Citalax Oral Drop declared as of standard quality whereas Novarise Syrup 120ml having less percentage of PG was declared as substandard.

6. However, it pertinent to mention that during the investigation process, FID-IV Lahore took samples from 06 drums of PG having same batch number and one other drum having different batch number and test/analysis results of each batch resulted in different quantities of DEG/EG impurities identified. Details are as under:

S#	**Material**	**Test Report No.**	**Test Results**	**Purported Manufacturer**
01	Propylene Glycol B#C856H85R55	RM-1-24-000084	Ethylene Glycol: 38.6277% Does not comply	M/s. Dow Chemicals, Thailand
02	-do-	RM-1-24-000085	Ethylene Glycol: 28.7166% Does not comply	-do-
03	-do-	RM-1-24-000086	Ethylene Glycol: 42.3126% Does not comply	-do-
04	-do-	RM-1-24-000087	Ethylene Glycol: 57.0006% Does not comply	-do-
05	-do-	RM-1-24-000088	Ethylene Glycol: 78.7802% Does not comply	-do-
06	-do-	RM-1-24-000089	Ethylene Glycol: 72.8081% Does not comply	-do-
07	Propylene Glycol B#F8900L8PPD6	RM-1-24-000091	Ethylene Glycol: 0.7624% Does not comply	M/s. Dow Chemicals, Germany

7. The matter mentioned in para 06 is still under investigation however the request of firm for appellate testing as informed by FID-IV Lahore vide para 02 is submitted for the consideration of the Board.

8. **Proceedings and Decision of 340th Meeting of Registration Board.**

Out of Specification (OOS) investigations provided by the firm and the Federal Government Analyst, CDL Karachi were presented before the Registration Board. The Board, after considering the facts of the case and after thorough deliberations, decided:

i. Not to accede the firm's request of retesting of sample from appellate Lab.

ii. Firm should submit the complete recall status of Novarise Syrup Batch No# 113 as per Recall Guidelines to the QALT Division, DRAP, Islamabad Doc No.

QALT/GL/RA/001 to the QA&LT Division, DRAP, Islamabad. (www.dra.gov.pk/wp-content/uploads/2022/02/Guidelines-on-Recalls-and-Rapid-alerts-of-defective-Theraputic-Goods.pdf).

iii. To issue show cause notice to M/s. Sharooq Pharmaceuticals (Pvt.) Ltd., Lahore under Section 42 of the Drugs Act, 1976 and call the representatives of **the firm** for personal hearing before Registration Board in its forthcoming meeting.

iv. Destruction of Propylene Glycol raw material declared substandard.

9. Division of QA&LT issued show cause notice vide office No F.03-34/2024-QC(340-RB) dated 29th October, 2024 under Section 42 of the Drugs Act 1976.

10. In response to said show cause, M/s. Shrooq Pharmaceuticals (Pvt) Ltd, Lahore vide letter DRAP/1124/006 dated 06th November, 2024 replied as under:

Kindly refer to your show cause notice # F.03-34/2024-QC (340-RB), dated 29th October 2024 received on 30th October 2024, wherein you have alleged that we have violated section 23(1)(a)(v) of Drug Act, 1976 and rules made there under with Schedule-II of the DRAP Act, 2012 as well as conditions of registration. We humbly submit that M/s Shrooq Pharmaceuticals (Pvt.) Ltd. is a GMP compliant firm and have manufacturing quality drug products for local as well as international market with a very good repute. Being a quality conscious company, we have taken all necessary steps to comply all the quality parameters. However, in context of impurities detection by CDL and your show cause notice, it is submitted that;

1) As per your show cause notice letter the Ethylene Glycol content is mentioned as 07818% and same results were mentioned in 340th meeting of Registration Board whereas actual results is 0.7818%, CDL report is attached herewith for your reference and record.

2) Soon after sampling of said batch by the competent authorities, we started immediate recall without any delay as per recall guidelines which indicate compliance of the firm. Complete recall status was already submitted to QA&LT division against letter # DRAP/0524/004 and again attached for your reference and record.

3) Also, complete destruction record of Propylene Glycol raw material lots (02 lots & 07 drums, 06 drums of Batch #C856H85R55 & 01 drum of Batch # F8900L8PPD6) declared as substandard is attached for reference and record.

4) It is important to mentioned as M/S Shrooq Pharmaceuticals itself take initiative and conveyed to respected authorities regarding sampling and testing of suspected lots and products which also Indicates quality consciousness of the firm and which also need to be acknowledged positively By the DRAP. Out top management also shared TTI reports to DRAP top authorities through WhatsApp and telephonically conveyed the subject matter to keep DRAP updated in the matter considering its sensitivity and responsibility of our firm.

5) As per quires by competent authorities in vide letter # F.03-34/2024-QC (340-RB) point 3 (i). firm response regarding product registration, M/S Shrooq Pharmaceuticals is manufacturer of quality products and providing medicinal supplies in local, export and government tenders as a trusted manufacturer and after DRAP SRO # F.6-30/2022-QA, we have initiated CAPA in the matter and started working on formulations without these solvents have EG/DEG impurities. We already performed successful trials batches of said product without Propylene Glycol, Glycerin and Sorbitol. Details of Trial batches were attached here for reference and record with satisfactory stability data.

6) As per quires by competent authorities in vide letter # F.03-34/2024-QC (340-RB) point 3 (ii), a Complete scientific justification/ grounds related to the retesting of Novarise was already submitted to competent authority against letter # DRAP/0624/005, considering this and organizational self-initiative for product quality, we request not to prosecute this matter in the court of competent jurisdiction. Moreover, product has been recalled and contamination lots are destroyed, we also in phase to change the formulation to prevent reoccurrence and improve product quality.

7) As per quires by competent authorities in vide letter # F.03-34/2024-QC (340-RB) point 3 (iii), board should consider the positivity of organization as Shrooq Pharmaceutical take self-initiative for faulty raw material detection and information to competent authority and futuristic product consistent quality approach for permanent solution of said cause with effective corrective and preventive action.

In light of above-mentioned justifications and have taken sufficient CAPA actions, it is requested to kindly revoke the show cause notice. We shall also welcome further regulatory requirements of DRAP, if required in the matter we assurance of cGMP compliance and all necessary actions in the matter.

11. Division of QA&LT issued a notice of personal hearing vide letter F.03-46/2024-QALT (342-RB) dated 28th November, 2024 under Section 42 of the Drug Act 1976

12. **Proceedings and Decision of 343rd Meeting of Registration Board**

Mr. Muhammad Tayyab Manager Quality Control of M/s. Shrooq Pharmaceuticals (Pvt.) Ltd., Lahore appeared before the Registration Board. He apprised that it was a self-initiative on detection of faulty raw material, we started immediate recall without any delay as per recall guidelines which indicate compliance of the firm & complete recall status was already submitted to QA&LT division against. He further added that formulation of product has been revised.

The Board after considering facts of the case, recall of the product by the firm, self-initiative for faulty raw material detection, information to DRAP and thorough deliberations decided to issue warning letter to the firm M/s Shrooq Pharmaceuticals (Pvt.) Ltd., Lahore with strict advise to comply various directions of DRAP issued from time to time for testing of PEG & DEG

CASE NO.6: ADULTERATED & SUBSTANDARD PARACET 1G INFUSION BY M/S STANDPHARM (PVT). LTD, LAHORE

BACK GROUND:

FID DRAP Quetta informed that he has done sampling of product Paracet 1g/100ml Infusion from M/S Usman Traders Yet Road Quetta on 16-11-2022.

S.No	Name of Product	Batch No.	Mfg. date	Expiry Date	Manufacturer	CDL Report
1	Paracet IV 1 G/100 ml Infusion. Reg.No.(083853)	CIJ170	20-09-2022	20-09-2024	M/s StandPharm (Pvt) Ltd, Lahore	Containing black color particles visible to the naked eye Does not comply. *Adulterated and Substandard*

CDL vide report No. KQ11-22-000234 dated has declared the above said sample to be **ADULTERATED AND SUBSTANDARD** based on the presence of visible black particles. Accordingly, FID issued copy of report to firm and also issued letter for recall and explanation.

2. The Product Recall Alert of Paracet 1g/100mL Infusion was also uploaded on DRAP website.

3. Firm Submitted their reply to FID vide letter Nil dated 03-01-2023 wherein the firm challenged the test result of the CDL section 22, sub-section 5 of Drug Act 1976 and requested for appellate test. Firm also stated that they did not received manufacture sample portion and also stated that they have check retained sample and do not found any bottle with black particles.

4. Letters were issued to manufacturer and FGA, dated 18-04-2023 for provision of OOS investigation as per the decision of 313th meeting of DRB

5. Reply has been received from M/s Standpharm, Lahore, dated 02-05-2023 wherein firm has submitted OOS investigation, stating that they have checked retained samples as well as recalled stock and did not find any quality contravention, moreover they have performed OOS investigation and declared that no OOS deviation was found, it is pertained to mention that the submitted OOS

investigation was conducted in response to PQCB Quetta.

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STANDPHARM	**STANDPHARM PAKISTAN (PVT) LTD.**	
Form No. FQC – 1399 – 01	**Investigation Report for Out of Specification Analytical Results**	
Reference Document No. QC – 600	Effective Date: 07-04-2023	Page 1 of 4

1. Summary of OOS Results:

Product: Paracet Infusion 1g/100ml
Batch Number: CIJ170
Title of SOP: SOP for Finished product testing of Paracet Infusion 1g/100ml
Effective date of SOP: 25-01-2023
OOS Generated by: DTL Quetta
OOS Investigation number: 002/2023

SOP number: QC-586-03
Product Stage: Finished Product Sample.
OOS Result: Sample found having foreign matter visible through naked eye. (By DTL Quetta)
Specification: FQC-1375-02
Analyst / Department: Govt. Analyst
QC Manager / Date: M. Shah Jahan/ 27-4-23

2. Description and Investigations of OOS:

All testing results including 'Particulate matter', were found satisfactory at the time of batch release. Investigation performed as sample was declared "Adulterated" by DTL Quetta due to the presence of foreign matter visible to naked eyes. All initial testing record was reviewed as a part of investigation.

Checklist	YES	NO	Not applicable
Documentation			
Write/transfer error	☐	☑	☐
Calculation error	☐	☐	☑
.....	☐	☐	☐
Carrying out			
Deviation from procedure	☐	☑	☐
Incorrect procedure	☐	☑	☐
.....	☐	☐	☐
Standard			
Correct standard	☐	☐	☑
Expiration date OK	☐	☐	☑
Storage OK	☐	☐	☑
Initial weight OK	☐	☐	☑
Dilution OK	☐	☐	☑
.....	☐	☐	☐

STANDPHARM	STANDPHARM PAKISTAN (PVT) LTD.	
Form No. FQC – 1399 – 01	**Investigation Report for Out of Specification Analytical Results**	
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Samples			
Correct sample	☑	☐	☐
Storage OK	☑	☐	☐
Initial weight OK	☐	☐	☑
Dilution OK	☐	☐	☑
.....	☐	☐	☐
.....	☐	☐	☐
Instrument *(Liquid Particle Counter)*			
Calibration OK	☐	☑	☐
Parameter set correctly	☐	☑	☐
Injector correct	☐	☐	☑
Detector correct	☐	☐	☑
.....	☐	☐	☐
.....	☐	☐	☐
.....	☐	☐	☐
System Suitability Test carried out	☐	☐	☑
.....Not Applicable.....	☐	☐	☑
.....	☐	☐	☑
.....	☐	☐	☑
.....	☐	☐	☑
.....	☐	☐	☑

Comments: No documentation, instrument, performance or sample related problem found. All testing result, including 'Particulate matter', were found satisfactory & valid.

3. Determinate Error ☐ Indeterminate Error ☐ Clerical Error ☐

QC Analyst: _____ Supervisor / QC Manager: _____

Akbar Ali Deputy Director (Lab Testing) Thursday, 01 August, 2024, 5:46:6 PM

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STANDPHARM	STANDPHARM PAKISTAN (PVT) LTD.	
Form No. FQC – 1399 – 01	Investigation Report for Out of Specification Analytical Results	
Reference Document No. QC – 600	Effective Date: 07-04-2023	Page 3 of 4

4. Investigation

4.1 Result of investigation:

No error found during initial investigation.

4.2 Corrective Action: (only if it is Determinate or Clerical Error)

As there is no OOS hence not applicable

4.3 Remarks:

Description / Appearance of solution, Particulate matter and all other results found satisfactory. Complete testing record is attached.

5. Retest

5.1 Retest by Analyst 'A' Result: NA Pass ☐ Fail ☐
(In case of Determinate Error)

5.1.1 If failed, determine the cause (s) of failure

Determinate Error ☐ Indeterminate Error ☐ Clerical Error ☐

5.1.2 If the result is Pass, Accept the results and release the sample.

5.1.3 Remarks: _____

5.2 Indeterminate Error

Retest Result: Analyst 'A': _____ Pass ☐ Fail ☐

Analyst 'B': _____ Pass ☐ Fail ☐

Remarks: _____

If required Result of Analyst 'C': _____ Pass ☐ Fail ☐

Resample Result: Analyst 'A': _____ Pass ☐ Fail ☐

Analyst 'B': _____ Pass ☐ Fail ☐

Remarks: _____

If required Result of Analyst 'C': _____ Pass ☐ Fail ☐

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STANDPHARM	STANDPHARM PAKISTAN (PVT) LTD.	
Form No. FQC – 1399 – 01	Investigation Report for Out of Specification Analytical Results	
Reference Document No. QC – 600	Effective Date: 07-04-2023	Page 4 of 4

6. **Discussion & Conclusion:**

Testing results at the time of batch release were satisfactory and valid. Retained sample of this batch was tested on 26-12-2022 and found the sample clear and having no sign of particulate matter. Result of other tests were also satisfactory and submitted to PQCB, Quetta on 26-12-2022 & Drug Inspector Zone-N, Quetta Baluchistan on 03-01-2023.

Analyst / Date: 27/4/2023 QC Manager / Date: 27/4/2023

7. **Remarks by QA:**

Batch recall has already been done. We have recalled 731 packs from market. We have also checked recalled pack and no sign of particulate matter visible to naked eye found in recalled packs.

QA Manager Signature / Date: 27/04/2023

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STANDPHARM	STANDPHARM PAKISTAN (PVT) LTD.	
Form No. FQC – 1400 – 01	**Formal Investigation for Un-Assignable Cause**	
Reference Document No. QC – 600	Effective Date: 07-04-2023	Page 1 of 2

Section I

Date of test: 26-12-2022	SOP #: QC-586-03
Title of SOP: : SOP for Finished product testing of Paracet Infusion 1g/100ml	Sample description: Paracet Infusion 1g/100ml, batch # CIJ170.
Observed value: No foreign matter found visible	Reason for investigation: Declared "Adulterated" by DTL Quetta
Specification: FQC-1375-02	Analyst name: Asad Nawaz
OOS Investigation number: 002/2023	

Section II

Impact on Process and Product Quality:

Determine whether or not Un-assignable OOS has impacted process or Product Quality

Yes ☐ The quality of product (s) impacted due to:

1-
2-
3-

No ☐ The quality of product (s) impacted due to:

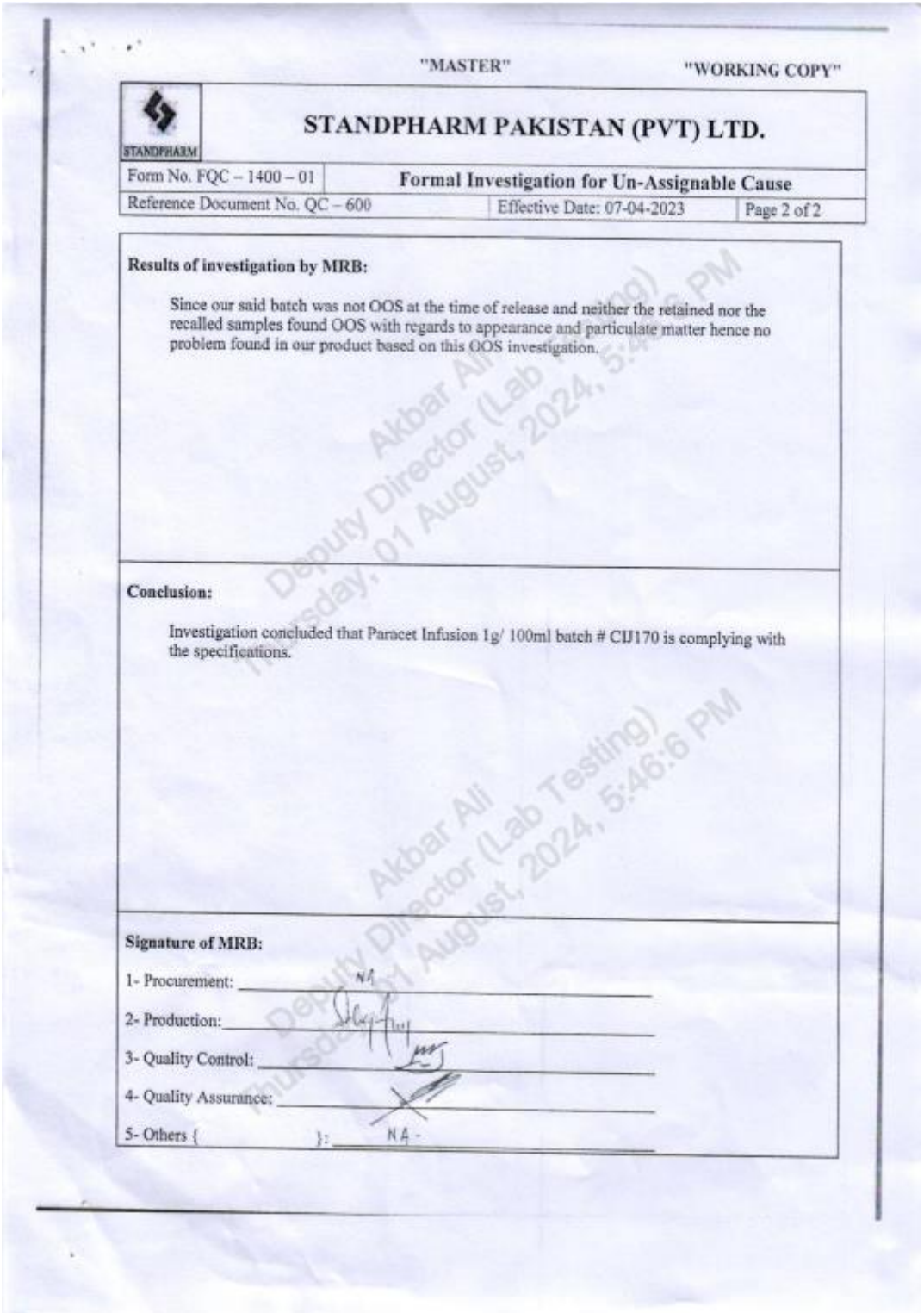
1-
2-
3-

NA ☑

Analyst Signature: _____

Identify batches / Lots / materials that are impacted:
NOT APPLICABLE

Material Review Board (MRB) Investigations:
From the review of Batch Processing record of Paracet infusion batch no. CIJ170, it was noted that batch was manufactured and filled on 21-09-2022. Vials washing, manufacturing, filtration & filling in closed loop were performed after proper line clearance and area clearance according to SOPs. Bags of pre-autoclaved Bromobutyle Rubber stoppers were opened under LFH and instilled in respective hopper to minimize the chance of contamination. Environmental condition during batch processing were satisfactory.
Non-viable count monitoring has been performed on 13-09-2022 with satisfactory results.
Filter integrity tests of HEPA filters has been performed on 08-09-2022 with satisfactory results.
Visual inspection was performed by 8 trained staff in 2 stages, i.e. first by 5 trained staff & then the passed vials were rechecked by 3 other trained staff.



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STANDPHARM PAKISTAN (PVT) LTD.

Form No. FQC – 1400 – 01	Formal Investigation for Un-Assignable Cause	
Reference Document No. QC – 600	Effective Date: 07-04-2023	Page 2 of 2

Results of investigation by MRB:

Since our said batch was not OOS at the time of release and neither the retained nor the recalled samples found OOS with regards to appearance and particulate matter hence no problem found in our product based on this OOS investigation.

Conclusion:

Investigation concluded that Paracet Infusion 1g/ 100ml batch # CIJ170 is complying with the specifications.

Signature of MRB:

1- Procurement: NA

2- Production:

3- Quality Control:

4- Quality Assurance:

5- Others { }: NA

6. It is further submitted that the Board Sample portion was received in broken form, and letter was issued to area FID Quetta to investigate this matter and fix the responsible person for packing and delivering broken, the reply of which is still pending.

7. PQCB Quetta was also request vide letter No.F.No.13-09/2023-QC dated 10-07-2023 and reminder dated 12-08-2023 to provide details of proceeding and results of DTL Quetta / NIH (if any) regarding this Batch of Paracet Infusion 100 ml batch No. CIJ170. No reply has been received from PQCB Quetta.

8. **Proceedings and decision of Registration Board 339th meeting:**

Board deliberated the case in detail and decided not to accede firm's request of appellant testing and decided to issue showcase notice to firm along for suspension /cancelation/prosecution in Drug Court of subject cited drug to M/s Standpharm Pakistan (Pvt) Ltd, Lahore and called for personal hearing before Registration Board.

9. Division of QA&LT issued show causes notice vide office No F.03-28/2024-DDLT (339-RB) dated 28th October, 2024 under Section 42 of the Drugs Act 1976.

10. In response to said show cause, M/s. Standpharm Pakistan (Pvt) Ltd, Lahore vide letter nil dated 11th November, 2024 replied:

*1. This is in response to the show cause notice dated 28-10-2024 (the "**Notice")** wherein your good office has directed M/s Standpharm Pakistan (Private) Limited ("**Standpharm**") to furnish a response to the allegations of violating the conditions of registration and manufacture of Paracet IV 1 G/100 ml Infusion (Registration No. 083853), Batch No. CIJ170 (the "Product") purportedly declared "adulterated and substandard" vide CDL, Karachi test report No. KQII-22-000234 dated 20-12-2023 (the "**CDL Report**")*

2. It is brought to your kind attention that Standpharnı has been engaged in the manufacturing, distribution and sale of the Product for the past several years and there has never been any complaint regarding any defect in the quality, safety and efficacy of the Product. Accordingly, the allegations contained in the Notice as well as the contents of the CDL Report ate vehemently denied by Standpharm in their entirety

3. Without prejudice to the foregoing, in response to the ill-founded and incorrect allegations contained in the Notice, we submit as under.

- *First and foremost, the sample of the warrantor/manufacturer's portion of the Product in question was never received from the Federal Inspector of Drugs by Standpharm in violation of the mandatory sampling requirements stipulated under Section 19 (6) of the Drugs Act, 1976 (the "**Drugs Act**"). As such, Standpharm has duly investigated and verified the batch manufacturing record of the Product and found the aforementioned product to be well within the permissible parameters. Standpharm has recalled the said batch from all distributors and submitted the details to Assistant Director QC-I (Mr. Shahrukh Ali) on 12 January 2023 and later on complete recall updates on 20 March 2023 with filled annexures as per "Guidelines on Recalls and Rapid Alerts of Defective Therapeutic Goods". Out the 7380 vials released for dispatch (Batch size 8000 vials) only 731 vials were received back. There have never been any complaints launched/ received regarding the consumed 6649 vials by any retailer/distributor/practitioner, leading to assume that the batch in general did not contain any visible particle. The Recalled vials as well as the retain samples within the premises were all checked and verified for any visible particles, but were found satisfactory.*

- *It is important to mention that for recall verification of said batch on 11 Jan 2023, the Provincial Drug Inspector did a surprise visit at Standpharm facility at 5pm to witness the recalled stock and have a look at our injectable facility. He was unable to indicate any visible particle in the recalled vials. He further took samples of other injectable products, namely Stanflox Infusion (batch # CIM211), Staxin 400mg Infusion (batch #CIM239) & Protoxil Infusion (batch #CU179) and sent to Drug Testing Laboratory Lahore for complete analysis. All of these sample were found satisfactory with respect to all physical, chemical and microbiological tests.*

Report of Test/ Analysis by Govt. Analyst, Punjab of these three products attached herewith as "Enclosures-I & III".

- *Moreover, Standpharm also performed OOS investigation and no defect was found in the quality of the Product. This report was submitted before the Registration Board in its 339 Meeting of Registration Board held on 6ª August to 8th August 2024.*

Copies of the OOS Investigation report, batch release certificate/report are attached herewith as "Enclosures-IV to V

i. *It is pertinent to note that the CDL Report is riddled with infirmities and defects and hence inadmissible as evidence of any violation of the Drugs Act or the rules framed thereunder on part of Standpharm. The CDL Report's findings are based on 'a naked eye test' to ascertain and conclude that the Product allegedly contains "Black particles visible to the naked eye" without carry out the liquid particulate matter test to verify the number, characteristics and type of the 'black particles purportedly found in the Product in question. On the contrary, in light of various precedents it is*

clear that tiny particles, if found, in any drug will not make by necessary corollary render the drug in question substandard or adulterated. This viewpoint is supported by the following judicial pronouncements:

a. 2003 YLR 3056 Lahore
"Simply remarking that the sample contained suspended particles which were visible to the naked eye, would not be sufficient to declare the drug substandard or adulterated."

b. In ICA No. 127 of 1989 the Lahore High Court, held that particles and fibers are not covered under the definition of adulteration.

c. 1996 PC.LJ 1183
"To hold the drug adulterated or substandard, it must be declared as filthy, purid or decomposed substance which contains any foreign matter, vermin, worm etc. Thus, the particles and fibers in the drug would not make it adulterated or for that matter substandard".

ii. Be that as it may be, the Product is manufactured at the state-of-the-art manufacturing facility of Standpharm and it is beyond comprehension that any particle could adulterate the Product in question during the manufacturing process or whilst the Product remained in the safe custody of Standpharm. Asa matter of fact, to maintain and ensure the integrity and quality of the liquid preparations, Standpharm has made a significant investment in procuring and installing the latest machinery as well as instated strict Standard Operating Procedures. These measures adopted by Standpharm ensure that the highest quality drugs are manufactured and made available for the consumption of the public en mass. Accordingly, there is no possibility of adulteration of the Product and the findings of the CDL Report are highly questionable and non-conclusive

List of the machinery along with its specifications and Standard Operating Procedures employed by Standpharm are attached herewith as "Enclosures VI & VII",

iii. From the registration of this product till date some other batches of said product have also been collected by drug inspectors of relevant areas and all of the samples have been found of "Standard" quality from different drug testing laboratories of the country. Below is the summary of batches and areas from where the samples have been taken:

Batch #	*Area*	*Date*
BID061	*Rawalpindi*	*Aug 2021*
DIJ138	*Umerkot (Sindh)*	*Feb 2024*

Report of Test! Analysis by Govt. Analyst, Punjab (by DTL Rawalpindi for batch # BID051) is attached as "Enclosure VIII".

iv. Moreover, Standpharm has been denied its statutory right provided under Section 22 (4) & (5) of the Drugs Act to raise evidence in contravention of the CDL Report and get the Product in question re-tested from the Appellate Laboratory without any fault or lapse on its part. As such, the burden of lapses in the sampling of the Product has been wrongly placed upon Standpharm outside the bounds of fair regulation and principles of equity since the re-testing request of Standpharm was denied because the Registration Board received broken sample of the Product from the Drug Inspector. Consequently, the safe delivery of the samples received by the CDL for the purpose of test and analysis is also questionable since the warrantor portion was never received by Standpharm and even the Board's sample was received broken which fact is admitted in the 339th Meeting of Registration Board held on 6 August to 8 August 2024. As such, the contents and findings of the CDL report are highly doubtful and lack credibility since the same cannot be verified through re-testing whatsoever.

v. Lastly, it is stressed that Standpharm has an impeccable reputation in the pharmaceutical sector and has never violated any term of registration of the Product or engaged in violation of the drug laws of the Country. Accordingly, it is futile to initiate any action against Standpharm and/or its officials.

4. In view of the foregoing, your good office is requested to withdraw the captioned show cause notice in the interest of justice, equity and fair play. It is further requested that, the Registration Board may reconsider and Standpharm (Private) Limited as well as its Officers be dropped of being misconceived.

11. Division of QA&LT issued a notice of personal hearing vide letter F.03-46/2024-QALT (342-RB) dated 28th November, 2024 under Section 42 of the Drug Act 1976.

12. **Proceedings and Decision of 343rd Meeting of Registration Board**

Mr. Shoaib Ashraf (Production Manager), Mr. Muhammad Shah Jahan (Head of Quality Operations) and Mr. Rao Tahir Umer (CFO / COO) of the firm M/s StandPharm (Pvt) Ltd, Lahore, appeared before the Board and stated that detailed reply has already been sent in response to Show Cause Notice. They further added that retained sample was tested and did not found any particulate matter, the product was manufactured in new facility which is functional since June, 2022.

After personal hearing the materre was deliberated in light of above facts and Mr. Syed Adnan Rizvi Director DTL, Govt. of Sindh, Karachi was of opinion that according to United States Pharmacopeia chapter *<788> Visible Particulates in Injections*, "If it becomes necessary to evaluate product that has been shipped to customers (e.g., because of a complaint or regulatory concern), sample and inspect 20 units. If particles available, additional units may be inspected to gain further information on the risk of particulates in the batch". Since additional units have not been inspected and also M/s Standpharm have not received any warrantor's portion for said batch which is mandatory as per law. Hence the decision for suspension of registration of Paracet IV 1G/100 ml infusion for a period of three months is opposed.

The Board after considering the facts of the case and after thorough deliberations decided to:

i. ***Suspend the Registration of Paracet IV 1 G/100 ml Infusion., Registration No. 083853 manufactured by M/s StandPharm (Pvt) Ltd, Lahore under section 42 of the Drugs Act, 1976 and rules framed thereunder, for a period of three months.***

ii. ***Product Specific Inspection by panel of inspectors/experts to be nominated by Director QA/LT.***

CASE NO.7: MANUFACTURING & SALE OF SUB-STANDARD WATER FOR INJECTION, BATCH NO. 440 MANUFACTURED BY M/S. KARACHI PHARMACEUTICAL LABORATORIES, KARACHI.

The Federal Inspector of Drug, DRAP, Karachi inspected M/s Sindh Government Children Hospital, North Nazimabad, Karachi on 16-09-2022 wherein following sample 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
Water for injection	M/s. Karachi Pharmaceutical Laboratories, Karachi	012570	440	Jun 22	Jun 25	Sub-Standard on conductivity.

2. The Federal Government Analyst, Central Drugs Laboratory, Karachi declared the sample as "Sub-Standard" quality vide test report No.KQ.9-22-000164 dated 11-10-2022 and No.KQ.9-22-000164 (Final) dated 28-10-2022. 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	Acceptance Criteria	Result	Reference
1.	Acidity or Alkalinity	Meet the requirements.	Complies.	BP 2020
2.	Conductivity	Not more than 25uS/cm	**48.09µS/cm-Does not comply.**	BP 2020
3	Sterility	Must be sterile	Complies	BP 2020
4	Bacterial endotoxin	Not more than 0.25IU/ml	**Does not comply**	BP 2020

5	Visible particulate matter	Meets the requirement	Complies	BP 2020

Remarks: The sample is of **"Sub-Standard"** quality under the Drugs Act, 1976.

3. FID, DRAP, Karachi informed that the firm has requested for retesting.

4. 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 21-06-2023.

5. Ms. Karachi Pharmaceutical Laboratories Karachi submitted their reply vide Ref. KPL/HR/7/23 dated 03-07-2023 along with OOS investigation, OOS results reproduced as:

"Handling of Out of specifications OOS results for samples in Karachi Pharmaceutical Laboratories. It is the policy of Karachi Pharmaceutical Laboratories that written procedures shall be followed to carry out laboratory investigations/product retest and assign probable cause and initiate appropriate CAPA for OOS results of samples."

6. Firm submitted recall log, the percentage of recall is **89.24%.** Area FID has been requested for verification of recalled stock, reply awaited.

7. Technical Evaluation of OOS Investigation:

i. The product was declared as sub-standard on the basis of conductivity and bacterial endotoxin.

ii. There may be issues during manufacturing processes, quality of API, and instability of product.

iii. Firm submitted reply without scientific justifications and clear conclusion, further, flow chart for investigation of OOS was not attached as mentioned in the conclusion. While CDL Karachi submitted that the final decision of the report is OOS valid.

8. Proceedings and Decision of 331st Meeting of Registration Board.

i. Out of Specification (OOS) investigations and testing records submitted by Ms. Karachi Pharmaceutical Laboratories Karachi and CDL, DRAP Karachi was presented before Registration Board.

ii. The Board deliberated the case in detail and decided not to accede the firm's request of appellate testing and to issue show cause notice for suspension/cancellation/ prosecution in Drug Court of the subject cited drug to Ms. Karachi Pharmaceutical Laboratories Karachi and called them for personal hearing before Registration Board.

09. Show cause notice to the firm was issued vide office letter No. F.No.03-38/2023-QC (331-RB) dated 13th December 2023.

10. Firm has been called for personal hearing as per decision of the Registration Board.

11. Proceedings and Decision of 336th Meeting of Registration Board

The Registration Board in its 336th Meeting held on 04-06 June, 2024 decided the case as follows:

"***No person on behalf of M/s. Karachi Pharmaceutical Laboratories Karachi appeared before the Board. Registration Board decided to provide last chance of personal hearing to the firm."***

In response to decision of Registration Board, Letter for Personal hearing, bearing number 03-21/2024-QC(336-RB) dated 27th September was issued.

12. Proceedings and Decision of 340th Meeting of Registration Board.

Mr. Mehboob Ismaili, Quality Assurance Manager, M/s Karachi Pharmaceutical Laboratories, Karachi appeared before board and explained that their sample declared sub-standard on basis of conductivity. They received letter of personal hearing because their product declared sub-standard on basis of conductivity only.

The Board after considering their hearing and facts of the case after thorough deliberations, directed the QA/LT division to share the final report to the company and present the case in next registration board meeting.

13. Firm was communicated decision of 340th meeting of RB, The final report of CDL showing non-compliance to endotoxin test was shared with firm as during personal hearing they said for non-communication of said report to them.

14. Firm submitted reply vide their letter No. KPL/RD/11?2024 dated 12-11-2024, wherein they submit that during personal hearing in 340th meeting of RB held on 28th October 2024, "Mr. Mehboob Ali Ismaili explained the reasons of conductivity and endotoxin / LAL Test results as per CDL report. Director and the members were satisfied. Director then asked to their members that they were satisfied, or they have any Question to ask then members showed their satisfaction about explanation and no question was raise by the members of the Board. Director warned me no such complain will occur in future and closed the case and allow me to leave. Sample drawn from the hospital did not have our Bill warranty therefore we are not responsible for the sample".

Proceeding and Decision of 343rd Meeting of Registration Board

QA & LT Division presented case before the Board. The Board was apprised that as per decision of 340th meeting of RB, report of CDL, Karachi has been shared with the firm. The Board considered the reply of firm and after threadbare deliberation decided to issue show cause notice to firm and call them for personal hearing in the forthcoming meeting of Registration Board.

CASE No.8: MANUFACTURE/SALE OF SUBSTANDARD DRUG NAMELY FAMILA INJECTION (REG. NO. 015615) BATCH NO. 083 MANUFACTURED BY M/S. ZAFA PHARMACEUTICAL LABORATORIES (PVT) LTD. KARACHI.

FID Karachi submitted letter No. F.SHM-56-92/2024-FID-IV (K) dated 01st October 2024, wherein he stated that he, in compliance to the directions contained on M/s / Zafa Pharmaceutical Laboratories (Pvt) Ltd., Karachi request letter received vide DRAP Karachi office Dy. No. 559 dated 19/07/2024, inspected the premise of M/s. Zafa Pharmaceutical Laboratories (Pvt) Ltd., 1-41 A&R Block-21 FB industrial Area, Karachi on 22/07/2024, wherein following samples of drugs were taken along with other drugs for the purpose of test analysis on prescribed Ferm-3 for PWD Sindh.

Name of Drug	Batch No.	Mfg. Date	Exp. Date	Manufactured by	CDL Report No. & Remarks
Famila Injection (015615)	083	02/24	02/29	M/s Zafa Pharmaceuticals Laboratories (Pvt.) Ltd., Karachi.	Report No.PWD-8-24- 000051 dated 10th September 2024. Non- Sterile Does Not Comply

2. The Government Analyst Central Drugs Laboratury, Karachi vide test report No.PWD-8-24-000051 dated 10th September, 2024 declared the above batch of Famila Injection as "SUBSTANDARD" quality under the Drugs Act, 1976, which is violation of Section 234(1) (a) (v) of Deng Act 1976 and rules framed there under.

3. M/s. Zafa Pharmaceutical Labvoratories (Pvt.) Ltd., L-4/1 A&B Block-21 FB Industrial Area, Karachi vide their letter No. Nil received in area FID's office vide Dy. No. 752 dated 30- 09-2024 submitted as following:

> *"The sample of Famillа Injection, Batch No. 083 was taken for the purpose of test/analysis and sent to Federal Government Analyst, Central Drugs Laboratory, Karachi. The Government Analyst, Central Drugs Laboratory, Karachi vide Test Report No. PWD-8-24-000051 dated 10-09-2024 (received along with your letter) declared the sample as substandard on the basis of Sterility Test whereas the Famila Injection is sterilized by terminal sterilization process. The filled and sealed vials of Famila Injection, Batch No. 083 were sterilized by heating in an autoclave at 121°C and 15 lb pressure for 30 minutes. The batch was released for packing by Quality Control after compliance of physical, chemical and microbiological tests including Sterility Test which was performed as per USP by Microbiologist. Therefore, in the light of our Quality Control Test Results you are requested to send the sample of Famila Injection, Batch No. 083 to the Federal Appellate Drug Laboratory for retesting under Section 22 (5) of the Drugs Act 1976".*

4. Firm submitted their reply (OOS Investigation) vide their letter no. Nil dated 07-11-2024. They stated as following:

The drug product was continuously manufactured from about last 20 years with name of Famila Injection. We have an established manufacturing method. As per our manufacturing method Famila Injection is sterilized by terminal sterilization process. The filled and sealed vials of Famila Injection, Batch No. 083 were sterilized by heating in an autoclave at 121°C and 15 lb pressure for 30 minutes. The batch was released for packing by Quality Control after compliance of physical, chemical and microbiological tests including Sterility Test which was performed as per USP by Microbiologist. The Government Analyst, Central Drugs Laboratory, Karachi vide Test Report No. PWD-8-24-000051 dated 10-09-2024 (received along with your letter) declared the sample as substandard on the basis of Sterility Test. Please note that Test Report No. PWD-8-24-000051 contains only single test that is Sterility Test whereas other tests including Appearance of Suspension, Identification of API, pH of Suspension, Assay of API and Bacterial Endotoxin Test are essential tests (copy of batch analysis enclosed) These tests were not performed by Government Analyst. Therefore, according to the Section 22 (5) of the Drug Act 1976, request submitted to Federal Inspector of Drugs-IV, Karachi for retesting the sample of Famila Injection, Batch No. 083 at the Federal Appellate Drug Laboratory and stop the sale till the re-testing report (Copy of Letter to Distributor enclosed). We have no doubt on the terminal sterilization process and sterility testing results. After receiving Government Analyst Test Report, Quality Control Microbiologist re-performed Sterility Test of Keeping Samples and found the results as per USP Specification (copy of re-testing of sterility enclosed). According to the Sterility Testing Results, batch of Famila Injection was sterile and complies with drug product specification. Therefore, there is no Out of Specification (OOS) Investigation required as per GMP.

5. Director, CDL, Karachi submitted, on 25-11-2024, OOS investigations of Drug Famila Injection (150mg/ml) Batch No. 083. According to OOS Investigation, OOS is valid with remarks as the sample is not complying with respect to Sterility Testing.

6. Request of the firm for the appellate testing under section 22 (5) is submitted before the Board.

Proceeding and Decision of 343rd Meeting of Registration Board

QA & LT Division presented the case before the Registration Board. The Board considered the request of firm and after threadbare deliberation decided to accede request of firm for appellate testing, under Section 22 (5) of the Drugs Act, 1976, of Famila Injection (015615), Batch No. 083 for sterility testing only.

CASE NO.9: SUB-STANDARD GLYCERIN BY M/S OPAL LABORATORIES, KARACHI.

CDL vide its report No. RM-8-24-000501 dated 10th October declared following sample as "Sub-standard":

Material	Lot No.	Manufacturer	Remarks on Report	Mfg By:	Mfg. Date	Exp. Date	Result
Mascerol Glycerin	000574B ND3C5L	M/s PT Musim Mas, Indonesia	Sub-standard	M/s PT MUSIM MAS, Indonesia	18-02-2024	18-02-2026	Propylene Glycol has been found as individual impurity up to level of 1.13%. **Does Not Comply**

2. Letter, numbered F.03-40/2024-DD(QA & LT-VIII) dated 07th November 2024, to the firm to provide details of consumption of the said batch and details of suppliers.

3. All DRAP field offices were asked to investigate the matter thoroughly vide letter No. F.03-40/2024-DD(QA & LT-VIII) dated 07th November 2024.

4. Letter, numbered F.03-40/2024-DD(QA & LT-VIII) dated 07th November 2024, to PPMA and Pharma Bureau to increase vigilance among member companies.

5. In response, the firm has submitted that they received the sample from Local supplier dated 07-08-2024 and the sample of said lot was forwarded to CDL for testing of impurities. After that, the said lot was declared sub-standard by CDL. As a result, the internal destruction was generated by the firm's Quality Assurance department, which was then sent for destruction to M/s National Environmental Services & Consultant in order to ensure safe disposal of material in the presence of firm representative dated 21-10-2024. Destruction letter of M/s National Environmental Services & Consultant also provided by the firm.

Proceedings and Decision of 343rd Meeting of Registration Board

The case was presented by the QA&LT Division before the Board. On scrutiny of record, it was observed that the Mascerol Glycerin (250 Kg) was procured by the firm M/s Opal Laboratories (Pvt.) Ltd, Karachi from the local market. The Board noted the information regarding destruction of Mascerol Glycerin, Lot No. 000574BND3C5L by M/s National Environmental Services & Consultant in order to ensure safe disposal of material in the presence of firm representative dated 21-10-2024. The Board decided to direct the Additional Director, DRAP, Karachi to depute any Federal Inspector of Drugs to visit the firm and take samples of liquid syrups containing Glycerin for testing by CDL for the purpose of test / analysis.

CASE NO 10: COMPARISON OF COUNTERFEITS OF "PYODINE SOLUTION" IN COMPLIANCE WITH DIRECTIONS OF REGISTRATION BOARD

Registration Board in its 339th meeting held on 06th to 08th of August, 2024, on the directions of the Honorable Islamabad High Court, Islamabad (Order dated 03-07-2024 passed W.P No. 2073/2024) decided as under:

"M/s Brooks Pharma (Pvt.) Ltd. Karachi (Complainant) through representative Dr. Arif Hussain Siddique along with Council Mr. Umar Hameed Advocate appeared before Board for personal hearing/representation and presented physical samples /Bottles of allegedly counterfeit Pyodine manufacturers along with list of 26 alleged counterfeit Pyodine Products and urged their claim that these products have close resemblance and imitation with their product Pyodine.

The Board after hearing the arguments of the firm in detail and after thorough discussion and deliberation and nominated Director QA&LT to review each individual claimed counterfeit product in comparison with Pyodine for resemblance of packs for lookalike imitation of label which may deceive the patients. The shortlisted reviewed imitation product cases on individual basis would be presented by QA/LT division before next Board meeting for consideration and further decision of the Board."

Accordingly, after extensive review by QA&LT division, following imitated / counterfeit products of "Pyodine Solution" of M/s Brookes Pharma, Karachi have been shortlisted below:

Resemblance status of Counterfeit Products of "Pyodine Solution" (Reg No. 009528)

Sr. No.	Name of the Manufacturer	Brand name	Reg. No / Product enlistment number	Resemblance parameters				Final Remarks
				Brand name	Color Scheme	Text	Graphic	
1.	M/s Cortex Pharmaceuticals, Rawalpindi. (DML No. 000826)	Pyidine Solution	080824	Yes	Yes	Yes	Yes	Both label and Brand name
2.	M/s Zanctok Pharmaceutical Laboratories, Sindh (DML No. 000251)	Zyodine Solution	045451	Yes	Yes	Yes	Yes	Both label and Brand name
3.	M/s Oval Pharmaceuticals, Lahore. (DML No. 000156)	Septodine Solution	049925	No	No	Yes	No	Only label
4.	M/s Lahore Pharma, Sheikhupura. (DML No. 000084)	Plasodine liquid	014228	Yes	Yes	Yes	Yes	Both label and Brand name
5.	M/s Paradise Pharma, Lahore. (DML No. 000742)	Povidone Iodine solution	071551	No	No	No	No	No resemblance
6.	M/s Kohinoor Industries, Sahiwal. (DML No. 000197)	Prodine Solution	037440	Yes	No	Yes	No	Both label and Brand name

7.	M/s Hoover Pharmaceuticals, Lahore. (DML No. 000676)	Poviderm Solution	094559	No	No	Yes	No	Only label revision
8.	M/s Pharmawise Labs, Lahore. (DML No. 000182)	Povine Solution	037527	Yes	No	No	No	Only Brand name
9.	M/s N.B.S. Pharma, Lahore. (DML No. 000467)	Povidone-I Solution	025552	No	No	Yes	No	Only label
10.	M/s Jawa Pharmaceuticals (Pvt.) Ltd, Lahore. (DML No. 000150)	Japodon Solution	096512	No	Yes	Yes	Yes	Only Label
11.	M/s Trigon Pharmaceuticals, Lahore. (DML No. 000342)	Halodine Solution	057302	No	Yes	No	Yes	Only Label
12.	M/s Perfect Pharma (Pvt.) Ltd. Lahore. (DML No. 000469)	Povidone Iodine Solution	026935	No	Yes	Yes	Yes	Only Label
13.	M/s Irza Pharma, Sheikhupura. (DML No. 000108)	Wondseptic Solution	030073	No	No	No	No	No resemblance
14.	M/s ISIS Pharmaceuticals & Chemical works, Karachi (DML No. 000126)	ISIS Povidone Iodine Solution	110071	No	No	Yes	Yes	Only label
15.	M/s A. Mannan Lab. Karachi.	Payodine Solution	004377	Yes	Yes	Yes	Yes	Both label and Brand name
16.	M/s Glorious Laboratories, Islamabad. (Mfg. Enl. No. 002)	Pyogon Solution	002. 0062	Yes	Yes	Yes	Yes	Both label and Brand name
17.	M/s Zaiam Pharma Nutraceuticals, Lahore. (Mfg. Enl. No. 00233)	Pyoline Solution	00233. 0001	Yes	Yes	Yes	Yes	Both label and Brand name

The findings of the Division of QA&LT are submitted for consideration by the Board.

Proceedings and Decision of 343rd Meeting of Registration Board

QA&LT Division presented the case in the light of decision of 339th meeting of Registration Board. After thorough deliberation, the Registration Board decided to proceed in the light of the findings / recommendations of Division of Quality Assurance and Laboratory Testing. Keeping in view findings / remarks of QA&LT Division, the Board decided to refer the cases as follows: -

a. **Registered Drugs under Section 7 of the Drugs Act, 1976 to the Pharmaceutical Evaluation & Registration (PE&R) Division for issuance of letters to the firms for respective variations.**

b. **Enlisted products under SRO 412 (I)/2014 to Health & OTC Division for necessary action at their end.**

Item No. IV Division of Biological Evaluation & Research

(Iqra Aftab)

(Deputy Director-IV):

Item No. 01: Imported Human Biological Products from Non-Reference Countries

Registration of Heberprot –P 75µg (Recombinant Human Epidermal Growth Factor)

1.	Name, address of Applicant / Importer	**M/s Herbion Pharma,** **Plot 30, Sector 28, Korangi Industrial Area, Malir Karachi, Pakistan**
	Details of Drug Sale License of importer	**Address of Godown:** Plot No 37/A/3, Landhi Industrial Area. Plot No. IT-2,A-3, Korangi Creek Industrial Area, Karachi **Status**: License to sell drugs by way of whole sale. **Validity**: 10-07-2028. **Renewal:** NA
	Name and address of marketing authorization holder (abroad)	Center of Genetic Engineering and Biotechnology (CIGB). Ave. 31 e/158 y 190. Playa, La Havana City, Cuba.
	Name, address of manufacturer(s)	**<u>As per COPP</u>** **Parenteral Products Plant 3 (PPP-3): Formulation, filling and lyophilization.** **Packaging Plant: Packaging.** National Center of Bioproducts (BIOCEN), Carretera Beltran. Km 1 ½, Bejucal, Mayabeque, Cuba . **<u>As per Section 3.2.P.3.1</u>** **1. Plant PP3: Formulation, filling, lyophilization** **2. Packing plant: Packaging of Heberprot-P®.** National Center of Bioproducts (BIOCEN) (Contract manufacturer) Address: Carretera de Beltrán, Km 1 ½, Bejucal, Mayabeque, Cuba. **3. Analytical control laboratory** Center for Genetic Engineering and Biotechnology (CIGB) Address: Avenida 31 e/ 158 y 190, Reparto Cubanacán, Playa, La Habana. Cuba. Quality Control Direction of CIGB: QC testing for release and for stabilities studies **4. Lot release** Center for Genetic Engineering and Biotechnology (CIGB) Address: Avenida 31 e/ 158 y 190, Reparto Cubanacán, Playa, La Habana. Cuba.
	Name of exporting country	Cuba
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**<u>Original Legalized and Valid COPP</u>** **Certificate No:** 11-034-24-PF-I **Certifying Authority:** Republic of Cuba Ministry of Public Health Center for State Control of Medicines, Equipment and Medical Devices ls this product licensed to be placed on the, market for use in the exporting country? YES Is this product actually on the market in the exporting country? YES Validity : March, 2026.
	Details of letter of authorization / sole agency agreement	**<u>Original Letter of Authorization Issued on 16th December 2022</u>** We, **Center for Genetic Engineering and Biotechnology** Address: Ave. 31 e/158 y 190. Playa, Havana city, Cuba By this letter, hereby **appoint** **HERBION PAKISTAN PVT LTD**

		A Pakistani company registered in the Registry _ Securities and Exchange Company of Pakistan with registration number K-198/7723 I 0011006 in said registry and with legal address in Plot 30, sector 28, Korangi Industrial Area, postal code: 74900, Karachi, Pakistan. To act on behalf of us under their name to make registration for product below: - Name of product: Heberprot-P75. - Active ingredient, strength: Recombinant Human Epidermal Grov\-1:h Factor 0,075mg. - Pharmaceutical form: Lyophilized powder for intralesional injection. at the Drug Regulatory Authority of Pakistan (DRAP). HERBION PAKISTAN PVT LTD - authorized company - shall be the marketing authorization holder and be responsible to Ministry of Health (Drug Administration) for aU matters penaining to this 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 ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	18749(R&I) Dated 25-07-2023
	Details of fee submitted	Challan No. 117620905470 Rs. 75,000/-
	The proposed proprietary name / brand name	Heberprot –P 75µg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Recombinant Human Epidermal Growth Factor (FCEhr)…75 µg
	Dosage form of applied drug	Lyophilized powder for intralesional injection
	Pharmacotherapeutic Group of (API)	It is an stimulation agent for cicatrization and citoprotection by the formation of useful granulation tissue that allows healing by second intention healing or a skin autograft.
	Finished product specifications	**Inhouse Specification (firm has mentioned NA in 1.5.6)**
	Proposed Pack size	6 R vial.
	Proposed unit price	As per SRO/DPC
	Shelf life	36 months
	Storage conditions	Store below 25 °C.
	The status in reference regulatory authorities	It's not registered in any SRA. Heberprot-P is a Novel Cuban-developed drug used primarily for treating diabetic foot ulcers. It has been successfully registered in 26 countries worldwide list of countries along with registration certificates and periodic safety update report (PSUR) is also attached herewith in annexure C Notably, this includes members of the Pharmaceutical Inspection Co-operation Scheme (PIC/S), such as Argentina, Turkey, Mexico, and South Africa & South Korea.

	For generic drugs (me-too status)	N/a
	Module-II (Quality Overall Summary)	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	**Plant 4: Manufacturing, labeling and storage of recombinant human Epidermal Growth Factor (rhEGF) active pharmaceutical ingredient (API)** **Quality Control Direction: Testing and stability studies.** Center for Genetic Engineering and Biotechnology (CIGB) Address: Avenida 31 e/ 158 y 190, Reparto Cubanacán, Playa, La Habana. Cuba
	Module 3 (Quality)	
	Module-III Drug Substance:	Firm has submitted information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, 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)	Formal Study In the formal study, t**he API remains stable during twelve (12) months at the temperature of 5 ± 3ºC, and during one (1) month at the temperature of 25 ± 2ºC**, stored in bags of ethylene-vinyl acetate wrapped in flexible metalized laminated packages. **The Purity by RP-HPLC (%) at 12 months is at borderline.(95%)** **Ongoing Study** In the on-going study, the API also remains stable during twelve (12) months at the temperature of 5 ± 3ºC, stored in the same bags. **Real Stability Study at 5 ± 3 ° C** All the evaluated characteristics met their respective acceptance criteria. From the organoleptic point of view, the product remained as a transparent solution free of particles. Through the ELISA technique, the EGF molecule was identified at each sampling time. The specific Activity fall within the specification limits and the variations found are due to the variability of the biological activity and the protein concentration. **The pH and purity by RP-HPLC remained without tendencies to increase or decrease with reasonable variations justifiable by the variability of the analytical technique, as well as the purity by SDS-PAGE**. The product remains sterile and pyrogen-free. **Conclusion** The data from the above studies and others done before have established that the rhEGF API is stable up to 12 months at the normal storage temperature of 2-8 ºC. A 12 month expiry date was assigned to rhEGF API.
	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.

		• **Scale up and technology transfer of Heberprot-P from CIGB Development Unit facility (600 vials/lot) to BioCen facility (15000 vials/lot).** • **Scale up and technology transfer of Heberprot-P from CIGB Development Unit facility (600 vials/lot) to CIGB Plant-4 facility (1600 vials/lot).** • **Scale up and technology transfer of Heberprot-P from CIGB Plant-4 facility (1800 mL batch formula) to Praxis facility (8300 mL batch formula)** In general, the comparison showed the consistency of the product between the P4 unit of CIGB (1600 vials/lot) and Praxis (7500 vials/lot).
	Analytical method validation/verification of product	All the stages from design to validation were complied with, technological commissioning of the facility, equipment, and systems of the formulation, filling and lyophilization processes.
	Container closure system of the drug product	Heberprot-P® is filled and lyophilized in a 6R (ISO 8362-1) vial of neutral clear borosilicate glass type I hydrolytic quality (5 mL capacity) that are capped with 20 mm bromobutyl type gray siliconized freeze-drying stopper and sealed with 20 mm flip-off aluminum seal covered with a lilac polypropylene plastic cap.
	Stability study data of drug product	Heberprot-P manufactured in PP3 plant of BioCen was approved to be stable at the recommended temperature of 2-8 ºC up to 36 months.
	Non-clinical (Module-IV)	

Module 4 (Non-clinical / Safety)			
4.2 Study Reports			
4.2.1	Pharmacology		
	4.2.1.1	Primary Pharmacodynamics	Effect of the local administration of EGF in an experimentalmodelof diabetic rats **Conclusion** the local treatment with Nepidermin accelerates the re-epithelization,inhibits the contraction and the creation of a subcutaneous tissue of analogous characteristics to the native one in excisional injuries under conditions of commitment of the healing.

	4.2.1.2	Secondary Pharmacodynamics	Studies of the cytoprotective effect of oral and subcutaneous administration of Human Recombinant Epidermal Growth Factor on ethanol-induced gastric ulcers in rats. The cases treated with different doses of the viscous solution of EGF-hr showed a therapeutic response by inhibiting the formation of ulcers. It was also observe a dose-response effect, because it was found a lower number of ulcers as the EGF-hr doses were increased. The middle and higher dose groups showed a therapeutic effect that did not differ from that caused by the Q-ulcer used as Positive Control or reference product. The study of percentage of inhibition confirms that the comprehensive analysis of the damage to the mucosa, allowed us to observe a protective effect of this formulation, as it decreased the severity of damage induced in the mucosa. Animals treated subcutaneously with EGF-hr in saline, also experienced a positive response with the dose-response effect. The therapeutic dose of the viscous solution III with EGF-hr and dose II EGF-hr in saline, was similar to the effect shown by the positive control.
	4.2.1.3	Safety Pharmacology	• Irwin Test: Multidimensional Screening in the Mouse. • Effects on Cardiovascular Function in the Telemetered Dog. • Effect on Respiratory Function (Whole Body Plethysmograph) in the Conscious Rat
	4.2.1.4	Pharmacodynamic Drug Interactions	We consider that drug interaction studies are not necessary. Most of the oral hypoglycemic agents used (Sulphonylureas, Meglitinides, Biguanides, Thiazolidinediones, Alpha Glucosidase Inhibitors, Dipeptidyl Peptidase 4 Inhibitors) are very safe drugs without drug interactions reported with products similar to Heberprot-P. On the other hand, insulin is a product of normal presence in the organism, so it is not considered relevant to study its interaction with FCEhr, which also occurs autogenously in humans. All of the above is compounded by the fact that, as pharmacokinetic studies have shown, EGFhr once administered, has a low level of permanence in blood, therefore it is not relevant to study an interaction that in practice it does not occur or if occurs is at extremely low levels with the ethical cost that the use of animals implies.
	4.2.2	Pharmacokinetics	The pharmacokinetic analysis carried out on Heberprot-P included 5 studies, in which the pharmacokinetic variables were analyzed after its single-dose administration in mice (subcutaneous route) and dogs (intravenous route), and in repeated-doses in rats

4.2.3	Toxicology		The toxicological studies conducted on Heberprot-P comprised a total of 11 studies involving four Single-Dose Toxicity Tests (in rats and rabbits), five Repeated-Dose Toxicity studies (rats, dogs and Non-Human Primates), one Reproduction study (rats) and a Local Tolerance study (rats)
	4.2.3.1	Single-Dose Toxicity (in order by species, by route)	2.4.4.2.1. Acute toxicity in Cenp:SPRD rats. Intravenous Administration. 2.4.4.2.2. Recombinant Epidermal Growth Factor (rhEGF) Acute Toxicity Test administered intramuscularly in Sprague Dawley rats. Study code: EP/TX/22.02 2.4.4.2.3. Evaluation of Acute Toxicity in Sprague Dawley rats of Heberprot-P, for the clinical treatment of diabetic foot ulcer. Subcutaneous administration. Study code: EP/TX/05.08 2.4.4.2.4. Evaluation of acute toxicity in F1 rabbits (White New Zealand x White Semi-giant) of Heberprot P, for the clinical treatment of diabetic foot ulcer. Subcutaneous administration. Study code: EP/TX/04.08
	4.2.3.2	Repeat-Dose Toxicity (in order by species, by route, by duration; including supportive	2.4.4.3.1. Evaluation of Repeated-Dose Toxicity of recombinant Epidermal Growth Factor in a parenteral formulation. Study code: EP/TX/06.04. 2.4.4.3.2. Evaluation of repeated-dose toxicity of Heberprot-P in Sprague-Dawley rats, for the clinical treatment of diabetic foot ulcer. Subcutaneous administration for 3 months. Study code: EP/TX/08.08. 2.4.4.3.3. Evaluation of repeated-dose toxicity of Heberprot P in Sprague-Dawley rats for the clinical treatment of diabetic foot ulcer. Subcutaneous administration for 6 months. Study code: EP/TX/01.10. 2.4.4.3.4. Evaluation of repeated-dose toxicity (8 weeks) of Heberprot-P in Beagles dogs for the clinical treatment of diabetic foot ulcer. Subcutaneous administration. Study code: EP/TX/12.08 2.4.4.3.5. 13-wek toxicity study by the subcutaneous route in cynomolgus monkeys followed by a 4-week treatment-free period. Study code: 37916TCP
	4.2.3.3	Genotoxicity	It is considered that genotoxicity studies are not required for Heberprot-P. In this sense, it is important to take into account provisions by the ICH guide, Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals S6 (R1), referring that - the range and type of genotoxicity studies routinely conducted for pharmaceuticals ***are not applicable to biotechnology-derived pharmaceuticals*** and therefore are not needed-.
	4.2.3.4	Carcinogenicity (including supportive toxicokinetics evaluations)	We agree with the authors that this type of study is not needed. In this sense, it is important to bear in mind that EGF is not a derivative of oncogenes and throughout the history of its basic research, there is evidence that it induces the death of tumor cells. A

	4.2.3.5	Reproductive and Developmental Toxicity (including range-finding studies and supportive toxicokinetics evaluations) (If modified study designs are used, the following sub-headings should be modified accordingly.)	**Study of fertility and early embryogenic development until Heberprot-P implantation, in Sprague-Dawley rats. Subcutaneous administration.**
	4.2.3.6	Local Tolerance	Evaluation of Local Tolerance in Sprague-Dawley rats of the recombinant Epidermal Growth Factor (rhEGF). Subcutaneous administration.

Clinical (Module-V)

Sr. No.	Name	Comments
	5.1 Table of Contents of Module 5	
	5.2 Tabular Listing of All Clinical Studies	
	5.3 Clinical Study Reports	
	5.3.1 Reports of Biopharmaceutic Studies	Biopharmaceutic study reports were not included in 5.3.1 section of Module 5. **5.3.1.1 Bioavailability (BA) Study Reports** The bioavailability (BA) studies for 5.3.1.1 section were considered not necessary since the product is injected directly on the target lesion. The comparative BA and bioequivalence (BE) studies. **5.3.1.2 Comparative BA and Bioequivalence (BE) Study Reports** for 5.3.1.2 section were not done since there is no other product to compare with. The in vitro – in vivo correlation studies **5.3.1.3 *In vitro-In vivo* Correlation Study Reports** for 5.3.1.3 section were not done since there is no in vitro experimental model for the disease. **5.3.1.4 Reports of Bioanalytical and Analytical Methods for Human Studies** The reports of bioanalytical and analytical methods for human studies for 5.3.1.4 section were not included because the bioanalytical and analytical methods used in clinical trials are described in each trial report.
	5.3.2 Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials	**5.3.2.1 Plasma Protein Binding Study Reports** EGF does not bind to any plasma proteins. **5.3.2.2 Reports of Hepatic Metabolism and Drug Interaction Studies** This information is not available. EGF in blood does not bind to any plasma protein and its metabolism consists, like other peptides and proteins, in degradation by proteases in blood or inside the cells, after binding to the receptor. **5.3.2.3 Reports of Studies Using Other Human Biomaterials** EGF in blood does not bind to any plasma protein and its metabolism consists, like other peptides and proteins, in degradation by proteases in blood or inside the cells, after binding to the receptor. EGF was detected in urine in the pharmacokinetics study (see 5.3.3) but this was

			considered to be endogenous production, mainly by the kidney itself.
		5.3.3 Reports of Human Pharmacokinetic (PK) Studies	**5.3.3.1 Healthy Subject PK and Initial Tolerability Study Reports** Since the product is to be injected directly on the lesions it is not possible to make studies in healthy subjects. **5.3.3.2 Patient PK and Initial Tolerability Study Reports** A Phase I, monocentric, randomised, double blind, with parallel groups clinical trial was performed to evaluate two dose levels of rhEGF (Group I: 25 µg and Group II :75 µg) added to the current standard treatment. **5.3.3.3 Intrinsic Factor PK Study Reports** Studies in human were considered unnecessary. **5.3.3.4 Extrinsic Factor PK Study Reports** Studies in human were considered unnecessary. **5.3.3.5 Population PK Study Reports** There is one study titled Pharmacokinetic of the intralesional administration with two doses of recombinant human Epidermal Growth Factor (rhEGF: 75 and 225 µg) in patients with advanced diabetic foot ulcer, coded IG/FCEI/PD/1114. See please section 5.3.3.2.
		5.3.4 Reports of Human Pharmacodynamic (PD) Studies	**5.3.4.1 Healthy Subject PD and PK/PD Study Reports** Since the product is to be injected directly on the lesions it is not possible to make studies in healthy subjects **5.3.4.2 Patient PD and PK/PD Study Reports** Information regarding PK study is contained in study report coded as 0707 and 1114 in section 5332. Pharmacodynamic evaluations were done in study coded as 0202, in section 5352 were immunohistochemistry was also done on biopsies from the ulcers.
		5.3.5 Reports of Efficacy and Safety Studies 5.3.5.2 Study Reports of Uncontrolled Clinical Studies 5.3.5.3 Reports of Analyses of Data from More Than One Study	**5.3.5.1 Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication** Phase III,nation wide, randomized, double blind,Placebo Controlled. **5.3.5.2 Study Reports of Uncontrolled Clinical Studies** Total 5 study reports. Conclusions The benefit-risk balance seems quite favorable. This was also suggested by the analysis done from the Bayesian approach comparing the probabilities of risk (given by the occurrence of serious adverse events including amputation) with that of benefit (given by complete granulation or

		complete re-epithelization) from data from all clinical trials. These results are shown in Figure 2.5-1 and Figure 2.5-2 . In all cases the differences between benefit and risk probabilities favor the former: the Bayes factors and differences are larger for the Heberprot P treated groups than for the placebo. The balance of the higher dose is much favorable. World-wide marketing experience. **Extent of the world-wide experience,** Information received from Russia, Argentina, Venezuela, Libya, Saint Lucia, Uruguay, Angola, Viet Nam, Algeria, Indonesia, Seychelles, and Turkey is summarized in the Clinical Summary/Table 2.7.4-3 and listed below. Only the 75 µg dose level, 3 times per week has been used in those countries. Data from 2704 subjects is available. The number of subjects exposed in Argentina are estimates from the number of vials sold, assuming that each patient received at most 12 doses. Exposure in Venezuela is much larger. Additional exposure abroad is referred in the 2012 PSUR to the Cuban Regulatory Authority. It is summarized in Table 2.5- 10.
	5.3.6 Reports of Post-Marketing Experience.	Submitted.
	5.3.7 Case Report Forms and Individual Patient Listings	Submitted.

Table 2.5-5. Efficacy results in postmarketing experiences of Heberprot P in subjects with DFU

Study	Dose	N	Complete granulation response (%)	Subsequent complete healing (%)	Time to complete healing (weeks)	Amputations
Pooled in clinical trials	Placebo	48	28 (58.3%) (43.4 - 73.3)	27 (56.3%) (41.2 - 71.3)	21.4 (8 – 35)	12 (25.0%) (11.7 - 38.3)
	25 µg	188	141 (75.0%) (68.8 - 81.2)	97 (51.6%) (44.5 - 58.7)	12 (9.7 - 14.3)	44 (23.4%) (17.4 - 29.5)
	75 µg	128	109 (85.2%) (79.0 – 91.3)	85/116 (73.3%) (65.2 - 81.3)	14.0 (11.6 - 16.3)	18 (14.1%) (8.0 – 20.1)
Introduction in Cuba (0704)	25 and 75 µg	1835 (ulcers)	1392 (75.9%)	1012/1659 (61.0%)	Not available	220 (11.9%) Major: 171 (9.3%

Remarks of the Evaluator.

Query of Evaluator: The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention.

Firms Response: It's not registered in any SRA. Heberprot-P is a Novel Cuban-developed drug used primarily for treating diabetic foot ulcers. The clinical trials conducted in Cuba have demonstrated its efficacy in promoting wound healing and reducing the need for amputations in patients with diabetic foot ulcers. Results showed significant improvement in ulcer healing rates compared to standard treatment. Heberprot-P was generally well-tolerated with a safety profile consistent with its mechanism of action.

Clinical trials in Cuba have provided substantial evidence supporting Heberprot-P's effectiveness in treating diabetic foot ulcers, contributing to its adoption in various countries. The drug was associated with a lower rate of amputations and better overall outcomes in wound management.

It has been successfully registered in 26 countries worldwide list of countries along with registration certificates and periodic safety update report (PSUR) is also attached Notably, this includes members of the Pharmaceutical Inspection Co-operation Scheme (PIC/S), such as Argentina, Turkey, Mexico, and South Africa & South Korea.

- South Korea have attained ML4 in medicines and vaccine producing.
- Turkish Medicines and Medical Devices Agency have attained WHO Maturity level III, in medicines and vaccines producing in 2023.
- South African Health Products Regulatory Authority (SAHPRA) has attained WHO maturity ML3 in vaccines producing in 2022

	• You can see Argentina, Colombia, Cuba, Mexico, in the list of transitional WLAs (World Health Organization Listed Authorities) with category D, meaning "Regional Reference Authorities for medicines in the Americas (AMRO/PAHO), as assessed against WHO Regional Office for the Americas (AMRO)/Pan American Health Organization (PAHO) standardized evaluation procedure and AMRO/PAHO data collection tool. • You can also see South Africa, Turkey and Viet Nam in the list of National Regulatory Authorities (NRAs) operating at the maturity level 3, meaning "stable, well-functioning and integrated regulatory systems. **Evaluator Comments:** The product is not approved in any Reference Regulatory Authority as approved by Registration Board in its 275th Meeting. **Query of Evaluator: Provide name and address of marketing authorization holder abroad.** **Firms Response**. a. Marketing authorization in Cuba belongs to CIGB, Center of genetic engineering & biotechnology Ave 31between entre 158y 190, playa, Havana Cuba. b. Registration letters are provided as reference. c. Because CIGB Researched, developed and produced the product at API Level and product is filled and packaged at the center of Bio prepared 'Biocen' in Cuba, registration Letter Attached. Product Registration Letter & contract agreement is also attached. **Evaluator Comments:** The Registration Certificate of Ministry of CUBA mentions the additional site of Finished product and solvent site i.e. • Praxis Pharmaceutical S.A, Spain. Finished product • Pharmaceutical Laboratories AICA, Havana, Cuba. Solvent **Query of Evaluator: The status of product holder in CoPP is A. Therefore, clarification is required for manufacturing sites mentioned in section 2A.3.1.** a. In Cuba, the entity responsible for product registration is the Center for Genetic Engineering and Biotechnology (CIGB). According to section 2A.3.1, CIGB was involved in the research, development, and production of the product at API Level at Plant 4, with packaging taking place at Plant 10 of CIGB. Additionally, the formulation, filling, and Lyophilization of the product are carried out at the Parenteral Products Plant 3 of the National Center for Bio Products (BIOCEN). b. Registration letter and contract certificate is attached as reference. **Evaluator Comments:** Firm has stated that it is contract manufacturing application. Therefore, status of product license holder in COPP is A. However, status should be C for contract manufacturing applications as per Guidelines on the implementation of the WHO certification scheme on the quality of pharmaceutical products moving in international commerce.	
Decision of 343rd Meeting: **The Registration Board deferred the case for submission of the following documents:** **1) Clarification for variation in manufacturing site activities mentioned on COPP and section 3.2.P.3.1 of drug product part of Module 3.** **2) Clarification for following additional sites specified on Registration Certificate of Ministry of CUBA which is inconsistent with submitted CoPP and Form 5 F.** • **Praxis Pharmaceutical S.A, Spain. Finished product** • **Pharmaceutical Laboratories AICA, Havana, Cuba. Solvent** **3) Clarify "Status of product license holder" in section 2.A.3 of COPP should be in accordance with the Guidelines on the implementation of the WHO certification scheme on the quality of pharmaceutical products moving in international commerce.** **4) Finished product specifications as per decision of 267th meeting of Registration Board.** **5) Supporting documents of stability data of drug product like raw data sheets, chromatograms COAs etc. at each time point.** **6) Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3.** **7) Clinical study Protocols as only study reports are provided.** **8) Evidence of published clinical studies in research journel.** **9) Complete listing/classification of ADRs and organs most commonly afftected by ADRs.**		
2.	Name, address of Applicant / Importer	**M/s The Searle Company Limited** Company Address: **F-319 Site Karachi**

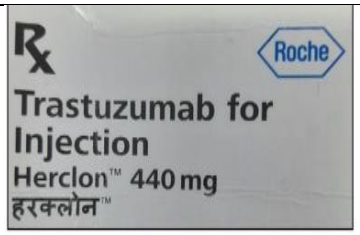
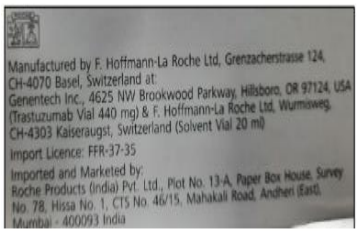
	Details of Drug Sale License of importer	**Address: F-319 Site Karachi** **Address of Godown:** Plot No. 1/5 Manghopir Road, Karachi **Status**: License to sell drugs by way of whole sale. **Validity**: 06-05-2028 **Renewal:** NA
	Name and address of marketing authorization holder (abroad)	M/s Hetero Biopharma Limited, Sy. No. 458 (Part),TSIIC-Formulation SEZ, Polepally (Village), Jadcherla (Mandal) Mahaboobnagar (District) – 509 301, Telangana State, India.
	Name, address of manufacturer(s)	**As per COPP** M/s Hetero Biopharma Limited, Sy. No. 458 (Part),TSIIC-Formulation SEZ, Polepally (Village), Jadcherla (Mandal) Mahaboobnagar (District) – 509 301, Telangana State, India. **As per revised section 3.2.P.3.1** M/s. Hetero Biopharma Limited, Sy. No. 458 (Part), TSIIC-Formulation SEZ, Polepalle Village, Jadcherla Mandal Mahabubnagar District – 509 301, Telangana State, India
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**<u>Notarized Copy, Legalized and Valid COPP</u>** **Certificate No:** 4247171/TS/2023 **Certifying Authority:** Drug Control Administration, Vengalroanagar ls this product licensed to be placed on the, market for use in the exporting country? Yes Is this product actually on the market in the exporting country? Yes Validity : 03-10-2026
	Details of letter of authorization / sole agency agreement	**<u>Notarized and Original Letter of Authorization</u>** M/s Hetero Biopharma Limited Address: Sy. No. 458 (Part),TSIIC - Formulation SEZ,Polepalle Village, Jadcherla Mandal Mahabubnagar District – 509 301, Telangana State, India. Authorize The Searle Company,Pakistan Dated: 12-02-2024 Validity: 2 years
	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	Tracking ID:53R-ZYN-3S85 Application Number:13357 Date of receiving :21-05-2024
	Details of fee submitted	Challan No. 48547146290 Rs. 300000.0
	The proposed proprietary name / brand name	TRASTAM 150mg (Powder for Concentrate for Solution for infusion)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Trastuzumab…….150mg
	Dosage form of applied drug	Lyophilized Powder for concentrate for solution for intravenous infusion
	Pharmacotherapeutic Group of (API)	Antineoplastic agents, monoclonal antibodies, ATC code: L01XC03

	Finished product specifications	As per Innovators Specifications.
	Proposed Pack size	As per DPC.
	Proposed unit price	As per SRO/DPC .
	Shelf life	18 months shelf life as per commercial batches.
	Storage conditions	2-8°C
	The status in reference regulatory authorities	Herceptin 150mg Powder for concentrate for solution for infusion Single Dose Vials Roche Products Limited United Kingdom
	For generic drugs (me-too status)	Trastuget 150mg Getz Pharma (Pvt.) Limited
	Module-II (Quality Overall Summary)	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. Hetero Biopharma Limited, Sy. No. 458 (Part), TSIIC-Formulation SEZ, Polepalle Village, Jadcherla Mandal Mahabubnagar District – 509 301, Telangana State, India.
	Module 3 (Quality)	
	Module-III Drug Substance:	Firm has submitted information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, 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)	Hetero trastuzumab FDS is stable at -20±5°C for 36 months, supporting the assigned shelf life of 24 months. However commercial batches stability study was planned for 60 months and stability study was ongoing with commercial batches. • Hetero trastuzumab FDS complies with the specifications when stored at accelerated conditions of 5±3°C 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.
	Analytical method validation/verification of product	All the analytical methods currently used for the lot release and stability testing of Hetero trastuzumab DS have been validated. The pharmacopoeial methods such as measurement of pH and physical appearance etc. have been well established in standard test procedures based on USP/EU general test procedures. The test methods are either validated / method suitability established except for few methods that are currently being validated.
	Container closure system of the drug product	Hetero trastuzumab drug product (DP) is 150 mg/vial, powder for concentrate for solution for infusion. DP container closure system (CCS) components are selected qualitatively similar to that of RMP. Final CCS components consists of 15mL clear tubular glass vials sterile (USP type 1, make: Schott Kaisha Pvt. Limited) and Tubular vial blow back LYO-clear 15mL (USP type 1, make: SGD) with 20mm lyo nova pure rubber stoppers as a primary packaging material are used to fill the trastuzumab drug product. The rubber stoppers are manufactured with elastomer chlorobutyl coated with FluroTec® (make: West Pharmaceutical service) and 20 mm flip off seals are used (make: West Pharmaceutical service) for sealing of filled vials.

Stability study data of drug product	The following conclusions made based on the stability studies performed. • Hetero trastuzumab DP pre-clinical batches have been tested for 4 years for the long term real time stability studies. There was no significant change in any of the quality attributes for the PCS batches for the long term real time stability studies. • For CT batches, the stability studies were performed until 36 M • **Based on CT batch data, it is concluded that the product is stable until 24 months at the storage conditions of 2-8°C.** • The accelerated stability data suggests that the product is stable for 6 M at 25OC + 2OCand there is no significant change in any of the quality attributes when DP was stored under these conditions. As per ICH Q5C, this data indicates stability of trastuzumab for short term temperature excursions.
Bio-similarity Studies as per WHO Guidelines	Not Submitted.
Module 4 Non Clinical Studies	Not Submitted.
Module 5 Clinical Studies	Not Submitted

Sr	Query	Firms Response	**Assessment of Response**
1	Documents/ evidence for acceptable shipping conditions for both finished product) & proof of shipping validation	We acknowledge the query, the cold chain validation for Drug Product (DP) is available with Hetero Biopharma. Hetero Trastuzumab DP storage condition at 5±3°C for both the strengths (440mg/Vial and 150mg/Vial) of lyophilized powder and including diluent vials (20mL/Vial and 10mL/Vial). The cold chain validation is not a product specific activity, by considering worst case scenario the product has been selected for cold chain validation is Hetero Rituximab DP which is containing highest vial volume and as well as quantity (500mg/50mL) of product from Hetero Biopharma. Hence, we are justifying data from Hetero Rituximab drug product to Hetero Trastuzumab drug product. The data from Rituximab has been provided further in detail below. Hetero Rituximab drug product storage condition is 5 ± 3 °C. The Rituximab drug product shipment and transportation validation study has been performed temperature between 5 ± 3°C. The scope of the validation study is applicable for the product transportation (Cold storage condition at 5±3°C) from Hetero Biopharma Ltd, Jadcherla, Hyderabad, India to destination location of AMROX pharma, Mexico. The transport validation	Cold chain validation report has been submitted.

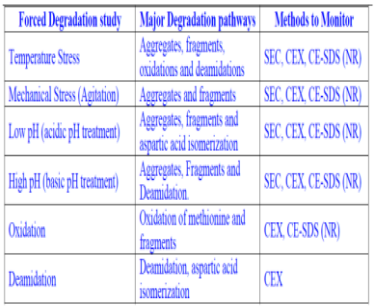
			was performed with the highest product of vial (500mg/50mL) and lowest product of vial (100mg/10mL) in 3 different shipments with representative quantity has been shipped by the same route which will be used for commercial lots. The shipment validation protocol and report has been enclosed for your reference as an annexure. Query-1_Annexure-1 Cold chain validation protocol Query-1_Annexure-2 Cold chain validation report.	
	2	Registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries.	Please find enclosed Trastuzumab Registration status as Query-2 Annexure-1.	India Kenya Cuba Product is approved in MHRA https://products.mhra.gov.uk/search/eptin&page=1
	3	Provide correct MAH details as per COPP in the MAH section of Eapp.	This is with reference to query regarding MAH holder details in section of e-App we bring into your kind knowledge that we are not able to find edit option on portal so,submitting correct details of MAH below for Local Registration of a Biological Drug (Finished Import) "TRASTAM 150mg (Powder for Concentrate for Solution for infusion) Trastuzumab 150mg (Combipack)".	The eapp systems needs to be updated as per COPP.
	4	Submit hard copy of original, legalized and valid COPP	Legalized COPP hard copy has been dispatched from india, we will submit hardy copy in a day or 2 to DRAP.	Applicant has submitted notarized copy of COPP.
	5	The COPP does not mention Unit III as per section 3.2.P.3.1 Clarification is required.	We acknowledge the query, the section 3.2.P.3.1 has been updated the manufacturing address as per COPP and updated section enclosed as an annexure _Annexure-1_32p31 manufacturer (150mg)	The firm has revised this section 3.2.P.3.1 and removed Unit III.

	6	Submit hard copy of original or notarized copy of valid Letter of Authorization /sole agency agreement	LOA has been dispatched from india, we will submit harde copy in a day or 2 to DRAP.	Applicant has submitted original notarized LOA.
		The innovator product is Herceptin whereas analytical comparability studies are with Herclon. Therefore, justification /clarification is required.	We acknowledge the query, we would like to mention that the original Trastuzumab product was developed by Roche/Genentech, which is used globally for treating HER2-positive breast cancer and gastric cancers under the brand name Herceptin. However, Herclon is another brand name for Herceptin, used by Roche. It is not a biosimilar but is the same innovator product as Herceptin, marketed under a different name to make it more accessible and affordable in these markets. Both Herceptin and Herclon are developed by Roche and contain the same active ingredient, Trastuzumab. However, Roche markets Herclon as part of its regional branding and pricing strategy to cater to specific market demands, particularly in countries like India. Hence Herclon is clinically identical to Herceptin, as it comes from the same manufacturing process. Since Herclon is available in India Hetero Biopharma has procured the clinically identical reference medicinal product to Herceptin and performed its comparability studies. For further information please find the below images of Herclon which encompasses the regional language of India (Hindi) along with Roche logo in Figure 01 and Manufacturer address, Imported and Marketed by address in Figure 02 which clearly states that the product is manufactured by Roche at Switzerland and is imported and marketed by Roche Products, India.	 Figure 02: 
	.8	The analytical comparabili	We acknowledge the query, the analytical comparability report provided in the section 3.2.R	Applicant has submitted Process comparability report instead of Analytical comparability.

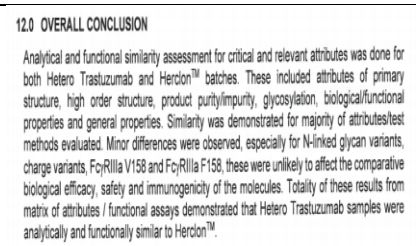
		ty report provided in section 3.2.P.2 is of 440mg whereas, applied strength is 150mg	Regional information as per CTD module-III and analytical comparability performed between Reference Medicinal Product (RMP) and Hetero Trastuzumab (440mg/Vial) with 3+3 lot comparison. The reason for selection of 440mg/Vial by considering higher strength of drug product will be the worst-case scenario. Except fill volume there is no difference in the composition of Formulated Drug Substance (FDS) between 150mg/Vial and 440mg/Vial. The section 3.2.P.2 Pharmaceutical development has been enclosed process comparability report containing both the strengths (150mg/Vial & 440mg/Vial). The report containing analytical data of for both the strengths and process comparability between clinical process validation batches and commercial process validation batches. The reports are enclosing as an annexure. _Annexure-1 Trastuzumab Drug Product Process Comparability report (150mg/Vial & 440mg/Vial)	As per WHO guidelines on evaluation of biosimiliars. The posology and route of administration of the biosimilar should be the same as that of the RP. However, depending on the jurisdiction, the strength, pharmaceutical form, formulation, excipients and presentation (for example, use of a different medical device or number of syringes in a pack) of the biosimilar might differ from the RP, if justified.
	9	The innovator formulation for 150 mg is a single dose vial whereas, the applied formulation is a multi-dose vial as per COPP and GMP certificate. Justification is required	We would like to clarify that BWFI diluent is used for our 150mg/Vial strength. We would like to reiterate the fact that, the manufacturing process of 150 mg and 440mg are also same except the linear scale up of excipients for the higher strength. Since all the process and product remains same in both the strengths, we have claimed that both the vials as "Multidose" and should be reconstituted with BWFI unless for any hypersensitive patients, SWFI is recommended. The same statements are mentioned in our SMPC and PI also.	The section 3.P.3.2 Batch Formula mentions drug product single use vial, 150 mg / vial. Whereas, COPP mentions multi-use vials.
	10	The Innovator product uses sterile WFI whereas, applied formulation contains	We acknowledge the query regarding the use of Bacteriostatic Water for Injection (BWFI) as a diluent in our proposed Trastuzumab formulation compared to the Sterile Water for Injection (SWFI) used by the	Justification is placed for consideration by Registration Board. **Herceptin MHRA** **Special precautions for disposal Herceptin IV** is provided in sterile, preservative-free, non-pyrogenic, single use vials.

			bacteriostatic WFI. Furthermore, the use of preservative is contrary to the Ph. Eur. Requirements. Therefore, justification and clarification is required	innovator product. Below is our justification and clarification: 1. Use of BWFI: The decision to use BWFI as a diluent in our formulation is based on the following considerations: - Multi-dose Formulation: BWFI contains a preservative (e.g., benzyl alcohol) to inhibit microbial growth, ensuring safety and efficacy during multiple withdrawals over the intended in-use period. This aligns with the intended multi-dose application of the proposed formulation. - Precedent in Innovator's History: The innovator product (Herceptin) previously utilized BWFI as a diluent for its multi-dose formulation. This is supported by publicly available regulatory data and historical usage records. For your easy of reference please find the precent FDA label of Herceptin where BWFI is used as a diluent for its multidose (440mg vial) Trastuzumab formulation enclosed - Regulatory Compliance: Hetero's BWFI meets the requirements of the European Pharmacopoeia (Ph. Eur.) monographs for sterile, preservative containing diluents, ensuring compliance with quality and safety standards as per the Ph. Eur. 5.1.3. EFFICACY OF ANTIMICROBIAL PRESERVATION (enclosed) 2. Comparison with SWFI: -While SWFI is suitable for single-dose applications due to its lack of preservatives, it does not provide the microbial protection necessary for multidose usage. 3. Ph. Eur. Compliance and Preservative Use: -The Ph. Eur. 5.1.3 allows the use of preservatives in specific cases, such as multidose containers, provided the formulation justifies its necessity and meets prescribed safety limits. - Our BWFI formulation adheres to Ph. Eur. specifications for benzyl alcohol, ensuring compliance with quality, safety, and efficacy standards.		

				4. Innovator's Discontinuation of Multi-dose Presentation: It is noted that the innovator has discontinued their multi-dose formulation with BWFI. However, this change does not reflect a safety concern related to the use of BWFI. Instead, it appears to align with market dynamics, simplified storage requirements, and reduced patient handling complexity associated with single-dose SWFI presentations. 5. Additional Supporting Data: - The safety and compatibility of BWFI with Trastuzumab are well-documented and supported by our stability, sterility, and compatibility studies. In conclusion, our choice of BWFI as a diluent is scientifically and technically justified based on product design, intended multi-dose use, historical precedent, and compliance with applicable Ph. Eur. requirements. List of Annexures: 1. Annexure 01: Herceptin precedent FDA label with multidose and BWFI 2. Annexure 02: Ph. Eur. 5.1.3 – Efficacy of Anti-microbial preservation.	
	11	Provide the amount of volume overage added in each vial	We acknowledge the query that Hetero Trastuzumab Drug Product (DP) does not contain any overages. Hetero Trastuzumab FDS is manufactured with target active substance concentration of 25 mg/mL and the fill volume in the vial is 6.3±0.3mL. Trastuzumab DP (Lyophilized powder) is to be reconstituted by using 7.2 mL of Bacteriostatic Water for Injection (BWFI) for 150mg/ Vial, active substance concentration in drug product theoretically minimum 19.3mg/mL to maximum 23.6 mg/mL (Total product range in the 7.2mL reconstituted vial is 139-170mg) similar to that of RMP. Hence, there are no overages for Trastuzumab DP 150 mg/vial strength.	There are no overages for Trastuzumab DP 150 mg/vial strength.	

	12	The degradation pattern of trastuzumab is complex. Therefore, provide which method has been used to assess the modes of degradation. Moreover, testing for purity and molecular consistency in production of trastuzumab is not performed on the Bulk for Storage	We acknowledged your query on Hetero Trastuzumab degradation pattern. In response to it we would like to mention that Forced degradation studies are conducted on Hetero's Trastuzumab Formulated Drug Substance (FDS) to confirm the use of analytical techniques and to assess the modes of degradation. Different types of forced degradations with major degradation pathways and its method to monitor are mentioned as in the below table.  Based on the above studies it can be concluded that CEX method, SEC method and CE-SDS methods are capable of resolving impurities generated under all stressed conditions. For further details please refer to the 3.2.P.8 and 3.2.S.7 sections which are enclosed. Further, purity and impurity testing of trastuzumab bulk (Formulated Drug Substance) is verified for every lot and release and stability conditions. Please find the enclosed lot release and stability specifications of Hetero Trastuzumab FDS for your reference. List of Annexures: 1. _Annexure 01: Drug Product stability section 3.2.P.8 2. _Annexure 02: Drug Substance stability section 3.2.S.7 3. _Annexure 03: FDS Lot Release Specification 4. _Annexure 04: FDS Stability Specification	Submitted.
	13	The stability data of drug substance and drug product of commercial batches is	We acknowledged your query and in response to it we would like to mention that the stability studies of Hetero Trastuzumab Formulated Drug Substance (FDS) and Drug Product (DP) for commercial batches are ongoing and is	Stability studies of Hetero Trastuzumab Formulated Drug Substance (FDS) and Drug Product (DP) for commercial batches are ongoing and is completed till 18 months for FDS and 18 months for DP

Forced Degradation study	Major Degradation pathways	Methods to Monitor
Temperature Stress	Aggregates, fragments, oxidations and deamidations	SEC, CEX, CE-SDS (NR)
Mechanical Stress (Agitation)	Aggregates and fragments	SEC, CEX, CE-SDS (NR)
Low pH (acidic pH treatment)	Aggregates, fragments and aspartic acid isomerization	SEC, CEX, CE-SDS (NR)
High pH (basic pH treatment)	Aggregates, Fragments and Deamidation.	SEC, CEX, CE-SDS (NR)
Oxidation	Oxidation of methionine and fragments	CEX, CE-SDS (NR)
Deamidation	Deamidation, aspartic acid isomerization	CEX

	not till claimed shelf life. Submit complete stability studies of commercial batches	completed till 18 months for FDS and 18 months for DP for Long Term / Real Time conditions and 6 months for Accelerated Conditions at both FDS and DP stages. We commit to submitting the completed stability data after the completion of the 24-months' time point (which is our next scheduled pull out) for the commercial batches to confirm and further validate the proposed shelf life. Further we would like to mention that our proposed shelf life for FDS and DP is till 36 months which is based on our Pre-clinical Trail and Clinical Trail batches stability studies. At these PCT and CT stages long term/ real time shelf life is studied till 60 months and found that all stability indicating parameters test results are within the acceptable criteria. For details please refer to the Query point 10_Annexure 01 and Annexure 02	
14.	Clarification is required whether the product will be marketed in combo pack or otherwise	Product will be marketed in combo pack.	Firm has not applied for combi pack.
15	Submit Comparability Protocols i.e., complete comparison of applied product with Innovator product in light of WHO guidelines on bio-similarity .	We acknowledge your query on the comparability studies of SBP (Similar Biotherapeutic Product) i.e., Hetero Trastuzumab Vs Innovator (Herclon®). We assure you that we have conducted the complete similarity study as per the WHO TRS no.: 977: Annex 2 – Guidelines on evaluation of Similar Biotherapeutic Product (SBP). Hetero Trastuzumab bio-similarity is focused on step-wise development that involves demonstration of following studies… 1. Structural & functional equivalence (Analytical/Quality Similarity) 2. Non-clinical equivalence (Non-Clinical Similarity) 3. Clinical equivalence (Clinical Similarity)	 12.0 OVERALL CONCLUSION Analytical and functional similarity assessment for critical and relevant attributes was done for both Hetero Trastuzumab and Herclon™ batches. These included attributes of primary structure, high order structure, product purity/impurity, glycosylation, biological/functional properties and general properties. Similarity was demonstrated for majority of attributes/test methods evaluated. Minor differences were observed, especially for N-linked glycan variants, charge variants, FcγRIIIa V158 and FcγRIIIa F158, these were unlikely to affect the comparative biological efficacy, safety and immunogenicity of the molecules. Totality of these results from matrix of attributes / functional assays demonstrated that Hetero Trastuzumab samples were analytically and functionally similar to Herclon™. The submitted report is of 440mg strength. Clinical equivalence **A phase iv multi-centric, post-marketing study** evaluating the safety, immunogenicity and efficacy of the marketed formulation of Hetero-Trastuzumab in female patients with her2+ breast cancer. Primary Objective To evaluate the safety of Hetero-Trastuzumab in patients with approved indication(s) in post marketing phase by assessing the reported adverse events during the study period. Secondary Objectives • To evaluate the longterm immunogenicity of Hetero-

				Analytical Similarity: Structural and functional characteristics of the proposed biosimilar (Hetero Trastuzumab) are compared with the reference medicinal product (Herclon®); similarity of these functions forms the foundation of the biosimilar development program (analytical similarity is enclosed). Non-Clinical Similarity: Potential animal studies (in Wistar Rats), with study title "Comparative 28-Day Intermittent Dose (4 Doses: Once Every Week) Intravenous Toxicity Study of Trastuzumab Vs Reference Item in Wistar Rats with 14 Days Recovery period" provides a human pharmacokinetics / pharmacodynamics (Pk/Pd) equivalence study. This was conducted to confirm the similar non clinical efficacy of Hetero Trastuzumab with respect to Herceptin (RMP). The study was shown to be well tolerated up to 248 mg/kg in Wistar Rats for four weeks, without any obvious signs of systemic toxicity under the proposed study condition and demonstrated comparable safety profile with reference drug (Trastuzumab-Herceptin®). None of the findings had a toxicological significance. For further details, please refer to the Module 4 of the CTD document. Clinical Significance: Comparative clinical studies are performed between Hetero Trastuzumab and Reference Product (Herclon®) to evaluate the safety, pharmacokinetic characteristics, and immunological potentials through the study title: "A randomized, multiple-dose, multi-centre, comparative parallel study to evaluate the efficacy, safety and pharmacokinetic characteristics of intravenous infusion of Hetero Trastuzumab and Reference Medicinal Product (Herclon®, sourced from Roche) in Indian Patients of metastatic breast cancer". A good correlation between the two study groups was	Trastuzumab in patients with approved indication(s) in post marketing phase by assessing AntiTrastuzumab Minimum 200 Patients Status Ongoing	

			demonstrated in terms of efficacy, immunogenicity and safety using relevant end points, for further details please refer to the Module 5 of the CTD document. Conclusion: In conclusion, development of Hetero Trastuzumab is focused on the minimization of potential differences between the Hetero Trastuzumab and Reference Medicinal Product (Herclon® & Herceptin) and the establishment of a robust manufacturing process to consistently produce a high-quality biosimilar product. Through the above rigorous quality/analytical, non-clinical, and clinical evaluations, Hetero Trastuzumab can be confirmed as a viable alternative and a biosimilar to Herclon® and Herceptin. List of Annexures: Annexure 01 – Analytical Similarity Report Annexure 01 – Herceptin FDA Label	
	16.	Proper justification with evidence of reference guidelines were "Not applicable" has been mentioned for non-clinical study data.	Non Clinical Data attached below	Firm has submitted non clinical data **TABLE 4.2-1: TABULAR SUMMARY OF THE STUDIES** **S. No. / Type of study / Test item dose (mg/kg)** 1. Single dose toxicity study in Swiss albino Mice by intravenous route. — 984 (10X) 2. Single dose toxicity study in Wistar Rat by intravenous route. — 496 (10X) 3. Repeated dose toxicity study in Wistar Rat by intravenous route with 14 days. — Low dose reference (1X): 49.6; Low dose (1X): 49.6; Mid dose (2X): 99.2; High dose (5X): 248; High dose (5X, Recovery): 248 4. Repeated dose toxicity study in New Zealand White Rabbit by intravenous route with 14 days reversal period. — Low dose (1X): 24.8; Mid dose (2X): 49.6; High dose (5X): 124; High dose (5X, Recovery): 124 5. Skin sensitization study in guinea pigs (GPMT) — Intradermal & topical
	17	Proper justification with evidence of reference guidelines were "Not applicable" has been mentioned for clinical study data.	Clinical Data attached below	Firm has submitted clinical data . III — An assessor blind (central radiologist), randomized, active controlled, parallel group clinical study to evaluate the efficacy, safety, pharmacokinetics and pharmacodynamics of intravenous infusion of Hetero-Trastuzumab and reference medicinal product (Roche-Trastuzumab) in patients with metastatic breast cancer.

Decision of 343rd Meeting:

The Registration Board deferred the TRASTAM 150mg for the submission of the following documents:

- **Evidence of approval of applied strength i.e. 150mg as multi-dose vial in any of the Reference Regulatory authority as approved by Registration Board in its 275th Meeting.**

• **Clarification for variation, as COPP mentions multi-dose vials and section 3.2.P.3.2 specifies single dose vials.** • **Justification for submission of comparability studies of multi-dose vial with single dose vial.**		
3.	Name, address of Applicant / Importer	**M/s The Searle Company Limited** Company Address: **F-319 Site Karachi**
	Details of Drug Sale License of importer	**Address: F-319 Site Karachi** **Address of Godown:** Plot No. 1/5 Manghopir Road, Karachi **Status**: License to sell drugs by way of whole sale. **Validity**: 06-05-2028 **Renewal:** NA
	Name and address of marketing authorization holder (abroad)	M/s Hetero Biopharma Limited, Sy. No. 458 (Part),TSIIC-Formulation SEZ, Polepally (Village), Jadcherla (Mandal) Mahaboobnagar (District) – 509 301, Telangana State, India.
	Name, address of manufacturer(s)	**As per COPP** M/s Hetero Biopharma Limited, Sy. No. 458 (Part),TSIIC-Formulation SEZ, Polepally (Village), Jadcherla (Mandal) Mahaboobnagar (District) – 509 301, Telangana State, India. **As per revised section 3.2.P.3.1** M/s. Hetero Biopharma Limited, Sy. No. 458 (Part), TSIIC-Formulation SEZ, Polepalle Village, Jadcherla Mandal Mahabubnagar District – 509 301, Telangana State, India
	Name of exporting country	India
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**<u>Notarized Copy, Legalized and Valid COPP</u>** **Certificate No:** 4247182/TS/2023 **Certifying Authority:** Drug Control Administration, Vengalroanagar ls this product licensed to be placed on the, market for use in the exporting country? YES Is this product actually on the market in the exporting country? YES Validity : 03-10-2026
	Details of letter of authorization / sole agency agreement	**<u>Original Notarized Letter of Authorization</u>** M/s Hetero Biopharma Limited Address: Sy. No. 458 (Part),TSIIC - Formulation SEZ,Polepalle Village, Jadcherla Mandal Mahabubnagar District – 509 301, Telangana State, India. Authorize The Searle Company,Pakistan Dated: 12-02-2024 Validity: 2 years
	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	Tracking ID: 95S-V2J-HHRU Application Number:13379 Date of receiving:16-05-2024
	Details of fee submitted	Challan No. 7906606780 Rs. 300000.0

	The proposed proprietary name / brand name	TRASTAM 440mg (Powder for Concentrate for Solution for infusion)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial contains: Trastuzumab…….440mg
	Dosage form of applied drug	Lyophilized Powder for concentrate for solution for intravenous infusion
	Pharmacotherapeutic Group of (API)	Antineoplastic agents, monoclonal antibodies, ATC code: L01XC03
	Finished product specifications	As per Innovators Specifications
	Proposed Pack size	As per DPC.
	Proposed unit price	As per SRO/DPC .
	Shelf life	3 years (As per data section 3.2.P.8.3)
	Storage conditions	2-8°C
	The status in reference regulatory authorities	Herceptin 440mg Powder for concentrate for solution for infusion Genentech, Inc. A Member of Roche Group
	For generic drugs (me-too status)	Trastuget 440mg Getz Pharma (Pvt.) Limited
	Module-II (Quality Overall Summary)	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. Hetero Biopharma Limited, Sy. No. 458 (Part), TSIIC-Formulation SEZ, Polepalle Village, Jadcherla Mandal Mahabubnagar District – 509 301, Telangana State, India.
	Module 3 (Quality)	
	Module-III Drug Substance:	Firm has submitted information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, 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)	Hetero trastuzumab FDS is stable at -20±5°C for 36 months, supporting the assigned shelf life of 24 months. However commercial batches stability study was planned for 60 months and stability study was ongoing with commercial batches. • Hetero trastuzumab FDS complies with the specifications when stored at accelerated conditions of 5±3°C 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.
	Analytical method validation/verification of product	All the analytical methods currently used for the lot release and stability testing of Hetero trastuzumab DS have been validated. The pharmacopoeial methods such as measurement of pH and physical appearance etc. have been well established in standard test procedures based on USP/EU general test procedures. The test methods are either validated / method suitability established except for few methods that are currently being validated.
	Container closure system of the drug product	Hetero trastuzumab drug product (DP) is 440 mg/vial, powder for concentrate for solution for infusion. DP container closure system (CCS) components are selected qualitatively similar to that of RMP. Final CCS components consists of 15mL clear tubular glass vials sterile (USP type 1, make: Schott Kaisha Pvt. Limited) and Tubular

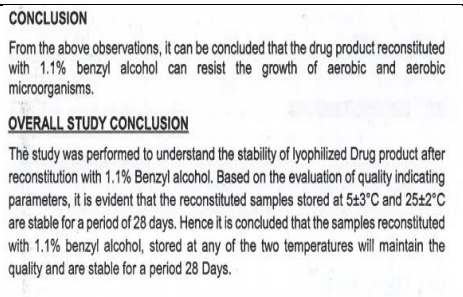
		vial blow back LYO-clear 15mL (USP type 1, make: SGD) with 20mm lyo nova pure rubber stoppers as a primary packaging material are used to fill the trastuzumab drug product. The rubber stoppers are manufactured with elastomer chlorobutyl coated with FluroTec® (make: West Pharmaceutical service) and 20 mm flip off seals are used (make: West Pharmaceutical service) for sealing of filled vials.
	Stability study data of drug product	The following conclusions made based on the stability studies performed. • Hetero trastuzumab DP pre-clinical batches have been tested for 60 M for the long term real time stability studies. There was no significant change in any of the quality attributes for the PCS batches for the long term real time stability studies. • For CT batches, the stability studies were performed until 36 M • The accelerated stability data suggests that the product is stable for 6 M at 2C and there is no significant change in any of the quality attributes when DP was stored under these conditions. As per ICH Q5C, this data indicates stability of trastuzumab for short term temperature excursions.
	Bio-similarity Studies as per WHO	Hetero Trastuzumab bio-similarity is focused on step-wise development that involves demonstration of following studies… 1. Structural & functional equivalence (Analytical/Quality Similarity) 2. Non-clinical equivalence (Non-Clinical Similarity) 3. Clinical equivalence (Clinical Similarity) Analytical Similarity: Structural and functional characteristics of the proposed biosimilar (Hetero Trastuzumab) are compared with the reference medicinal product (Herclon®); similarity of these functions forms the foundation of the biosimilar development program (analytical similarity is enclosed). Non-Clinical Similarity: Potential animal studies (in Wistar Rats), with study title "Comparative 28-Day Intermittent Dose (4 Doses: Once Every Week) Intravenous Toxicity Study of Trastuzumab Vs Reference Item in Wistar Rats with 14 Days Recovery period" provides a human pharmacokinetics / pharmacodynamics (Pk/Pd) equivalence study. This was conducted to confirm the similar non clinical efficacy of Hetero Trastuzumab with respect to Herceptin (RMP). The study was shown to be well tolerated up to 248 mg/kg in Wistar Rats for four weeks, without any obvious signs of systemic toxicity under the proposed study condition and demonstrated comparable safety profile with reference drug (TrastuzumabHerceptin®). None of the findings had a toxicological significance. For further details, please refer to the Module 4 of the CTD document. Clinical Significance: Comparative clinical studies are performed between Hetero Trastuzumab and Reference Product (Herclon®) to evaluate the safety, pharmacokinetic characteristics, and immunological potentials through the study title: "A randomized, multiple-dose, multicentre, comparative parallel study to evaluate the efficacy, safety and pharmacokinetic characteristics of intravenous infusion of Hetero Trastuzumab and Reference Medicinal Product (Herclon®, sourced from Roche) in Indian Patients of metastatic breast cancer". A good correlation between the two study groups was demonstrated in terms of efficacy, immunogenicity and safety using relevant end points, for further details please refer to the Module 5 of the CTD document. Conclusion: In conclusion, development of Hetero Trastuzumab is focused on the minimization of potential differences between the Hetero Trastuzumab and Reference Medicinal Product (Herclon® & Herceptin) and the establishment of a robust manufacturing process to consistently produce a high-quality biosimilar product. Through the above rigorous quality/analytical, non-clinical, and clinical evaluations,

	Hetero Trastuzumab can be confirmed as a viable alternative and a biosimilar to Herclon® and Herceptin.
Module 4 Non Clinical Studies	Biosimiliar to Herclon.
Module 5 Clinical Studies	Biosimiliar to Herclon.

Sr No.	Query	Firms Response	Evalutors Assesment
1.	The Innovator product uses sterile WFI whereas, applied formulation contains bacteriostatic WFI. Furthermore, the use of preservative is contrary to the Ph. Eur. Requirements. Therefore, justification and clarification is required	We would like to clarify that BWFI diluent is used for our 150mg/Vial strength. We would like to reiterate the fact that, the manufacturing process of 150 mg and 440mg are also same except the linear scale up of excipients for the higher strength. Since all the process and product remains same in both the strengths, we have claimed that both the vials as "Multidose" and should be reconstituted with BWFI unless for any hypersensitive patients, SWFI is recommended. The same statements are mentioned in our SMPC and PI also.	For hypersensitive patients, SWFI is recommended. The same statements are mentioned in our SMPC and PI also.
2.	The stability data of drug substance and drug product of commercial batches is not till claimed shelf life. Submit complete stability studies of commercial batches	We acknowledged your query and in response to it we would like to mention that the stability studies of Hetero Trastuzumab Formulated Drug Substance (FDS) and Drug Product (DP) for commercial batches are ongoing and is completed till 18 months for FDS and 18 months for DP for Long Term / Real Time conditions and 6 months for Accelerated Conditions at both FDS and DP stages. We commit to submitting the completed stability data after the completion of the 24-months' time point (which is our next scheduled pull out) for the commercial batches to confirm and further validate the proposed shelf life. Further we would like to mention that our proposed shelf life for	Commercial batches are ongoing and is completed till 18 months for FDS and 18 months for DP. that our proposed shelf life for FDS and DP is till 36 months which is based on our Pre-clinical Trail and Clinical Trail batches

			FDS and DP is till 36 months which is based on our Pre-clinical Trail and Clinical Trail batches stability studies. At these PCT and CT stages long term/ real time shelf life is studied till 60 months and found that all stability indicating parameters test results are within the acceptable criteria. For details please refer to the Query point 10_Annexure 01 and Annexure 02.	
	3.	Submit Comparability Protocols i.e., complete comparison of applied product with Innovator product in light of WHO guidelines on bio-similarity .	We acknowledge your query on the comparability studies of SBP (Similar Biotherapeutic Product) i.e., Hetero Trastuzumab Vs Innovator (Herclon®). We assure you that we have conducted the complete similarity study as per the WHO TRS no.: 977: Annex 2 – Guidelines on evaluation of Similar Biotherapeutic Product (SBP). Hetero Trastuzumab bio-similarity is focused on step-wise development that involves demonstration of following studies… 1. Structural & functional equivalence (Analytical/Quality Similarity) 2. Non-clinical equivalence (Non-Clinical Similarity) 3. Clinical equivalence (Clinical Similarity) Analytical Similarity: Structural and functional characteristics of the proposed biosimilar (Hetero Trastuzumab) are compared with the reference medicinal product (Herclon®); similarity of these functions forms the foundation of the biosimilar development program (analytical similarity is enclosed). Non-Clinical Similarity: Potential animal studies (in Wistar Rats), with	Submitted.

			study title "Comparative 28-Day Intermittent Dose (4 Doses: Once Every Week) Intravenous Toxicity Study of Trastuzumab Vs Reference Item in Wistar Rats with 14 Days Recovery period" provides a human pharmacokinetics / pharmacodynamics (Pk/Pd) equivalence study. This was conducted to confirm the similar non clinical efficacy of Hetero Trastuzumab with respect to Herceptin (RMP). The study was shown to be well tolerated up to 248 mg/kg in Wistar Rats for four weeks, without any obvious signs of systemic toxicity under the proposed study condition and demonstrated comparable safety profile with reference drug (TrastuzumabHerceptin®). None of the findings had a toxicological significance. For further details, please refer to the Module 4 of the CTD document. Clinical Significance: Comparative clinical studies are performed between Hetero Trastuzumab and Reference Product (Herclon®) to evaluate the safety, pharmacokinetic characteristics, and immunological potentials through the study title: "A randomized, multiple-dose, multicentre, comparative parallel study to evaluate the efficacy, safety and pharmacokinetic characteristics of intravenous infusion of Hetero Trastuzumab and Reference Medicinal Product (Herclon®, sourced from Roche) in Indian Patients of metastatic breast cancer".	

			A good correlation between the two study groups was demonstrated in terms of efficacy, immunogenicity and safety using relevant end points, for further details please refer to the Module 5 of the CTD document. Conclusion: In conclusion, development of Hetero Trastuzumab is focused on the minimization of potential differences between the Hetero Trastuzumab and Reference Medicinal Product (Herclon® & Herceptin) and the establishment of a robust manufacturing process to consistently produce a high-quality biosimilar product. Through the above rigorous quality/analytical, non-clinical, and clinical evaluations, Hetero Trastuzumab can be confirmed as a viable alternative and a biosimilar to Herclon® and Herceptin.	
	4.	The solution of innovator product HERCEPTIN for infusion diluted with 0.9% Sodium Chloride for Injection may be stored at room temperature 2–25°C for up to 24 hours prior to use.). However, since diluted HERCEPTIN contains no effective preservative, the reconstituted and diluted solution should be stored refrigerated (2–8°C) whereas, Hetero trastuzumab DP reconstituted in BWFI and diluted in saline is stable for 48 hours when	We acknowledge your query on reconstitution stability and infusion stability of Hetero Trastuzumab in comparison with Innovator [brand name: Herceptin, make: Roche]. Hetero Trastuzumab is reconstituted primarily with BWFI (Bacteriostatic Water For Injection) whereas innovator is using preservative free diluents i.e., SWFI (Sterile Water for Injection) for reconstitution. Hetero Trastuzumab DP is reconstituted with Bacteriostatic Water for Injection (BWFI) which contains 1.1% Benzyl alcohol as preservative. As per the reconstitution stability study the demonstrated stability is up to 28 days when stored	 **CONCLUSION** From the above observations, it can be concluded that the drug product reconstituted with 1.1% benzyl alcohol can resist the growth of aerobic and aerobic microorganisms. **OVERALL STUDY CONCLUSION** The study was performed to understand the stability of lyophilized Drug product after reconstitution with 1.1% Benzyl alcohol. Based on the evaluation of quality indicating parameters, it is evident that the reconstituted samples stored at 5±3°C and 25±2°C are stable for a period of 28 days. Hence it is concluded that the samples reconstituted with 1.1% benzyl alcohol, stored at any of the two temperatures will maintain the quality and are stable for a period 28 Days.

		stored at 2-8°C and 25°C. Clarification /justification is required for difference in reconstitutions and dilutions between innovator and proposed bio-similar drug	at 5±3°C and 25±2°C. Based on the evaluation of quality-indicating parameters, it is concluded that reconstituted samples stored at these temperatures will maintain their quality and stability for a period of 28 days (for details please refer to the Query 07_Annexure 01 – Reconstitution stability). Further the reconstituted drug product is infused in 0.9% (w/v) saline and observed that it is stable for 48 hours when stored at either 5±3°C and 25±2°C (for details please refer to the Query 07_Annexure 02 – Infusion stability). List of Annexures: 1. _Annexure 01 – Hetero Trastuzumab Reconstituted stability study report Clinical Data attached below 2. _Annexure 02 – Hetero Trastuzumab Infusion stability study report	
	5.	There are no reconstitution studies of drug product with sterile water of injection. Justification/clarification is required as benzyl alcohol, used as a preservative in BWFI, has been associated with toxicity in neonates and children up to 3 years old and patients with a known hypersensitivity to it	We acknowledge your query on the reconstitution studies of Trastuzumab Drug Product. However, we would like to bring to notice that Trastuzumab innovator "Roche" (with brand name: Herceptin) has discontinued the use of diluents containing preservatives (like Benzyl alcohol). Please find the recent FDA label of Herceptin enclosed as Query 08_Annexure 01 which emphasizes the neonatal precautions also. Thus, it can be inferred that clinical indications on "toxicity in neonates and children up to 3 years old" are independent of BWFI (Bacteriostatic Water for Injection) use. The label specifies Sterile Water for Injection (SWFI) for reconstitution, not BWFI. Further, it can be	The reconsitution studies with sterile WFI are not submitted by the applicant.

			interpreted that the neonatal risks are primarily attributed to Trastuzumab's pharmacological effects, particularly its potential to cause embryo-fetal toxicity when administered during pregnancy or shortly before conception but not due to BWFI. For further details please refer to the below screenshot from Herceptin FDA label (which do not use BWFI). FDA Label of Herceptin: Exposure to Herceptin during pregnancy can result in oligohydramnios and oligohydramnios sequence menifesting as pulmonary hypoplasia, skeletal abnormalities and neonatal death. Advise patient of these risks and the need for effective contracetion [see warnings and precautions (5.3) and use in specific population (8.1,8.3)]. Inference: The neonatal precautions mentioned in the label likely relate to pregnancy-associated fetal risks, such as embryo-fetal toxicity (e.g., oligohydramnios, pulmonary hypoplasia). These are independent of reconstitution practices but underscore the product's comprehensive risk evaluation. We at Hetero has taken outmost care in mentioning the above precautions and warnings in our package insert also which outweighs the risk of using BWFI as a diluent. List of Annexures: _Annexure 01 – Herceptin FDA Label	
	6.	Proper justification with evidence of reference guidelines were "Not applicable" has been mentioned	Non Clinical Data attached.	Submitted.

		for non-clinical study data		
	7.	Proper justification with evidence of reference guidelines were "Not applicable" has been mentioned for clinical study data.	Clinical Data attached.	III An assessor blind (central radiologist), randomized, active controlled, parallel group clinical study to evaluate the efficacy, safety, pharmacokinetics and pharmacodynamics of intravenous infusion of Hetero-Trastuzumab and reference medicinal product (RocheTrastuzumab) in patients with metastatic breast cancer. Primary Objective: • To compare the efficacy of HeteroTrastuzumab with Reference medicinal product (RocheTrastuzumab) in patients with metastatic breast cancer Secondary Objectives: • To evaluate pharmacokinetic characteristics of two formulations of Trastuzumab (HeteroTrastuzumab and Roche-Trastuzumab) • To compare the immunogenic potential of two formulations of Trastuzumab (HeteroTrastuzumab and Roche-Trastuzumab) 227 Completed

Decision of 343rd Meeting:
Keeping in view the legalized CoPP indicating product availability in the country of origin, Registration Board approved the product with 18 months' shelf life subject to compliance to the current Import Policy for finished drugs. Registration letter will be issued after submission of in use stability studies after reconstitution with sterile water of injection .

4.	Name, address of Applicant / Importer	**M/s The Searle Company Limited** Company Address: **F-319 Site Karachi**
	Details of Drug Sale License of importer	**Address: F-319 Site Karachi** **Address of Godown:** Plot No. 1/5 Manghopir Road, Karachi **Status**: License to sell drugs by way of whole sale. **Validity**: 06-05-2028 **Renewal:** NA
	Name and address of marketing authorization holder (abroad)	M/s Suzhou Union Biopharm Co., Ltd. No. 999 Longqiao Road, Wujiang Economic and Technological Development Zone, Suzhou, Jiangsu
	Name, address of manufacturer(s)	M/s Suzhou Union Biopharm Co., Ltd. No. 999 Longqiao Road, Wujiang Economic and Technological Development Zone, Suzhou City, Jiangsu Province
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**Scanned Copy of Legalized and Valid COPP** **Certificate No:** No. Shanghai20230222 **Certifying Authority:** Shanghai Municipal Medical Products Administration ls this product licensed to be placed on the, market for use in the exporting country? YES Is this product actually on the market in the exporting country? YES Validity : 24-09-2025
	Details of letter of authorization / sole agency agreement	**Scanned copy of Letter of Authorization** Shanghai Junshi Biosciences CO Ltd, Room 1003, 10th Floor, Building 2, NO 36,58 Haiqu Road, China Authorise The Searle Company for Adalimumab For Injection. Issue Date is missing and validity is 5 years. **Contract Manufacturing Agreement between MAH and Shanghai Union Biopharm Co. Ltd.**

		Dated 17-09-2019 **Relationship letter Between Shanghai, Mabwell and Suzhou Union Biopharm**
	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	Tracking ID: Y1L-U9H-2RN8 Application Number:874
	Details of fee submitted	Challan No. 50561955778 Rs. 150,000/-
	The proposed proprietary name / brand name	ADMAB Solution for injection 40mg/0.8ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 0.8ml Pre-filled Syringe contains: Adalimumab……...…40mg
	Dosage form of applied drug	Solution for injection in pre-filled syringe
	Pharmacotherapeutic Group of (API)	Tumor Necrosis Factor alpha (TNF-α) inhibitor ATC Code: L04AB04
	Finished product specifications	As per Innovators Specifications.
	Proposed Pack size	As per DPC.
	Proposed unit price	As per SRO/DPC .
	Shelf life	2 years
	Storage conditions	2-8°C and protect from light.
	The status in reference regulatory authorities	Humira Solution for Injection 40mg/0.8mL USFDA APPROVED
	For generic drugs (me-too status)	Adalimab Solution for Injection 40mg/0.8ml in Vial (Approved in 323rd DRB Meeting) Getz Pharma
	Module-II (Quality Overall Summary)	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 Suzhou Union Biopharm Co., Ltd. No. 999 Longqiao Road, Wujiang Economic and Technological Development Zone, Suzhou City, Jiangsu Province
	Module 3 (Quality)	
	Module-III Drug Substance:	Firm has submitted information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process, Characterization, 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)	All test items of the drug substance are stable during the long-term stability study (-80°C/-40°C). During the accelerated stability study (2°C-8°C) of the drug substance, all test items are stable without apparent change except for a slight decrease observed in monomer (SEC-HPLC), The data support a shelf life of 24 months at the storage condition (-40°C).

	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	All in-house methods for Adalimumab Solution for Injection have been validated or verified according to the Chinese Pharmacopoeia 2015, and the validation results demonstrate that these methods are suitable for product release testing and can ensure the quality controllability of Adalimumab Solution for Injection.
	Container closure system of the drug product	The assemblage of prefilled syringe and bromobutyl rubber plungers for prefilled syringes were selected as the primary packaging form of the drug product.
	Stability study data of drug product	The long-term stability test results (2-8°C) of the finished products shown a slight decrease in monomer content (SEC-HPLC) and a minimum of 76.1% of the lysine variants content (CEXHPLC) throughout 36 months, which met the specification of ≥ 75.0%; and all other test parameters remained stable; the data above support the storage conditions of the product: stored and shipped at 2-8°C, protected from light, avoid freezing. The shelf life of this product: 24 months.
	Bio-similarity Studies as per WHO guidelines	Not Submitted.
	Module 4 Non Clinical Studies	Not Submitted.
	Module 5 Clinical Studies	Not Submitted

Remarks of the Evaluator.DD-IV: Reply Awaited from the Applicant

Clarification of certifying authority Shanghai Municipal Medical Products Administration is required.

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.3	• The MAH details mentioned in Eapp section are incorrect. Provide the MAH abroad details as per COPP. • Submit hard copy of original, legalized and valid COPP. • Submit hard copy of original or notarized copy of valid Letter of Authorization /sole agency agreement.
2.	2.3.R.1.2 Comparability Protocols	Summary of quality comparison of applied product with Innovator product is required as per WHO bio similarity guidelines.
3.	3.2.P.2	The comparability should include all the tests as specified in section 3.2.P.5.1. The COA of innovator product only include Bioassay, Protein content,oligomer,oxidized follitropin,Free subunuits and isoelectric focusing.
4.	3.2.P.5.1	• The pH specifications of innovator product "Gonal F" is 6.7 to 7.3 whereas, applied formulation pH range is 6.0 to 8.0.Clarification/justification is required. • The specifications do not include test of degradation products. Justification is required for not performing aforementioned test.
5.	3.2.A.1	The facilities and equipment details are not provided in this section.
6.	3.2.R Regional Information	Comparability Protocols • Complete comparison of applied product with Innovator product in light of WHO Bio-similarity Guidelines is required.

			• The comparability should include all the tests as specified in section 3.2.P.5.1. The COA of innovator product only include bioassay, protein content, oligomer, oxidized follitropin,free subunuits and isoelectric focusing.
	7.	Module 4 Non-Clinical Data	The nonclinical data is not of applied strength. Therefore, submit proper justification on the basis of guidelines for acceptance of data of different strength.
	8.	Module 5 Clinical Data	The Phase III clinical studies with recombinant follicle stimulating hormone in prefilled pen device are still ongoing. Therefore, submit proper justification for acceptance of clinical data of different pharmaceutical form i.e. lyophilized powder.

Decision of 343rd Meeting:
Registration Board deferred for submission of following:

- The MAH details mentioned in E-app section are incorrect. Provide the MAH abroad details as per COPP.
- Submit hard copy of original, legalized and valid COPP.
- Submit hard copy of original or notarized copy of valid Letter of Authorization /sole agency agreement.
- Summary of quality comparison of applied product with Innovator product is required as per WHO bio similarity guidelines.
- The comparability should include all the tests as specified in section 3.2.P.5.1. The COA of innovator product only include Bioassay, Protein content,oligomer,oxidized follitropin,Free subunuits and isoelectric focusing.
- The pH specifications of innovator product "Gonal F" is 6.7 to 7.3 whereas, applied formulation pH range is 6.0 to 8.0.Clarification/justification is required.
- The specifications do not include test of degradation products. Justification is required for not performing aforementioned test.
- The facilities and equipment details are not provided in this section.
- Comparability Protocols
- Complete comparison of applied product with Innovator product in light of WHO Bio-similarity Guidelines is required.
- The comparability should include all the tests as specified in section 3.2.P.5.1. The COA of innovator product only include bioassay, protein content, oligomer, oxidized follitropin,free subunuits and isoelectric focusing.
- The nonclinical data is not of applied strength. Therefore, submit proper justification on the basis of guidelines for acceptance of data of different strength.
- The Phase III clinical studies with recombinant follicle stimulating hormone in prefilled pen device are still ongoing. Therefore, submit proper justification for acceptance of clinical data of different pharmaceutical form i.e. lyophilized powder.

5.	Name, address of Applicant / Importer	**M/s The Searle Company Limited** Company Address: **F-319 Site Karachi**
	Details of Drug Sale License of importer	**Address: F-319 Site Karachi** **Address of Godown:** Plot No. 1/5 Manghopir Road, Karachi **Status**: License to sell drugs by way of whole sale. **Validity**: 06-05-2028 **Renewal:** NA
	Name and address of marketing authorization holder (abroad)	Hisun Biopharmaceutical Co., Ltd Address: 8 Haizheng Road, Xukou Town, Fuyang District, Hangzhou City, Zhejiang Province, China
	Name, address of manufacturer(s)	Hisun Biopharmaceutical Co., Ltd Address: 8 Haizheng Road, Xukou Town, Fuyang District, Hangzhou City, Zhejiang Province, China
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**Scanned Copy of Legalized and Valid COPP** **Certificate No:** No. Zhejiang20220061 **Certifying Authority:** Zhejiang Medical Products

		ls this product licensed to be placed on the, market for use in the exporting country? YES Is this product actually on the market in the exporting country? YES Validity :12 April 2024 **COPP is not valid.**
	Details of letter of authorization / sole agency agreement	**Scanned copy of Letter of Authorization** Hisun Biopharmaceutical Co., Ltd Address: 8 Haizheng Road, Xukou Town, Fuyang District, Hangzhou City, Zhejiang Province, China authorize The Searle Company Limited (2nd Floor One IBL Center DMCHS Tipu Road. Dated: 02-08-2023 Brand name is Adalib in LOA
	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	Tracking ID: YY1-R22-5YH9 Application Number: 1383
	Details of fee submitted	Challan No. 08682205535 Rs. 300,000/-
	The proposed proprietary name / brand name	ALIMRA 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
	Dosage form of applied drug	Solution for injection in pre-filled syringe
	Pharmacotherapeutic Group of (API)	Tumor Necrosis Factor alpha (TNF-α) inhibitor ATC Code: L04AB04
	Finished product specifications	As per Innovators Specifications
	Proposed Pack size	As per DPC.
	Proposed unit price	As per SRO/DPC .
	Shelf life	2 years
	Storage conditions	2-8°C and protect from light.
	The status in reference regulatory authorities	Humira Solution for Injection 40mg/0.8mL USFDA APPROVED
	For generic drugs (me-too status)	Adalimab Solution for Injection 40mg/0.8ml in Vial (Approved in 323rd DRB Meeting) Getz Pharma
	Module-II (Quality Overall Summary)	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	Hisun Biopharmaceutical Co., Ltd Address: 8 Haizheng Road, Xukou Town, Fuyang District, Hangzhou City, Zhejiang Province, China
	Module 3 (Quality)	
	Module-III Drug Substance:	Firm has submitted information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers,

		description of manufacturing process, Characterization, 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)	Stability Conclusions According to the available stability data, Hisun proposes a expiry period of 18 months for Adalimumab drug substance packaged in heat-sealed BPC, coated with 2 layers of PE bags and heat-sealed, and stored below -70℃, protected from light.
	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	All test items except appearance, visible particles, particulate matter, osmolality, volume variation, pH and abnormal toxicity have been appropriate validated according to in-house acceptance criteria since adalimumab has not been adopted to any official pharmacopeia.
	Container closure system of the drug product	The assemblage of prefilled syringe and bromobutyl rubber plungers for prefilled syringes were selected as the primary packaging form of the drug product.
	Stability study data of drug product	Stability Conclusions According to the available stability data, Hisun proposes a expiry period of 24 months for HS016 packaged in PFS, and stored below 5℃±3℃, protected from light.
	Bio-similarity Studies as per WHO guidelines	Not Submitted.
	Module 4 Non Clinical Studies	Not Submitted.
	Module 5 Clinical Studies	Not Submitted

Remarks of the Evaluator DD-IV:Reply Awaited from the Applicant

S. No	Sections	Observations/Deficiencies/ Short-comings
1.	1.3.3	a) The MAH details mentioned in Eapp section are incorrect. Provide the MAH details as per COPP. b) Submit hard copy of original, legalized and valid COPP as submitted one is valid till 12 April 2024. c) Submit hard copy of original or notarized copy of valid Letter of Authorization /sole agency agreement. d) The trade name on letter of authorization is "Adalib Solution" which is different then applied name "Alimra Solution". Clarification/justification is required. e) The address of importer on Letter of authorization is 2nd Floor ,1 IBL Center, DMCHS,Tipu Sultan Road, Karachi which is different than Address on DSL i.e. F-319 Site Karachi. Justification is required for variation in addresses.
2.	2.3.R.1.2 Comparability Protocols	Summary of quality comparison of applied product with Innovator product is required as per WHO bio similarity guidelines.

	3.	3.2.S.1.2	a) Provide the approximate intact mass of 2 kappa light chains and 2 IgG1 heavy chains. b) The number of amino acid residues in the light chain and heavy chain. c) The major carbohydrate chain forms and their percentage. d) The percentage of the glutamic acid cyclization at position 1 of the heavy chain N-terminal. e) The percentage of lysine clipping of the heavy chain. f) The number of disulphide bonds and their forms.
	4.	3.2.S.1.3	A list should be provided of physicochemical and other relevant properties of the drug substance, including biological activity with reference to Q6A and Q6B.
	5.	3.2.S.3.1.2	Justification is required for failing the similarity results for % total afucosylation, % afucosylation, % high mannose and % galactosylation for HS016 range with Humira.
	6.	3.2.S.4.1	a) Justification for variation in the specification/results of protein content is required i.e. 55.00mg/ml to 75mg/ml as the results of protein content for drug substance and innovator product in section 3.2.S.3.1.2 is in the range of 47mg/ml to 52mg/ml. b) Provide reference for drug substance specification.
	7.	3.2. S.7	The innovator drug substance has claimed a shelf life of 18 months for active substance stored at -80 ° C or between -20 to -25 ° C whereas, the drug substance manufacturer of M/s Hisun data support a shelf life of 24 months at the storage condition (-40°C).Justification and clarifications is required on the basis of scientific rationale.
	8.	3.2.P.3.3	The drug product manufacturing doesn't provide any step about addition of excipients. Justification/Clarification is required.
	9.	3.2.R Regional Information	**Comparability Protocols** Complete quality comparison of their product with Innovator product in light of guidelines approved by Registration Board in its 297th meeting.
	10.	Module 4 Non-Clinical Data	Proper justification with evidence of reference guidelines were "Not applicable" has been mentioned for non-clinical study data.
	11.	Module 5 Clinical Data	Proper justification with evidence of reference guidelines were "Not applicable" has been mentioned for non-clinical study data.

Decision of 343rd Meeting: Registration Board deferred for submission of the following documents:

- The MAH details mentioned in Eapp section are incorrect. Provide the MAH details as per COPP.
- Submit hard copy of original, legalized and valid COPP as submitted one is valid till 12 April 2024.
- Submit hard copy of original or notarized copy of valid Letter of Authorization /sole agency agreement.
- The trade name on letter of authorization is "Adalib Solution" which is different then applied name "Alimra Solution". Clarification/justification is required.
- The address of importer on Letter of authorization is 2nd Floor ,1 IBL Center, DMCHS,Tipu Sultan

Road, Karachi which is different than Address on DSL i.e. F-319 Site Karachi. Justification is required for variation in addresses.

- Summary of quality comparison of applied product with Innovator product is required as per WHO bio similarity guidelines.
- Provide the approximate intact mass of 2 kappa light chains and 2 IgG1 heavy chains.
- The number of amino acid residues in the light chain and heavy chain.
- The major carbohydrate chain forms and their percentage.
- The percentage of the glutamic acid cyclization at position 1 of the heavy chain N-terminal.
- The percentage of lysine clipping of the heavy chain.
- The number of disulphide bonds and their forms.
- A list should be provided of physicochemical and other relevant properties of the drug substance, including biological activity with reference to Q6A and Q6B.
- Justification is required for failing the similarity results for % total afucosylation, % afucosylation, % high mannose and % galactosylation for HS016 range with Humira.
- Justification for variation in the specification/results of protein content is required i.e. 55.00mg/ml to 75mg/ml as the results of protein content for drug substance and innovator product in section 3.2.S.3.1.2 is in the range of 47mg/ml to 52mg/ml.
- Provide reference for drug substance specification.
- The innovator drug substance has claimed a shelf life of 18 months for active substance stored at -80 ° C or between -20 to -25 ° C whereas, the drug substance manufacturer of M/s Hisun data support a shelf life of 24 months at the storage condition (-40°C). Justification and clarifications is required on the basis of scientific rationale.
- The drug product manufacturing doesn't provide any step about addition of excipients. Justification/Clarification is required.
- Complete quality comparison of their product with Innovator product in light of guidelines approved by Registration Board in its 297th meeting.
- Proper justification with evidence of reference guidelines were "Not applicable" has been mentioned for non-clinical study data.
- Proper justification with evidence of reference guidelines were "Not applicable" has been mentioned for non-clinical study data.

6.	**Name, address of Applicant / Importer**	M/s AJM Pharma (Pvt.) Ltd, Karachi Postal Address: 1st Floor, Shafi Court, Merewether Road, Civil Lines. Karachi–Pakistan.
	Details of Drug Sale License of importer	Drug License by Way of Whole Sale License No: 262 **Address:** Ist Floor Shafi Cour Civil Line Merether Road Validity: 22-02-2028
	Name and address of marketing authorization holder (abroad)	M/s Sinocelltech, Ltd. Room 301, Building 5, No 31, Kechuang 7th Street, Beijing Economic and Technological Development Area, Beijing, China
	Name, address of manufacturer(s)	M/s Sinocelltech, Ltd. Manufacturing site Address No. 31, Kechuang 7th Street, Beijing Economic and Technological Development Area, Beijing, China
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	**Original Apostille CoPP** Certificate No: No. Beijing20240313 Certifying Authority: Beijing Municipal Medical Products Administration Is this product strength licensed to be placed on the market for use in China: Yes Is this product strength actually on the market in China: Yes Validity:19-07-2026
	Details of letter of authorization / sole agency agreement	**Original Sole Agency Letter** M/s Sinocelltech, Ltd, Room 301, Building 5, No 31, Kechuang 7th Street, Beijing Economic and Technological Development Zone authorize M/s AJM Pharma Pvt., Ltd. Dated: 11, August, 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	Form -5F Dy. No.: 1456 Dated:02/03/2023
	Details of fee submitted	Rs: 75,000/-. Dated: 10/02/2023 Deposit Slip No. 536518802
	The proposed proprietary name / brand name	Octafile Vial 250 IU
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Freeze-Dried Powder Vial : Each powder vial contains: Recombinant human coagulation factor VIII (omfiloctocog alfa)……250 IU After reconstitution, 1 mL of solution contains approximately 62.5 IU omfiloctocog alfa. **Solvent**: Each ampoule contains Sterile Water for injection…..10ml
	Dosage form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Antihemorrhagics, blood coagulation factor VIII, ATC code: B02BD02 **Proposed indications**: Treatment and prophylaxis of bleeding in previously treated patients ≥12 years of age with hemophilia A (congenital factor VIII deficiency).
	Reference to Finished product specifications	Manufacturer Specifications.
	Proposed Pack size	Pack size : 1's One package of 250IU contains: □ 1 vial of recombinant human coagulation factor VIII freeze-dried powder for injection □ 1 ampoule of sterilized water for injection(SFDA approval number H20044102 or H20153112）
	Proposed unit price	As per current SRO.
	Shelf Life	36 Months
	Storage Conditions	Store at 2-8°C. Protect from light.
	The status in reference regulatory authorities	Reference List Drug : Recombinant Human Coagulation Factor VIII Manufacturer Name: Wyeth Pharmaceuticals LLC Brand Name: XYNTHA Strength: 250IU Dosage Form: white to off-white lyophilized powder Pack Size: I's USFDA Approved Product.
	For generic drugs (me-too status)	NA

	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 Sinocelltech, Ltd.,No. 31, Kechuang 7th Street, Beijing Economic and Technological Development Area, Beijing
	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)	According to the stability study results, the container closure system of the two materials can support storage of the drug substance for 36 months below -65°C. 9,12, 18, 24,36 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.
	Analytical method validation/verification of product	Firm has submitted the following analytical method validation reports. 1 Validation of identification test methodology 2 Method verification of moisture assay 3 Method validation of purity (RP-HPLC) 4 Method validation of purity (SEC-HPLC) 5 Method validation of potency / specific activity 6 Method validation of protein Content 7 Method validation of sucrose assay 8 Method validation of histidine content analysis 9 Method validation of arginine hydrochloride assay 10 Method validation results of polysorbate 80 assay 11 Method validation results of calcium chloride content 12 Validation results of sterility test methodology 13 Confirmation results of bacterial endotoxin test methodology
	Container closure system of the drug product	The packaging materials of SCT800 include injection vials made of middle borosilicate glass tubing, bromobutyl rubber stopper for freeze-drying and aluminum-plastic combination cap for antibiotic vial.
	Stability study data of drug product, shelf life and storage conditions	The 6mL transparent injection vials made of middle borosilicate glass tubing, bromobutyl rubber stopper for freeze-drying, and aluminum-plastic combination cap, were proposed to have the shelf life of 36 months when storing at 2 ~ 8°C.
	Module-IV Non-Clinical	

Module 4 (Non-clinical / Safety)			
4.2	Study Reports		
4.2.1	Pharmacology		
	4.2.1.1	Primary Pharmacodynamics	Invitro and invivo studies are performed.

	4.2.1.2	Secondary Pharmacodynamics	Not conducted. Because no other irrelevant interaction except the main mechanism for the treat target was observed during the study in the relevant animal - cynomolgus monkeys.
	4.2.1.3	Safety Pharmacology	The study was conducted with the Four-Week Repeat-Dose Toxicity Study, the study number was P13-38-CD. The results showed that there was no statistically significant difference in body temperature, blood pressure, and electrocardiogram parameters of the animals in each of the administration groups compared with the control group. And there was no statistically significant difference in body temperature and blood pressure before and after dosing in the same group. Safety pharmacology studies in cynomologus monkey showed that there were no adverse effects in central nervous system, cardiovascular system and respiratory system after repeated-dose administrating with SCT800 for 4 weeks by slow intravenous injection.
	4.2.1.4	Pharmacodynamic Drug Interactions	No study on interaction of SCT800 with other medical products has been conducted. At present,the data on possible drug-drug interactions of related products with other drugs is very limited.
4.2.2	Pharmacokinetics		In summary, it has been proven that the pharmacokinetic characteristics of SCT800 are clearly dose-dependent, and comparable with the similar marketed product XynthaR.
4.2.3	Toxicology		Cynomolgus monkeys were repeatedly administrated with 50, 250, and 1250 IU·kg-1 of SCT800 and adjuvant control by intravenous injection, once a day for 28 days. The Safety Pharmacology, Local Tolerance, Immunogenicity and Immunotoxicity studies were conducted combining in the 4-week repeated dose toxicity study.
	4.2.3.1	Single-Dose Toxicity (in order by species, by route)	The single dose toxicity study was not carried out in consideration of Repeat-Dose Toxicity being more reliable and closely mimics the clinical dosing regimen.
	4.2.3.2	Repeat-Dose Toxicity (in order by species, by route, by duration; including supportive	A Four-Week Repeat-Dose Toxicity Study of SCT800 in Cynomolgus Monkey was conducted (Study Number: P13-38-CD; GLP) to evaluate the toxicity of SCT800 which may also provide the dose reference for clinical usage.
	4.2.3.3	Genotoxicity	None
	4.2.3.4	Carcinogenicity (including supportive toxicokinetics evaluations)	None

	4.2.3.5	Reproductive and Developmental Toxicity (including range-finding studies and supportive toxicokinetics evaluations) (If modified study designs are used, the following sub-headings should be modified accordingly.)	Since the SCT800 belongs to human's own protein and few women suffer from hemophilia A, the animal reproductive and developmental toxicity study was not conducted.
	4.2.3.6	Local Tolerance	To evaluate the site injection irritation of cynomolgus monkeys after 4 weeks repeated intravenous injection of SCT800. (Combined with the Four-Week Repeat-Dose Toxicity Study of SCT800; Study Number: P13-38-CD; GLP)

Module-V Clinical Studies

A Multi-center, Open-label, Uncontrolled Phase III Clinical Trial to Evaluate the Safety and Efficacy of Recombinant Human Coagulation Factor VIII (SCT800) as On-demand Treatment in Haemophilia A Patients Who had Previously Received Factor VIII Treatment.

Remarks of Evaluator(DD-IV)

- Arrange the documents of Module 5 as per Form 5 F sequence.
- It is a bio-similiar product of Xantha not an innovator product.

Shortcoming	Responded
CoPP is not of combo pack, while you have applied for registration of the product in combo pack with diluent. Provide CoPP of combo pack indicating diluent also.	Attached for your reference.
SmPC and proposed label are not provided.	attached for your review
DSL is expired. Provide valid copy.	Valid DSL provided Dated: 22/02/2028
Solvent manufacturer is not mentioned in the dossier.	Solvent manufacturer is attached in 3.2.P.3.1
Evidence of availability of applied formulation in reference regulatory authority is required.	XYNTHA USFDA
You have mentioned reference product as **Xyntha** which is "Monoctocog alfa" while your applied product is "Omfiloctocog alfa".	1. Justification is attached 2. Efficacy & Safety data is attached
Detail about overages mentioned in Module 3.2.P.2.2.3 of the dossier and its justification and calculation is required.	Justification of Overages detailed is attached for your reference
Finished product specifications in the light of 267th meeting of Registration Board is not provided.	Finish product specification is attached as 3.2.P.5.1
Details of reference standard used in testing of product along with its certificate of analysis is required.	Details of reference standard with COA attached
Specifications of excipients used in formulation is also required.	Specification of excipient is attached
Batch size is not mentioned in stability data.	Stability data with batch size is attached in 3.2.P.8.1
All parameters are not tested in stability data as mentioned in Finished Product specifications.	All parameters are tested in stability data as mentioned in FPP specification and attached in 3.2.P.8.3 with all parameters

Stability data of solvent is not provided.	Please find attached in 3.2.P.8.3
Certificate of analysis of Finished Product is required.	Please find attached COA of FPP in 3.2.P.5.4
Compatibility studies with container closure system under Module 3.2.P.2.6 is not provided.	Please find attached in 3.2.P.2.6
In Module 4, Single dose toxicity, Geno toxicity, Carcinogenicity, Reproductive and developmental toxicity not performed. Provide justification with proper reference.	Please find the attached toxicity data.

Decision of 343rd Meeting: 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. The applicant shall submit differential requisite fee being generic.	
7.	**Name, address of Applicant / Importer**	M/s AJM Pharma (Pvt.) Ltd, Karachi Postal Address: 1st Floor, Shafi Court, Merewether Road, Civil Lines. Karachi–Pakistan.
	Details of Drug Sale License of importer	Drug License by Way of Whole Sale License No: 262 **Address:** Ist Floor Shafi Cour Civil Line Merether Road Validity: 22-Feb-2028
	Name and address of marketing authorization holder (abroad)	M/s Sinocelltech, Ltd. Room 301, Building 5, No 31, Kechuang 7th Street, Beijing Economic and Technological Development Area, Beijing, China
	Name, address of manufacturer(s)	M/s Sinocelltech, Ltd. Manufacturing site Address No. 31, Kechuang 7th Street, Beijing Economic and Technological Development Area, Beijing, China
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	**<u>Original Apostille CoPP</u>** Certificate No: No. Beijing20240318 Certifying Authority: Beijing Municipal Medical Products Administration Is this product strength licensed to be placed on the market for use in China: Yes Is this product strength actually on the market in China: Yes Validity:19-07-2026
	Details of letter of authorization / sole agency agreement	**<u>Original Sole Agency Letter</u>** M/s Sinocelltech, Ltd, Room 301, Building 5, No 31, Kechuang 7th Street, Beijing Economic and Technological Development Zone authorize M/s AJM Pharma Pvt., Ltd. Dated: 11, August, 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	Form -5F Dy. No.: 5927 Dated:02/03/2023
	Details of fee submitted	Rs: 75,000/-. Dated: 10/02/2023 Deposit Slip No. 6652311364
	The proposed proprietary name / brand name	Octafile Vial 1000 IU
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Freeze-Dried Powder Vial : Each powder vial contains: Recombinant human coagulation factor VIII (omfiloctocog alfa)……1000 IU After reconstitution, 1 mL of solution contains approximately 250 IU omfiloctocog alfa. **Solvent**: Each ampoule contains Sterile Water for injection…..10ml

	Dosage form of applied drug	Injection
	Pharmacotherapeutic Group of (API)	Antihemorrhagics, blood coagulation factor VIII, ATC code: B02BD02 **Proposed indications**: Treatment and prophylaxis of bleeding in previously treated patients ≥12 years of age with hemophilia A (congenital factor VIII deficiency).
	Reference to Finished product specifications	Manufacturer Specifications.
	Proposed Pack size	Pack size : 1's One package of 1000IU contains: □ 1 vial of recombinant human coagulation factor VIII freeze-dried powder for injection □ 1 ampoule of sterilized water for injection(SFDA approval number H20044102 or H20153112）
	Proposed unit price	As per current SRO.
	Shelf Life	36 Months
	Storage Conditions	Store at 2-8°C. Protect from light.
	The status in reference regulatory authorities	Reference List Drug : Recombinant Human Coagulation Factor VIII Manufacturer Name: Wyeth Pharmaceuticals LLC Brand Name: XYNTHA Strength: 1000IU Dosage Form: white to off-white lyophilized powder Pack Size: I's USFDA Approved Product.
	For generic drugs (me-too status)	NA
	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 Sinocelltech, Ltd.,No. 31, Kechuang 7th Street, Beijing Economic and Technological Development Area,Beijing
	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)	According to the stability study results, the container closure system of the two materials can support storage of the drug substance for 36 months below -65°C. 9,12, 18, 24,36 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.
	Analytical method validation/verification of	Firm has submitted the following analytical method validation reports. 1 Validation of identification test methodology

	product	2 Method verification of moisture assay 3 Method validation of purity (RP-HPLC) 4 Method validation of purity (SEC-HPLC) 5 Method validation of potency / specific activity 6 Method validation of protein Content 7 Method validation of sucrose assay 8 Method validation of histidine content analysis 9 Method validation of arginine hydrochloride assay 10 Method validation results of polysorbate 80 assay 11 Method validation results of calcium chloride content 12 Validation results of sterility test methodology 13 Confirmation results of bacterial endotoxin test methodology
	Container closure system of the drug product	The packaging materials of SCT800 include injection vials made of middle borosilicate glass tubing, bromobutyl rubber stopper for freeze-drying and aluminum-plastic combination cap for antibiotic vial.
	Stability study data of drug product, shelf life and storage conditions	The 6mL transparent injection vials made of middle borosilicate glass tubing, bromobutyl rubber stopper for freeze-drying, and aluminum-plastic combination cap, were proposed to have the shelf life of 36 months when storing at 2 ~ 8°C.

Module-IV Non-Clinical Studies

Module 4 (Non-clinical / Safety)			
4.2	Study Reports		
4.2.1	Pharmacology		
	4.2.1.1	Primary Pharmacodynamics	Invitro and invivo studies are performed.
	4.2.1.2	Secondary Pharmacodynamics	Not conducted. Because no other irrelevant interaction except the main mechanism for the treat target was observed during the study in the relevant animal - cynomolgus monkeys.
	4.2.1.3	Safety Pharmacology	The study was conducted with the Four-Week Repeat-Dose Toxicity Study, the study number was P13-38-CD. The results showed that there was no statistically significant difference in body temperature, blood pressure, and electrocardiogram parameters of the animals in each of the administration groups compared with the control group. And there was no statistically significant difference in body temperature and blood pressure before and after dosing in the same group. Safety pharmacology studies in cynomologus monkey showed that there were no adverse effects in central nervous system, cardiovascular system and respiratory system after repeated-dose administrating with SCT800 for 4 weeks by slow intravenous injection.
	4.2.1.4	Pharmacodynamic Drug Interactions	No study on interaction of SCT800 with other medical products has been conducted. At present,the data on possible drug-drug interactions of related products with other drugs is very limited.
4.2.2	Pharmacokinetics		In summary, it has been proven that the pharmacokinetic characteristics of SCT800 are clearly dose-dependent, and comparable with the similar marketed product XynthaR.

4.2.3	Toxicology		Cynomolgus monkeys were repeatedly administrated with 50, 250, and 1250 IU·kg-1 of SCT800 and adjuvant control by intravenous injection, once a day for 28 days. The Safety Pharmacology, Local Tolerance, Immunogenicity and Immunotoxicity studies were conducted combining in the 4-week repeated dose toxicity study.
	4.2.3.1	Single-Dose Toxicity (in order by species, by route)	The single dose toxicity study was not carried out in consideration of Repeat-Dose Toxicity being more reliable and closely mimics the clinical dosing regimen.
	4.2.3.2	Repeat-Dose Toxicity (in order by species, by route, by duration; including supportive	A Four-Week Repeat-Dose Toxicity Study of SCT800 in Cynomolgus Monkey was conducted (Study Number: P13-38-CD; GLP) to evaluate the toxicity of SCT800 which may also provide the dose reference for clinical usage.
	4.2.3.3	Genotoxicity	None
	4.2.3.4	Carcinogenicity (including supportive toxicokinetics evaluations)	None
	4.2.3.5	Reproductive and Developmental Toxicity (including range-finding studies and supportive toxicokinetics evaluations) (If modified study designs are used, the following sub-headings should be modified accordingly.)	Since the SCT800 belongs to human's own protein and few women suffer from hemophilia A, the animal reproductive and developmental toxicity study was not conducted.
	4.2.3.6	Local Tolerance	To evaluate the site injection irritation of cynomolgus monkeys after 4 weeks repeated intravenous injection of SCT800. (Combined with the Four-Week Repeat-Dose Toxicity Study of SCT800; Study Number: P13-38-CD; GLP)

Module-V Clinical Studies

A Multi-center, Open-label, Uncontrolled Phase III Clinical Trial to Evaluate the Safety and Efficacy of Recombinant Human Coagulation Factor VIII (SCT800) as On-demand Treatment in Haemophilia A Patients Who had Previously Received Factor VIII Treatment

Remarks of Evaluator(DD-IV)

The applicant applied as New Drug Product, however it has been obsereved that application is of generic product since Factor VIII is already registered namely; Koate 250 Injection.
Arrange the documents of Module 5 as per Form 5 F .
It is a biosimiliar product of Xantha not an innovator product as per studies.

Shortcoming	Responded
CoPP is not of combo pack while you have applied for registration of the product in combo pack with diluent. Provide CoPP of combo pack indicating diluent also.	Attached for your reference.
SmPC and proposed label are not provided.	attached for your review
DSL is expired. Provide valid copy.	Valid DSL provided Dated: 22/02/2028
Solvent manufacturer is not mentioned in the dossier.	Solvent manufacturer is attached in 3.2.P.3.1
Evidence of availability of applied formulation in reference regulatory authority is required.	XYNTHA USFDA
You have mentioned reference product as **Xyntha** which is "Monoctocog alfa" while your applied product is "Omfiloctocog alfa".	1. Justification is attached 2. Efficacy & Safety data is attached
Detail about overages mentioned in Module 3.2.P.2.2.3 of the dossier and its justification and calculation is required.	Justification of Overages detailed is attached for your reference
Finished product specifications in the light of 267th meeting of Registration Board is not provided.	Finish product specification is attached as 3.2.P.5.1
Details of reference standard used in testing of product along with its certificate of analysis is required.	Details of reference standard with COA attached
Specifications of excipients used in formulation is also required.	Specification of excipient is attached
Batch size is not mentioned in stability data.	Stability data with batch size is attached in 3.2.P.8.1
All parameters are not tested in stability data as mentioned in Finished Product specifications.	All parameters are tested in stability data as mentioned in FPP specification and attached in 3.2.P.8.3 with all parameters
Stability data of solvent is not provided.	Please find attached in 3.2.P.8.3
Certificate of analysis of Finished Product is required.	Please find attached COA of FPP in 3.2.P.5.4
Compatibility studies with container closure system under Module 3.2.P.2.6 is not provided.	Please find attached in 3.2.P.2.6
In Module 4, Single dose toxicity, Geno toxicity, Carcinogenicity, Reproductive and developmental toxicity not performed. Provide justification with proper reference.	Please find the attached toxicity data.

Decision of 343rd Meeting: 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.

Item No. 02: Registration Applications for Local Manufacturing of Biological Drugs (Priority Registration Applications of Export Facilitation)

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 M/s Getz Pharma (Pvt) Ltd have achieved the benchmark of USD 686,055,89 during the fiscal Year 2023-2024 and 5 molecules had already been prioritized against said benchmark. In pursuance of decision of the authority, the firm has requested one additional molecule against their remaining benchmark and submitted following two applications for priority consideration in lieu of export facilitation for Registration Board, please.

- ✓ Sematide Solution for Injection 2mg/1.5ml
- ✓ Sematide Solution for Injection 4mg/3ml

Registration of Semaget Solution for Injection (Bulk import Concentrate Local Filling)

8.	Name, address of Applicant / Importer	M/s Getz Pharma (Pvt) Limited Company Address: 29-30/27,Korangi Industrial Area, Karachi

	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 Getz Pharma (Pvt.) Limited Address: Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi – 74900, Pakistan
	GMP of manufacturer & Evidence of Section	DML No. 000284 Regularization of layout plan for Liquid Injectable vial and Cartridges.(Biotech rDNA)
	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 Import of Bulk Concentrate and Local Manufacturing
	Dy. No. and Date of submission	Tracking ID:SML-X5J-BBWU Application Number:54048 Date of Receiving: 29-11-2024
	Details of fee submitted	Challan Number: 7509710942 Division: Biological Evaluation & Registration Paid Fee: 37000.0 Paid Date: 2024-09-26 Fee Head: Drug for local manufacture Challan Number :412992834 Drug for local manufacture :263000.0 Paid Date: 2024-10-25
	The proposed proprietary name / brand name	**Semaget Solution for Injection 2mg/1.5mL**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each mL contains: Semaglutide…… 1.34mg
	Pharmaceutical form of applied drug	Solution for Injection in vial
	Pharmacotherapeutic Group of (API)	Glucagon-like peptide-1 (GLP-1) analogues ATC Code: A10BJ06
	Reference to Finished product specifications	As per Innovator's Specifications
	Proposed Pack size	1's Vial
	Proposed unit price	As per SRO 228(I)/2024 dated 19-02-2024
	Shelf Life	24 Months
	Storage Condition	Store in a refrigerator (2 -8 °C), Do not freeze. Protect from heat and light.
	The status in reference regulatory authorities	OZEMPIC (semaglutide) solution for injection 2 mg/1.5 ml (USFDA APPROVED)
	For generic drugs (me-too status)	Seglutide Injection 2mg/1.5ml 120535

	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	M/s Hangzhou Jiuyuan Gene Engineering Co., Ltd Manufacturing Site and Manufacturing Scope: East of No. 8th Street, Hangzhou Economic and Technological Development Zone: Freeze-dried powder for injection, drug substance, small volume parenteral solution (containing antineoplastic drug), therapeutically biological product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, impurities, specifications, analytical procedures and its validation, batch analysis an justification of specification, reference standard, container closure system and stability studies of drug substance concentrate. Firm has submitted assay method validation report by drug product manufacturer **Stability Studies data** Accelerated 6-month and long-term9-month sampling surveys have been completed. There is no significant change in the Appearance, Identification, pH, Related substances, HMWPs, Phenol, Bacterial endotoxins, Osmolality, Particulate matter, Sterility, Content & Biological activity and all are within the standard control limits. According to the trend of the samples in the long-term stability test, semaglutide is stable in nature.
	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 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 **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.	The firm has stated as follows: Please note that M/s Hangzhou Jiuyuan Gene Engineering Co., Ltd China has EUDRA GMP Certificate for their site. Certificate #: DE_HH_01_GMP_2019_0020 Validity: 31 December 2024 Issuing Authority: Freie und Hansestadt Hamburg, Ministry of Health and Consumer Protection. (Assesor Remarks: This GMP is of Filgrastim) We are also enclosing the legalized Drug Manufacturing License valid till November 08, 2025. DML No.: ZHE20000009 Issue Date: March 20, 2024 Issuing Authority: Zhejiang Medical Products Administration China.

		(Assesor Remarks: The manufacturing scope mentions semaglutide injection.)
	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.	The firm has stated as follows: This is to bring to your kind information that issuance of COPP is not required by country of origin as we are importing Semaglutide Solution in bulk from M/s Hangzhou Jiuyuan Gene Engineering Co., Ltd China, hence COPP is not applicable. Please note that Registration Board in its 336th meeting dated 04 to 06 June, 2024 has approved the product registration of Semaglutide Injection for M/s BF Biosciences Ltd Lahore and M/s Macter International Limited Karachi with the same justification. (Assesor Remarks:M/s BF Biosciences Ltd Lahore and M/s Macter International Limited Karachi were importing API not concentrate for filling.
	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 drug substance at accelerated and real time conditions. The real time stability data is conducted at 5°C ± 3°C for 6 months, and the accelerated stability data is conducted Under 25°C ± 2°C for 6 months. Batch No: S202303013-2 Batch No: S202303014-2 Batch No: S202303015-2 Production Date: May 04, 2023 **Conclusion** Accelerated 6-month and long-term 9-month sampling surveys have been completed. There is no significant change in the Appearance, Identification, pH, Related substances, HMWPs, Phenol, Bacterial endotoxins, Osmolality, Particulate matter, Sterility, Content & Biological activity and all are within the standard control limits. According to the trend of the samples in the long-term stability test, semaglutide is stable in nature.
	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.	The applicant has submitted agreement between both parties.
	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 by the 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.	Submitted by the 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.	Undertaking has been submitted.
	Pharmaceutical Equivalence	Firm has submitted Pharmaceutical Equivalence with innovator product.
	Analytical method validation/verification of product	Firm has submitted details of analytical method validation.
	Container closure system of the drug product	Semaget Solution for Injection 2mg/1.5mL are available as 1.5ml x 1's in clear glass vial USP-Type I.
	Documents for the procurement of API with approval from DRAP	The applicant has submitted the following documents: • Form 6 (License to import drug). • Commercial invoice. • Goods Declaration.
	Stability study data of drug product, shelf life and storage conditions	718DS01 March 2024 March 2026 718DS02 March 2024 March 2026 718DS03 March 2024 March 2026 Storage Condition: 5°C ± 3°C Shelf Life : 24 months Data Submitted:6 months
	Module IV	In summary, the non-clinical studies of the proposed product was conducted in comparison with the reference product OZEMPIC, including pharmacodynamics (in vitro biological activity, single-dose and repeat-dose studies in db/db mice), pharmacokinetics (single-dose studies in Cynomolgus monkeys at multiple dose levels), and repeat-dose safety evaluation (a repeat-dose toxicity study on Cynomolgus monkeys with a 4-week treatment followed by a 4- week recovery). The studies showed that the proposed product was similar to OZEMPIC without significant differences or safety risks.
	Module V	**<u>Phase I Clinical trials</u>** **Pharmacokinetic Comparison Study Report of Semaglutide Injection** A Single-center, Randomized, Open-label, Single-dose (Fasting), Subcutaneous Administration, Two-preparation, Parallel Pharmacokinetic Comparison Study of Semaglutide Injection and Ozempic® in Healthy Male Chinese Subjects **Conclusion** The PK of semaglutide injection (test preparation) manufactured by Hangzhou Jiuyuan Gene Engineering Co., Ltd. with a strength of 1.34 mg/mL, 1.5 mL (prefilled injection pen) and semaglutide injection (reference preparation) manufactured by Novo Nordisk

		A/S with a strength of 1.34 mg/mL, 1.5 mL (pre-filled injection pen) are similar. Safety data showed that no SAEs occurred in either group, and most AEs were Grade 1 (mild) and resolved, with no AEs leading to withdrawal from the study. This product was safe and well tolerated at the administered dose. **Phase III Clinical Trials** Study Title: A Multi-center, Randomized, Open-Label, Parallel-controlled, Phase III Clinical Study Comparing the Efficacy and Safety of Semaglutide Injection Versus Ozempic® in Combination with Metformin in the Treatment of T2DM **Conclusion** This study adopted a multi-center, randomized, open-label, parallel-controlled clinical equivalence study design. The results have demonstrated that the efficacy of the test drug, semaglutide injection, in combination with metformin for the treatment of T2DM met the criteria for similarity evaluation compared to the control drug, Ozempic®, with similar safety profiles. Furthermore, the results of the population PK model analysis showed that the PK characteristics of semaglutide injection and Ozempic® were similar in patients with T2DM, further supporting the similarity between the test drug and the control drug. In summary, in accordance with the guidelines for biosimilar drug development, we gradually demonstrated the similarity of the study drug semaglutide injection to the control drug Ozempic® in pharmaceutical, non-clinical and clinical studies. These findings supported the application for marketing authorization of semaglutide injection as a biosimilar drug in China, which will provide more treatment options and improve accessibility for patients with T2DM. **Pharmacokinetics** 1) The PopPK models for both T and R drugs were one-compartment models fitting linear absorption and elimination 2) Body weight had effects on the distribution and elimination of T drug, as well as the elimination of R drug. The population (healthy subjects/patients with T2DM) had effects on the distribution of T and R drugs, and the population had effects on the exposure of both drugs within the range of 15%. Both drugs showed a higher exposure for a lower body weight. The exposure was 22–29% lower in the subjects with the body weight at the 95th percentile compared to those with the median body weight, and 18–25% higher in the subjects with the body weight at the 5th percentile compared to those with the median body weight patient. 3) Liver function (baseline total bilirubin, baseline alanine aminotransferase, baseline aspartate aminotransferase, baseline total protein and baseline total bilirubin), renal function (glomerular filtration rate level), anti-drug antibodies, and injection site were found not to have effects on the PK profile of T and R drugs. 4) The 90% CIs for the log-transformed geometric mean ratios (T drug/R drug) for the steadystate exposure (Cmax, ss, Cmin, ss, and AUCtau) fell within the range

of 80.00% to 125.00%, and the PK profile was similar in patients with T2DM between the two drugs.

3 CLINICAL SIMILARITY

3.1 Clinical pharmacology Two clinical pharmacology studies were conducted to support the development of the proposed product, and the PK endpoints and evaluation plan are shown in Table 69. The primary objectives are as follows: Phase I clinical trial: to compare the PK similarity of the proposed product with the reference product OZEMPIC in healthy male subjects subcutaneously given single-dose administration. Phase III clinical trial: to compare the steady-state PK profile (including popPK analysis)

3.2 Efficacy

3.3 Safety

3.4 Immunogenicity

In the clinical trials of this product, a total of 271 subjects were exposed to the test drug, including 33 healthy subjects and 238 patients with type 2 diabetes, and a total of 271 subjects were exposed to the reference drug (OZEMPIC), including 33 healthy subjects and 238 patients with type 2 diabetes. All subjects in the trials were negative in the anti-semaglutide antibody testing.

3.5 Overall assessment of clinical similarity

Single-dose PK study in healthy subjects and popPK model analysis demonstrated similar pharmacokinetic profiles between the proposed product and the reference product (OZEMPIC).

The comparative effectiveness trial in patients with type 2 diabetes demonstrated that the proposed product and the reference product (OZEMPIC) had similar efficacy, comparable safety, and equivalent immunogenicity.

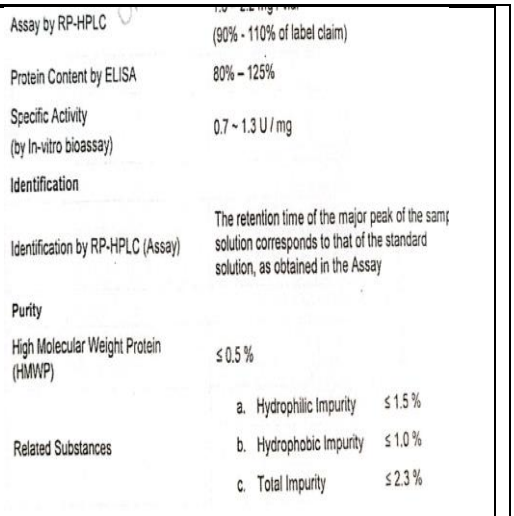
OVERALL ASSESSMENT OF BIOSIMILARITY The comprehensive comparisons of the CMC, non-clinical and clinical studies described above demonstrate that the proposed product is highly similar to the reference product OZEMPIC in CMC, non-clinical and clinical profiles, and could support the application for marketing authorization of this product as a biosimilar.

CTD Section	Requirements	Data Submitted by Bulk Concentrate Manufacturer.
3.2.S.1	Structure 3.2.S.1.2	Chemical structure, , molecular formula & molecular mass, Monoisotopic mass,Conjugation site: fatty acid side chain conjugated at ε-NH_2 terminal of lysine at position 26 of Aib8 ,Arg34GLP-1(7-37)
	General Properties 3.2.S.1.3 (Water content, isoelectric point, pH of a solution of the peptide, optical rotation, biological activity and solubility in different media, hygroscopicity with moisture sorption isotherms)	Appearance, solubility, hygroscopicity, specific optical rotation, molecular weight, Isoelectric point.
Characterisation 3.2.S.3	Elucidation of Structure and other Characteristics 3.2.S.3.1 Sr. No | Tests | Analytical techniques	**Comparative testing with originator brand (Ozempic):** • **Primary Structure** (Molecular mass, Isoelectric Point,

		1. Molecular Mass — MS, LC-MS 2. Amino acid sequence confirmation — LC-MS/MS of intact molecule LC-MS of enzymatically treated material (peptide mapping for long peptides) 3. Secondary structure — Far-UV circular dichroism (CD) spectroscopy FT-IR spectroscopy 4. Tertiary structure — Near UV CD spectroscopy 5. Biological characterisation — Cell-based and other biological assays Physicochemical Characteristics: Solubility and hygroscopicity studies, determination of the isoelectric point (pI) and thermogravimetric studies. Morphology by powder X-ray diffraction (PXRD), differential scanning calorimetry (DSC) and light microscopy	**Amino Acid composition,** N-terminal amino acid sequence,C terminal amino acid sequence, Sequence Coverage, Peptide Map Consistency,Peptide map Peak assignment, Elucidation of fatty acid chain,modification analysis) • **Secondary Structure** (circular dichroism,Fluorescence Spectroscopy • **Biological Profile** (Albumin Affinity, GLP-1 receptor Stimulation of cAMP in cells in vitro Physicochemical Characteristics: Date of three batches submitted for appearance, solubility in various solvents & acid buffer solution, hygroscopicity, specific optical rotation and photosensitivity.
Impurities 3.2.S.3.2	Peptide related impurities: • starting materials; • formation during the manufacturing process; • resulting from degradation during the manufacturing process or during storage. Inorganic impurities	**Process related impurities** Total 32 impurities **Product Related Impurities** High molecular weight proteins Hydrophilic and Hydrophobic Impurities **Residual Solvents** 11 impurities **Elemental** Impurities Mutagenic Impurities
3.2. S.4	Appearance Identification; Amino acid analysis; Purity (total impurities; individual impurities (unspecified/specified); Aggregates / oligomers by SEC-HPLC (if relevant); Assay/content; e.g., by HPLC or elemental analysis; Acetic acid content/counter-ion content (residual) TFA content; pH of solution; **Water content;** Mass balance;	Appearance, Solubility, Identification pH related Substances High Molecular Weight proteins Phenol Propylene Glycol Bacterial Endotoxin Osmolality Particulate Matters Sterility Content Biological Activity

	Residual solvents; 464 Elemental impurities (e.g. in case of use of metal catalyst); Bacterial endotoxins; **Microbiological purity**		

Sr No.	Observations	Firms Response	Assessment of Response
1.	3.2.S.2.3 to 3.2.S.2.6 The data in these sections are required as per DRAP CTD guidance document as NOT APPLICABLE has been mentioned.	Please refer to Annex – 01 for documents related to 3.2.S.2.3 to 3.2.S.2.6.	As it is bulk concentrate and local filling .Therefore, these sections are not addressed as per CTD guidance document by the applicant.
2.	3.2.S.3.1 The analytical techniques required for characterization of primary structure, high level structure and biological profile is required	Please refer to Annex – 02 for analytical techniques required for characterization of primary structure, high level structure and biological profile.	**Analytical Techniques Used in Structural Elucidation Studies** Structure Type / Test Item / Analytical Techniques Primary Structure: Molecular mass — High-resolution mass spectrometry Isoelectric point — Whole column imaging capillary isoelectric focusing electrophoresis Amino acid composition — UPLC N-terminal amino acid sequence — Edman sequencing method / LC-MS/MS C-terminal amino acid sequence — Tandem mass spectrometry Sequence Coverage — Tandem mass spectrometry Peptide map consistency — HPLC Peptide mapping peak assignment — Two-dimensional liquid phase tandem mass spectrometry (2D LC MS/MS) Elucidation of fatty acid chain — Edman sequencing combined with tandem mass spectrometry (LC-MS/MS) Modification analysis — Tandem mass spectrometry High Level Structure: Circular dichroism — Circular dichroism Fluorescence spectroscopy — Fluorescence spectroscopy Biological Profile: Albumin Affinity — Super streptavidin (SSA) biosensors GLP-1 receptor affinity — The specific cells expressing the GLP1 receptor (Tag-lite Glucagon GLP-1 cells, labeled with Terbium) and the Glucagon GLP-1 Receptor red agonist Fluorescent Ligand (shortened to red agonist) are adopted in the test Stimulation of cAMP in cells in vitro — HEK293/CRE-Luc/GLP1R reporter gene method
3.	3.2.S.4.3 The drug concentrate analytical method report of assay conducted by drug substance manufacturer is required.	Please refer to Annex – 03 for drug concentrate analytical method validation report of assay conducted by drug substance manufacturer.	The method validation was carried out based on the range of API concentrations i.e.,0.68mg/ml to 3.2mg/ml.

4.	3.2.S.4.4 The results of multiple batches of the drug product, methodology studies as well as stability data for establishing limits of specifications specifically for related substances and High Molecular weight proteins need to be submitted for justification of relaxed specifications. HMWP: NMT 1.5% Hydrophilic impurities ≤ 4.5% Hydrophobic impurities 1 ≤ 4.0% Hydrophobic impurities 2 ≤ 1.1% Total impurities ≤ 8.1%	Please note that the specifications of Related Substances and HMWP were established based on the detailed characterization of the Originator product. Accelerated stability studies were conducted on the Originator Product (RLD) to assess the extent and the quantum of degradation. Please refer to Annex – 04 for Justification of setting of specifications of Related Substances and HMWP.	
5.	3.2.S.5 The COA of reference standard is required.	Please refer to Annex – 05 for the COA of reference standard.	COA of primary reference standard has been submitted by the applicant.
6.	3.2.S.7.3 The batch size and volume of the glass container along with fill volume is required. Submit stability data of bulk concentrate till claimed shelf life as provided data is of only 9 months.	Please refer to Annex – 06 for updated Stability Study data completed till 18 months along with details of batch size and volume of glass container. Further, we are also submitting Stability Study data till claimed shelf life.	Stability data till 24 months at 2-8C has been submitted by the applicant.

7.	3.2.P.3.5 Description, documentation, and results of the validation and/or evaluation studies should be provided for critical steps or critical assays used in the manufacturing process (e.g., validation of the sterilization process or aseptic processing or filling). Viral safety evaluation should be provided in 3.2.A.2.	This is to inform you that we have manufactured 03 stability batches, during manufacturing of stability batches all the critical process parameters and sterilization of aseptic processes were evaluated and found according to predetermined specifications. Please refer to Annex – 07 for Preliminary Process Validation Report conducted on stability batches and commitment to perform detailed process validation on 1st 03 commercial batches.	Preliminary Process Validation Report conducted on stability batches and commitment to perform detailed process validation on 1st 03 commercial batches has been submitted by the applicant.
8.	3.2.P.4 Data relevant to Control of Excipients is not submitted. Justification is required.	Please refer to Annex – 08 for Control of Excipients.	Applicant has submitted Test methods of excipients in this section.
9.	3.2.P.5.3 The analytical method validation studies of only assay has been provided. Justification is required.	This is to inform you that detailed analytical method validation studies of High Molecular Weight Proteins, Related Substances and Phenol has been performed by M/s Hangzhou Jiuyuan Gene Engineering Co., Ltd China and we are using same methods for testing of our product. Please refer to Annex – 09 for analytical method validation studies conducted by M/s Hangzhou Jiuyuan Gene Engineering Co., Ltd China.	High Molecular Weight Proteins, Related Substances and Phenol has been performed by M/s Hangzhou Jiuyuan Gene Engineering Co., Ltd China.
10.	3.2.P.8.3 Documents for the procurement of API with approval from DRAP.	Please refer to Annex – 10 for procurement documents of Semaglutide Solution with approval from DRAP.	The applicant has submitted the following documents: • Form 6 (License to import drug). • Commercial invoice. • Goods Declaration.
11.	3.2.A.2, 3.2.A.3 Submit justification for NA.	Please refer to Annex – 11 for 3.2.A.2 & 3.2.A.3.	BSE and TSE declaration has been submitted by the applicant. No novel excipient is used in the formulation.

	12.	3.2.R.3 Submit product interchangeability report	Please refer to Annex – 12 for product interchangeability report.	A full quality comparison study on multiple batches of JY29-2 concentrate and reference product OZEMPIC was conducted from the aspects of properties of drug product, product related impurities and process-related impurities to evaluate the quality similarity between the proposed product and the reference product. - Properties of drug product: The proposed product was similar to the reference product in pH, phenol, propylene glycol,osmolality, content and biological activity. The dose accuracy of the proposed product complied with the acceptance criteria. It was proved that the proposed product is similar to the reference product in properties of drug product. - Product-related impurities: Through the comparisons of related substances and high molecular weight proteins, it was demonstrated that the proposed product is similar to the reference product in product-related impurities. Non clinical and Clinical similarity studies also submitted.	

13.	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.	Please note that M/s Hangzhou Jiuyuan Gene Engineering Co., Ltd China has **EUDRA GMP Certificate** for their site. Certificate #: DE_HH_01_GMP_2019_0020 Validity: 31 December 2024 Issuing Authority: Freie und Hansestadt Hamburg, Ministry of Health and Consumer Protection. We are also enclosing the legalized Drug Manufacturing License valid till November 08, 2025. DML No.: ZHE20000009 Issue Date: March 20, 2024 Issuing Authority: Zhejiang Medical Products Administration China. Please refer to Annex – 13 for copy of EUDRA GMP Certificate and copy of legalized DML.	The Eudra GMP mentions No 23 in the manufacturing site address and is for Filgrastim. Legalized DML valid upto 8 November 2025 provided by the applicant which specifies semaglutide injection in its scope.

14.	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.	This is to bring to your kind information that issuance of COPP is not required by country of origin as we are importing Semaglutide Solution in bulk from M/s Hangzhou Jiuyuan Gene Engineering Co., Ltd China, hence COPP is not applicable. Please note that Registration Board in its 336th meeting dated 04 to 06 June, 2024 has approved the product registration of Semaglutide Injection for M/s BF Biosciences Ltd Lahore and M/s Macter International Limited Karachi with the same justification.	M/s BF Biosciences Ltd Lahore and M/s Macter International Limited Karachi are importing API not bulk from country of origin.
15.	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	-
16.	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 Biological shall be strictly adhered to.	Please refer to Annex – 14 for Undertaking.	Submitted.

Proceedings of the Registeration Board:

Keeping in view the previous approvals granted to semaglutide injection in M-336 of Registration Board meeting and on the basis of already well established principles for subsequent registrations, the Board decided to approve the formulation.

The Board was further apprised with the following facts for deliberation and final decision:

- **The applicant has not submitted CoPP either from country of origin or by any RRA as an evidence that the final product has been manufactured by same concentrate, as per guidelines of 278th Registration Board for bulk concentrate and local filling. Furthermore, it was discussed regarding the previously approved cases of M/s Macter and M/s BF Sciences which were importing only API but not bulk concentrate from the exporting country. The Board was already acquainted with the fact that currently semaglutide drugs are covered under the patent rules in China, that's why these generic products cannot be registered in NMPA (National Medical Product Administration) China, till the expiry of patent and therefore, COPP cannot be issued by the certifying authority.**

- **The applicant as an evidence that the manufacturer of bulk concentrate is an authorized manufacturer of biological drug in the country of origin has submitted valid DML stating semaglutide injection in its manufacturing scope.**
- **The product interchangeability with innovator has been established based on the quality, safety and efficacy comparison of "bulk concentrate with reference product OZEMPIC" from the aspects of properties of drug product, product related impurities, process-related impurities, nonclinical and clinical similarity studies.**
- **The specifications set for HMWP and impurities are not stringent. The Board emphasized that applicant should adhere to the innovator's Specification.**

Decision of 343rd Meeting: Registration Board decided to approve Semaget 2mg/1.5ml "as per innovator's Specification" subject to Product Specific Inspection (PSI) by the below mentioned panel:

1.Mr. Syed Adnan Rizvi, Member Registration Board /Director Drug Testing Laboratory, Karachi.

2. Mr. Sajjad Ahmed Abbassi, Deputy Director, CDL, DRAP, Karachi.

Additionally, after registration the applicant is responsible to perform and submit the following:

i. **Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.**
ii. **Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.**
iii. **PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. (Timeline may be discussed with Reg Board)**

9.	Name, address of Applicant / Importer	M/s Getz Pharma (Pvt) Limited Company Address: 29-30/27,Korangi Industrial Area, Karachi
	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 Getz Pharma (Pvt.) Limited Address: Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi – 74900, Pakistan
	GMP of manufacturer & Evidence of Section	DML No. 000284 On October 05, 2012, Central Licensing Division of DRAP has granted section approval of Biotech Facility. This area is currently used for the manufacturing of Human Insulin and Insulin Analogue. Now, Regularization of layout plan for Liquid Injectable vial and Cartridges.(Biotech rDNA)
	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 Import of Bulk Concentrate, Local Manufacturing
	Dy. No. and Date of submission	Tracking ID: GGD-QLV-3EG8 Application Number: 54057 Date of Receiving: 29-11-2024
	Details of fee submitted	Challan Number: 7509710942 Division: Biological Evaluation & Registration Paid Fee: 37000.0 Paid Date: 2024-09-26 Fee Head: Drug for local manufacture Challan Number :412992834 Drug for local manufacture :263000.0 Paid Date: 2024-10-25

	The proposed proprietary name / brand name	**Semaget Solution for Injection 4mg/3mL**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each mL contains: Semaglutide…… 1.34mg
	Pharmaceutical form of applied drug	Solution for Injection in vial
	Pharmacotherapeutic Group of (API)	Glucagon-like peptide-1 (GLP-1) analogues ATC Code: A10BJ06
	Reference to Finished product specifications	As per Innovator's Specifications
	Proposed Pack size	1's Vial
	Proposed unit price	As per SRO 228(I)/2024 dated 19-02-2024
	Shelf Life	24 Months
	Storage Condition	Store in a refrigerator (2 -8 °C), Do not freeze. Protect from heat and light.
	The status in reference regulatory authorities	OZEMPIC (semaglutide) solution for injection 4 mg/3 ml (USFDA APPROVED)
	For generic drugs (me-too status)	Seglutide Injection 4mg/3ml 120536
	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	M/s Hangzhou Jiuyuan Gene Engineering Co., Ltd Manufacturing Site and Manufacturing Scope: East of No. 8th Street, Hangzhou Economic and Technological Development Zone: Freeze-dried powder for injection, drug substance, small volume parenteral solution (containing antineoplastic drug), therapeutically biological product.
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, physical form, manufacturers, impurities, specifications, analytical procedures and its validation, batch analysis an justification of specification, reference standard, container closure system and stability studies of drug substance concentrate. Firm has submitted assay method validation report by drug product manufacturer **Stability Studies data** Accelerated 6-month and long-term 9-month sampling surveys have been completed. There is no significant change in the Appearance, Identification, pH, Related substances, HMWPs, Phenol, Bacterial endotoxins, Osmolality, Particulate matter, Sterility, Content & Biological activity and all are within the standard control limits. According to the trend of the samples in the long-term stability test, semaglutide is stable in nature.
	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 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.	The firm has stated as follows: Please note that M/s Hangzhou Jiuyuan Gene Engineering Co., Ltd China has EUDRA GMP Certificate for their site. Certificate #: DE_HH_01_GMP_2019_0020 Validity: 31 December 2024 Issuing Authority: Freie und Hansestadt Hamburg, Ministry of Health and Consumer Protection. (Assesor Remarks: This GMP is of Filgrastim) We are also enclosing the legalized Drug Manufacturing License valid till November 08, 2025. DML No.: ZHE20000009 Issue Date: March 20, 2024 Issuing Authority: Zhejiang Medical Products Administration China. (Assesor Remarks: The manufacturing scope mentions semaglutide injection.)
	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.	The firm has stated as follows: This is to bring to your kind information that issuance of COPP is not required by country of origin as we are importing Semaglutide Solution in bulk from M/s Hangzhou Jiuyuan Gene Engineering Co., Ltd China, hence COPP is not applicable. Please note that Registration Board in its 336th meeting dated 04 to 06 June, 2024 has approved the product registration of Semaglutide Injection for M/s BF Biosciences Ltd Lahore and M/s Macter International Limited Karachi with the same justification. (Assesor Remarks:M/s BF Biosciences Ltd Lahore and M/s Macter International Limited Karachi were importing API not concentrate for filling.
	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 drug substance at accelerated and real time conditions. The real time stability data is conducted at 5°C ± 3°C for 6 months, and the accelerated stability data is conducted Under 25°C ± 2°C for 6 months. Batch No: S202303013-2 Batch No: S202303014-2 Batch No: S202303015-2 Production Date: May 04, 2023 **Conclusion** Accelerated 6-month and long-term 9-month sampling surveys have been completed. There is no significant change in the Appearance, Identification, pH, Related

		substances, HMWPs, Phenol, Bacterial endotoxins, Osmolality, Particulate matter, Sterility, Content & Biological activity and all are within the standard control limits. According to the trend of the samples in the long-term stability test, semaglutide is stable in nature.
	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.	The applicant has submitted agreement between both parties.
	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 by the 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.	Submitted by the 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.	Undertaking has been submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence with innovator product.
	Analytical method validation/verification of product	Firm has submitted details of analytical method validation.
	Container closure system of the drug product	Semaget Solution for Injection 4mg/3mL are available as 3ml x 1's in clear glass vial USP-Type I.
	Documents for the procurement of API with approval from DRAP	The applicant has submitted the following documents: • Form 6 (License to import drug). • Commercial invoice. • Goods Declaration.
	Stability study data of drug product, shelf life and storage conditions	719DS01 March 2024 March 2026 719DS02 March 2024 March 2026 719DS03 March 2024 March 2026 Storage Condition: 5°C ± 3°C Shelf Life : 24 months Data Submitted:6 months
	Module IV	In summary, the non-clinical studies of the proposed product was conducted in comparison with the reference

		product OZEMPIC, including pharmacodynamics (in vitro biological activity, single-dose and repeat-dose studies in db/db mice), pharmacokinetics (single-dose studies in Cynomolgus monkeys at multiple dose levels), and repeat-dose safety evaluation (a repeat-dose toxicity study on Cynomolgus monkeys with a 4-week treatment followed by a 4- week recovery). The studies showed that the proposed product was similar to OZEMPIC without significant differences or safety risks.
	Module V	**<u>Phase I Clinical trials</u>** **Pharmacokinetic Comparison Study Report of Semaglutide Injection** A Single-center, Randomized, Open-label, Single-dose (Fasting), Subcutaneous Administration, Two-preparation, Parallel Pharmacokinetic Comparison Study of Semaglutide Injection and Ozempic® in Healthy Male Chinese Subjects **Conclusion** The PK of semaglutide injection (test preparation) manufactured by Hangzhou Jiuyuan Gene Engineering Co., Ltd. with a strength of 1.34 mg/mL, 1.5 mL (prefilled injection pen) and semaglutide injection (reference preparation) manufactured by Novo Nordisk A/S with a strength of 1.34 mg/mL, 1.5 mL (pre-filled injection pen) are similar. Safety data showed that no SAEs occurred in either group, and most AEs were Grade 1 (mild) and resolved, with no AEs leading to withdrawal from the study. This product was safe and well tolerated at the administered dose. **<u>Phase III Clinical Trials</u>** Study Title: A Multi-center, Randomized, Open-Label, Parallel-controlled, Phase III Clinical Study Comparing the Efficacy and Safety of Semaglutide Injection Versus Ozempic® in Combination with Metformin in the Treatment of T2DM **Conclusion** This study adopted a multi-center, randomized, open-label, parallel-controlled clinical equivalence study design. The results have demonstrated that the efficacy of the test drug, semaglutide injection, in combination with metformin for the treatment of T2DM met the criteria for similarity evaluation compared to the control drug, Ozempic®, with similar safety profiles. Furthermore, the results of the population PK model analysis showed that the PK characteristics of semaglutide injection and Ozempic® were similar in patients with T2DM, further supporting the similarity between the test drug and the control drug. In summary, in accordance with the guidelines for biosimilar drug development, we gradually demonstrated the similarity of the study drug semaglutide injection to the control drug Ozempic® in pharmaceutical, non-clinical and clinical studies. These findings supported the application for marketing authorization of semaglutide injection as a biosimilar drug in China, which will provide more treatment options and improve accessibility for patients with T2DM. **Pharmacokinetics**

		1) The PopPK models for both T and R drugs were one-compartment models fitting linear absorption and elimination 2) Body weight had effects on the distribution and elimination of T drug, as well as the elimination of R drug. The population (healthy subjects/patients with T2DM) had effects on the distribution of T and R drugs, and the population had effects on the exposure of both drugs within the range of 15%. Both drugs showed a higher exposure for a lower body weight. The exposure was 22–29% lower in the subjects with the body weight at the 95th percentile compared to those with the median body weight, and 18–25% higher in the subjects with the body weight at the 5th percentile compared to those with the median body weight patient. 3) Liver function (baseline total bilirubin, baseline alanine aminotransferase, baseline aspartate aminotransferase, baseline total protein and baseline total bilirubin), renal function (glomerular filtration rate level), anti-drug antibodies, and injection site were found not to have effects on the PK profile of T and R drugs. 4) The 90% CIs for the log-transformed geometric mean ratios (T drug/R drug) for the steadystate exposure (Cmax, ss, Cmin, ss, and AUCtau) fell within the range of 80.00% to 125.00%, and the PK profile was similar in patients with T2DM between the two drugs. **3 CLINICAL SIMILARITY** **3.1 Clinical pharmacology** Two clinical pharmacology studies were conducted to support the development of the proposed product, and the PK endpoints and evaluation plan are shown in Table 69. The primary objectives are as follows: Phase I clinical trial: to compare the PK similarity of the proposed product with the reference product OZEMPIC in healthy male subjects subcutaneously given single-dose administration. Phase III clinical trial: to compare the steady-state PK profile (including popPK analysis) **3.2 Efficacy** **3.3 Safety** **3.4 Immunogenicity** In the clinical trials of this product, a total of 271 subjects were exposed to the test drug, including 33 healthy subjects and 238 patients with type 2 diabetes, and a total of 271 subjects were exposed to the reference drug (OZEMPIC), including 33 healthy subjects and 238 patients with type 2 diabetes. All subjects in the trials were negative in the anti-semaglutide antibody testing. **3.5 Overall assessment of clinical similarity** Single-dose PK study in healthy subjects and popPK model analysis demonstrated similar pharmacokinetic profiles between the proposed product and the reference product (OZEMPIC). The comparative effectiveness trial in patients with type 2 diabetes demonstrated that the proposed product and the reference product (OZEMPIC) had similar efficacy, comparable safety, and equivalent immunogenicity. *OVERALL ASSESSMENT OF SIMILARITY The comprehensive comparisons of the CMC, non-clinical and clinical studies described above demonstrate that*

		the proposed product is highly similar to the reference product OZEMPIC in CMC, non-clinical and clinical profiles, and could support the application for marketing authorization of this product as a biosimilar.

Remarks of Deputy Director IV

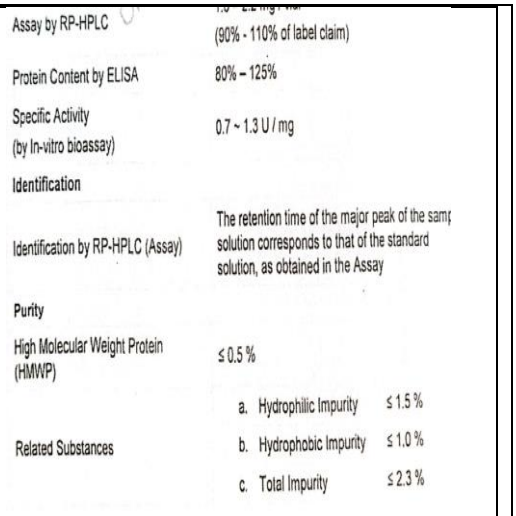
<table>
<tr><th>CTD Section</th><th>Requirements</th><th>Data Submitted by Bulk Concentrate Manufacturer.</th></tr>
<tr><td>3.2.S.1</td><td>Structure 3.2.S.1.2</td><td>Chemical structure, , molecular formula & molecular mass, Monoisotopic mass,Conjugation site: fatty acid side chain conjugated at ε-NH2 terminal of lysine at position 26 of Aib8 ,Arg34GLP-1(7-37)</td></tr>
<tr><td></td><td>General Properties 3.2.S.1.3
(Water content, isoelectric point, pH of a solution of the peptide, optical rotation, biological activity and solubility in different media, hygroscopicity with moisture sorption isotherms)</td><td>Appearance, solubility, hygroscopicity, specific optical rotation, molecular weight, Isoelectric point.</td></tr>
<tr><td>Characterisation 3.2.S.3</td><td>Elucidation of Structure and other Characteristics 3.2.S.3.1
<table>
<tr><th>Sr. No</th><th>Tests</th><th>Analytical techniques</th></tr>
<tr><td>6.</td><td>Molecular Mass</td><td>MS, LC-MS</td></tr>
<tr><td>7.</td><td>Amino acid sequence confirmation</td><td>LC-MS/MS of intact molecule
LC-MS of enzymatically treated material (peptide mapping for long peptides)</td></tr>
<tr><td>8.</td><td>Secondary structure</td><td>Far-UV circular dichroism (CD) spectroscopy
FT-IR spectroscopy</td></tr>
<tr><td>9.</td><td>Tertiary structure</td><td>Near UV CD spectroscopy</td></tr>
<tr><td>10.</td><td>Biological characterisation</td><td>Cell-based and other biological assays</td></tr>
</table>
<u>Physicochemical Characteristics:</u>
Solubility and hygroscopicity studies, determination of the isoelectric point (pI) and thermogravimetric studies. Morphology by powder X-ray</td><td>Comparative testing with originator brand (Ozempic):
• Primary Structure
(Molecular mass,
Isoelectric Point,
Amino Acid composition,
N-terminal amino acid sequence,C terminal amino acid sequence, Sequence Coverage, Peptide Map Consistency,Peptide map Peak assignment, Elucidation of fatty acid chain,modification analysis)
• Secondary Structure
(circular dichroism,Fluorescence Spectroscopy
• Biological Profile
(Albumin Affinity,
GLP-1 receptor
Stimulation of cAMP in cells in vitro

<u>Physicochemical Characteristics:</u>
Date of three batches submitted for appearance, solubility in various solvents & acid buffer solution, hygroscopicity,</td></tr>
</table>

	diffraction (PXRD), differential scanning calorimetry (DSC) and light microscopy	specific optical rotation and photosensitivity.
Impurities 3.2.S.3.2	Peptide related impurities: • starting materials; • formation during the manufacturing process; • resulting from degradation during the manufacturing process or during storage. Inorganic impurities	**Process related impurities** Total 32 impurities **Product Related Impurities** High molecular weight proteins Hydrophilic and Hydrophobic Impurities **Residual Solvents** 11 impurities **Elemental** Impurities Mutagenic Impurities
3.2. S.4	Appearance Identification; Amino acid analysis; Purity (total impurities; individual impurities (unspecified/specified); Aggregates / oligomers by SEC-HPLC (if relevant); Assay/content; e.g., by HPLC or elemental analysis; Acetic acid content/counter-ion content (residual) TFA content; pH of solution; **Water content;** Mass balance; **Residual solvents; 464** Elemental impurities (e.g. in case of use of metal catalyst); Bacterial endotoxins; **Microbiological purity**	Appearance, Solubility, Identification pH related Substances High Molecular Weight proteins Phenol Propylene Glycol Bacterial Endotoxin Osmolality Particulate Matters Sterility Content Biological Activity

Sr No.	Observations	Firms Response	Assessment of Response
1.	3.2.S.2.3 to 3.2.S.2.6 The data in these sections are required as per DRAP CTD guidance document as NOT APPLICABLE has been mentioned.	Please refer to Annex – 01 for documents related to 3.2.S.2.3 to 3.2.S.2.6.	As it is bulk concentrate and local filling .Therefore, these sections are not addressed as per CTD guidance document by the applicant.

<table>
<tr>
<td>2.</td>
<td>3.2.S.3.1
The analytical techniques required for characterization of primary structure, high level structure and biological profile is required</td>
<td>Please refer to Annex – 02 for analytical techniques required for characterization of primary structure, high level structure and biological profile.</td>
<td>
Analytical Techniques Used in Structural Elucidation Studies
<table>
<tr><th>Structure Type</th><th>Test Item</th><th>Analytical Techniques</th></tr>
<tr><td rowspan="9">Primary Structure</td><td>Molecular mass</td><td>High-resolution mass spectrometry</td></tr>
<tr><td>Isoelectric point</td><td>Whole column imaging capillary isoelectric focusing electrophoresis</td></tr>
<tr><td>Amino acid composition</td><td>UPLC</td></tr>
<tr><td>N-terminal amino acid sequence</td><td>Edman sequencing method / LC-MS/MS</td></tr>
<tr><td>C-terminal amino acid sequence</td><td>Tandem mass spectrometry</td></tr>
<tr><td>Sequence Coverage</td><td>Tandem mass spectrometry</td></tr>
<tr><td>Peptide map consistency</td><td>HPLC</td></tr>
<tr><td>Peptide mapping peak assignment</td><td>Two-dimensional liquid phase tandem mass spectrometry (2D LC MS/MS)</td></tr>
<tr><td>Elucidation of fatty acid chain</td><td>Edman sequencing combined with tandem mass spectrometry (LC-MS/MS)</td></tr>
<tr><td>Modification analysis</td><td>Tandem mass spectrometry</td></tr>
<tr><td rowspan="2">High Level Structure</td><td>Circular dichroism</td><td>Circular dichroism</td></tr>
<tr><td>Fluorescence spectroscopy</td><td>Fluorescence spectroscopy</td></tr>
<tr><td rowspan="3">Biological Profile</td><td>Albumin Affinity</td><td>Super streptavidin (SSA) biosensors</td></tr>
<tr><td>GLP-1 receptor affinity</td><td>The specific cells expressing the GLP1 receptor (Tag-lite Glucagon GLP-1 cells, labeled with Terbium) and the Glucagon GLP-1 Receptor red agonist Fluorescent Ligand (shortened to red agonist) are adopted in the test</td></tr>
<tr><td>Stimulation of cAMP in cells in vitro</td><td>HEK293/CRE-Luc/GLP1R reporter gene method</td></tr>
</table>
</td>
</tr>
<tr>
<td>3.</td>
<td>3.2.S.4.3
The drug concentrate analytical method report of assay conducted by drug substance manufacturer is required.</td>
<td>Please refer to Annex – 03 for drug concentrate analytical method validation report of assay conducted by drug substance manufacturer.</td>
<td>The method validation was carried out based on the range of API concentrations i.e.,0.68mg/ml to 3.2mg/ml.</td>
</tr>
</table>

4.	3.2.S.4.4 The results of multiple batches of the drug product, methodology studies as well as stability data for establishing limits of specifications specifically for related substances and High Molecular weight proteins need to be submitted for justification of relaxed specifications. HMWP: NMT 1.5% Hydrophilic impurities ≤ 4.5% Hydrophobic impurities 1 ≤ 4.0% Hydrophobic impurities 2 ≤ 1.1% Total impurities ≤ 8.1%	Please note that the specifications of Related Substances and HMWP were established based on the detailed characterization of the Originator product. Accelerated stability studies were conducted on the Originator Product (RLD) to assess the extent and the quantum of degradation. Please refer to Annex – 04 for Justification of setting of specifications of Related Substances and HMWP.	 Assay by RP-HPLC (90% - 110% of label claim) Protein Content by ELISA 80% – 125% Specific Activity (by In-vitro bioassay) 0.7 - 1.3 U / mg Identification Identification by RP-HPLC (Assay) The retention time of the major peak of the samp solution corresponds to that of the standard solution, as obtained in the Assay Purity High Molecular Weight Protein (HMWP) ≤ 0.5 % Related Substances a. Hydrophilic Impurity ≤ 1.5 % b. Hydrophobic Impurity ≤ 1.0 % c. Total Impurity ≤ 2.3 %
5.	3.2.S.5 The COA of reference standard is required.	Please refer to Annex – 05 for the COA of reference standard.	COA of primary reference standard has been submitted by the applicant.
6.	3.2.S.7.3 The batch size and volume of the glass container along with fill volume is required. Submit stability data of bulk concentrate till claimed shelf life as provided data is of only 9 months.	Please refer to Annex – 06 for updated Stability Study data completed till 18 months along with details of batch size and volume of glass container. Further, we are also submitting Stability Study data till claimed shelf life.	Stability data till 24 months at 2-8C has been submitted by the applicant.

7.	3.2.P.3.5 Description, documentation, and results of the validation and/or evaluation studies should be provided for critical steps or critical assays used in the manufacturing process (e.g., validation of the sterilization process or aseptic processing or filling). Viral safety evaluation should be provided in 3.2.A.2.	This is to inform you that we have manufactured 03 stability batches, during manufacturing of stability batches all the critical process parameters and sterilization of aseptic processes were evaluated and found according to predetermined specifications. Please refer to Annex – 07 for Preliminary Process Validation Report conducted on stability batches and commitment to perform detailed process validation on 1st 03 commercial batches.	Preliminary Process Validation Report conducted on stability batches and commitment to perform detailed process validation on 1st 03 commercial batches has been submitted by the applicant.
8.	3.2.P.4 Data relevant to Control of Excipients is not submitted. Justification is required.	Please refer to Annex – 08 for Control of Excipients.	Applicant has submitted Test methods of excipients in this section.
9.	3.2.P.5.3 The analytical method validation studies of only assay has been provided. Justification is required.	This is to inform you that detailed analytical method validation studies of High Molecular Weight Proteins, Related Substances and Phenol has been performed by M/s Hangzhou Jiuyuan Gene Engineering Co., Ltd China and we are using same methods for testing of our product. Please refer to Annex – 09 for analytical method validation studies conducted by M/s Hangzhou Jiuyuan Gene Engineering Co., Ltd China.	High Molecular Weight Proteins, Related Substances and Phenol has been performed by M/s Hangzhou Jiuyuan Gene Engineering Co., Ltd China.
10.	3.2.P.8.3 Documents for the procurement of API with approval from DRAP.	Please refer to Annex – 10 for procurement documents of Semaglutide Solution with approval from DRAP.	The applicant has submitted the following documents: • Form 6 (License to import drug). • Commercial invoice. • Goods Declaration.
11.	3.2.A.2, 3.2.A.3 Submit justification for NA.	Please refer to Annex – 11 for 3.2.A.2 & 3.2.A.3.	BSE and TSE declaration has been submitted by the applicant. No novel excipient is used in the formulation.

	12.	3.2.R.3 Submit product interchangeability report	Please refer to Annex – 12 for product interchangeability report	A full quality comparison study on multiple batches of JY29-2 concentrate and reference product OZEMPIC was conducted from the aspects of properties of drug product, product related impurities and process-related impurities to evaluate the quality similarity between the proposed product and the reference product. - Properties of drug product: The proposed product was similar to the reference product in pH, phenol, propylene glycol,osmolality, content and biological activity. The dose accuracy of the proposed product complied with the acceptance criteria. It was proved that the proposed product is similar to the reference product in properties of drug product. - Product-related impurities: Through the comparisons of related substances and high molecular weight proteins, it was demonstrated that the proposed product is similar to the reference product in product-related impurities. Non clinical and Clinical similarity studies also submitted.

13.	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.	Please note that M/s Hangzhou Jiuyuan Gene Engineering Co., Ltd China has **EUDRA GMP Certificate** for their site. Certificate #: DE_HH_01_GMP_2019_0020 Validity: 31 December 2024 Issuing Authority: Freie und Hansestadt Hamburg, Ministry of Health and Consumer Protection. We are also enclosing the legalized Drug Manufacturing License valid till November 08, 2025. DML No.: ZHE20000009 Issue Date: March 20, 2024 Issuing Authority: Zhejiang Medical Products Administration China. Please refer to Annex – 13 for copy of EUDRA GMP Certificate and copy of legalized DML.	The Eudra GMP mentions No 23 in the manufacturing site address and is for Filgrastim. Legalized DML valid upto 8 November 2025 provided by the applicant which specifies semaglutide injection in its scope.

14.	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.	This is to bring to your kind information that issuance of COPP is not required by country of origin as we are importing Semaglutide Solution in bulk from M/s Hangzhou Jiuyuan Gene Engineering Co., Ltd China, hence COPP is not applicable. Please note that Registration Board in its 336th meeting dated 04 to 06 June, 2024 has approved the product registration of Semaglutide Injection for M/s BF Biosciences Ltd Lahore and M/s Macter International Limited Karachi with the same justification.	M/s BF Biosciences Ltd Lahore and M/s Macter International Limited Karachi are importing API not bulk from country of origin.
15.	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	-
16.	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 Biological shall be strictly adhered to.	Please refer to Annex – 14 for Undertaking.	Submitted.

Proceedings of the Registeration Board:

Keeping in view the previous approvals granted to semaglutide injection in M-336 of Registration Board meeting and on the basis of already well established principles for subsequent registerations, the Board in the best of public interest decided to approved the formulation.

The Board was further apprised with the following facts for deliberation and final decision:

- **The applicant has not submitted CoPP either from country of origin or by any RRA as an evidence that the final product has been manufactured by same concentrate, as per guidelines of 278th Registration Board for bulk concentrate and local filling. Furthermore, it was discussed regarding the previously approved cases of M/s Macter and M/s BF Sciences which were importing only API but not bulk concentrate from the exporting country. The Board was already acquainted with the fact that currently semaglutide drugs are covered under the patent rules in China, that's why these generic products cannot be registered in NMPA (National Medical Product Administration) China, till the expiry of patent and therefore, COPP cannot be issued by the certifying authority.**

- **The applicant as an evidence that the manufacturer of bulk concentrate is an authorized manufacturer of biological drug in the country of origin has submitted valid DML stating semaglutide injection in its manufacturing scope.**
- **The product interchangeability with innovator has been established based on the quality, safety and efficacy comparison of "bulk concentrate with reference product OZEMPIC" from the aspects of properties of drug product, product related impurities, process-related impurities, nonclinical and clinical similarity studies.**

The specifications set for HMWP and impurities are not stringent. The Board emphasized that applicant should adhere to the innovator's Specification.

Decision of 343rd Meeting: Registration Board decided to approve Semaget 2mg/1.5ml "as per innovator's Specification" subject to Product Specific Inspection (PSI) by the below mentioned panel:

1. Mr. Syed Adnan Rizvi, Member Registration Board /Director Drug Testing Laboratory, Karachi.

2. Mr. Sajjad Ahmed Abbassi, Deputy Director, CDL, DRAP, Karachi.

Additionally, after registration the applicant is responsible to perform and submit the following:

iv. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

v. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.

i. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. (Timeline may be discussed with Reg Board)

Item No 03: Deferred Cases of Imported Human Products

10.	Name, address of Applicant / Importer	**M/s Ghazi Brothers.** Address: Ghazi House, D-35, KDA Scheme No, 1 Miran Muhammad Shah Road, Karachi 75350, Pakistan.
	Details of Drug Sale License of importer	**Drug License by Way of Wholesale** DSL No: 0358 Address: D-35, KDA Scheme No, 1 Miran Muhammad Shah Road, Karachi Address of go-down: • B-32, Al-Hilal Society, KDA Scheme No. 7, 335/15, Allahwala Town ,Korangi,Karachi • A-09,NWIZ Bin Qasim,Karachi. Validity: 29-06-2028
	Name and address of marketing authorization holder (abroad)	**Huons BioPharma Co., Ltd.** Address: 50 Bio valley 2-ro, Jecheon-si, Chungcheongbuk-do, Republic of Korea
	Name, address of manufacturer(s)	**Huons BioPharma Co., Ltd.** Address: 50 Bio valley 2-ro, Jecheon-si, Chungcheongbuk-do, Republic of Korea
	Name of exporting country	Republic of Korea
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**Original Legalized CoPP** No. 2021-A1-0401 dated 06-05-2021 issued by Ministry of Food and Drug Safety, Republic of Korea.
	Details of letter of authorization / sole agency agreement	Original Power of attorney issued dated 01-August-2022 valid till 01-August-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** ☐ Bulk import and local repackaging ☐ Bulk import and local repackaging for export purpose only
	Dy. No. and date of submission	Dy. No: 33029 Dated: 17-11-2022
	Details of fee submitted	Deposit Slip # 408632679382 of Rs.150,000/- (One lac fifty thousand rupees only) Dated 10-Dec-2022
	The proposed proprietary name / brand name	HUTOX Injection 100 Units
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Clostridium botulinum toxin Type A……..100 units.
	Dosage form of applied drug	Lyophilized powder for injection
	Pharmacotherapeutic Group of (API)	Pharmacological Class of API: Muscle-Relaxant peripherally acting agent ATC Class: M03A X01
	Finished product specifications	Ph. Eur. Specifications
	Proposed Pack size	100 Unit vial
	Proposed unit price	As per SRO.
	Shelf Life	24 months(Data is of 18months)
	Storage Conditions	2°C-8°C
	The status in reference regulatory authorities	Reference Regulatory Authority: US-FDA Botox Cosmetics 100 Units/Vial of M/s ALLERGAN **Biologic License Application (BLA)**: 103000 Approved with Box warning.
	For generic drugs (me-too status)	Brand name: Botox Injection Manufacturer/Registration holder: Barrett Hodgson Pakistan (Private) Limited (Reg # 018959)
	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, manufacturers, Characterization, 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, description and composition, pharmaceutical development.
	Name, address of drug substance manufacturer	**M/S. Huons BioPharma Co., Ltd. (Section A/B)** Address: 50 Bio valley-2ro, Jecheon-si, Chungcheongbuk-do, Republic of Korea [27159]
	Module-III Drug Substance:	Firm has submitted detailed drug substance data related to nomenclature, structure, general properties, manufacturers, description of manufacturing process and controls, material, intermediate, critical steps control, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance (Clostridium botulinum toxin type A.

	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	The long-term stability studies of drug substances (3 lots) are completed up to 24 months under the influence of temperature in the proposed storage condition (≤ - 70°C). The accelerated stability study of drug substance (3 lots) is completed up to 6 months under the influence of temperature (5 ± 3°C). **Evaluation** **12 months stability data provided.**
	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 data from the product manufacturing process consistently yields drug product that meets the predetermined acceptance criteria for all quality attributes and the in-process tests suitable to monitor the manufacturing process.
	Container closure system of the drug product	5 mL Vial (USP Type I Clear Glass Vial), sealed with Rubber Stoppers (USP Type I Closure), and capped with Aluminum Flipp off Cap.
	Stability study data of drug product, shelf life and storage conditions	Stability was investigated under the following storage conditions: • Long term Stability study for 36 months at 5°C ±3°C (24 months submitted), • Accelerated Stability study for 6 months at 25 ± 2°C/ RH 60 ± 5% • After Reconstitution for 24 hours at 5 ± 3°C. **Evaluation** **The stability data is of 18 months.**
	Module-IV	**4.2.1 Pharmacology** **4.2.1.1 Primary Pharmacodynamics:** 4.2.1.1.1 Biological Activity (FRET) Identification of Drug Product, Hutox Injection 100 Unit (Botulinum toxin type A) (HU014-RPT-032) 4.2.1.1.2 Electromyographic Evaluation of Huons Botulinum Toxin (20150586) **4.2.1.3 Safety Pharmacology.** 4.2.1.3.1 A Safety Pharmacology Study: Effects of Botulinum toxin type A on the Central Nervous System in ICR Mice after a Single Intramuscular Administration (14-MS-302) 4.2.1.3.2 A Safety Pharmacology Study: Effects of Botulinum toxin type A on the Respiration Rate and Tidal Volume of Sprague-Dawley Rats after a Single Intramuscular Administration (14-RS-303) 4.2.1.3.3 Botulinum toxin type A: Effects of Single Intramuscular Administration on the Cardiovascular System in Male Beagle Dogs Using Telemetry (G14192) 4.2.1.3.4 Botulinum toxin type A: hERG Potassium Channel Study in CHO hERG Cells (G14191) **4.2.2 Pharmacokinetic studies:** Not applicable. **4.2.3 Toxicology studies:** 4.2.3.1 Single-Dose Toxicity: 4.2.3.1.1 Single-Dose Intramuscular Toxicity Study of Botulinum toxin type A in Sprague-Dawley Rats (14-RA-382) 4.2.3.1.2 Single-Dose Intramuscular Toxicity Study of Botulinum toxin type A in Beagle Dogs (14-DA-338) **4.2.3.2 Repeat-Dose Toxicity** 4.2.3.2.1 A 4-Week Repeated Dose Toxicity Study of Botulinum toxin type A by 5 Times Intramuscular Administration with 1-Week Intervals Followed by a 4- Week Recovery in Sprague-Dawley Rats

(14-RR-339) 4.2.3.2.2 A 4-Week Repeated Dose Toxicity Study of Botulinum toxin type A by 5 Times Intramuscular Administration with 1-Week Intervals Followed by a 4- Week Recovery in Beagle Dogs (14-DR-223)

4.2.3.2.3 A 4-Week (once a week) Repeated Intramuscular Injection Toxicity Study of HUTOX Inj. 100 Units (Clostridium Botulinum Toxin Tpye A) with 4-Week Recovery in Rabbits (B16741)

4.2.3.2.4 6-Month Intramuscular Repeated Dose Toxicity Study in Wistars Rats with HUTOX Inj. 100 Units Including a 6-Month Recovery Period (167940)

4.2.3.5 Reproductive and Development Toxicity

4.2.3.5.1 Fertility and Early Embryonic Development Not applicable.

4.2.3.5.2 Embryo-fatal Development

4.2.3.5.2.1 Effects of Botulinum toxin type A on Embryo-Fetal Development in Sprague-Dawley Rats by Intramuscular Administration (14-RP-299)

4.2.3.5.2.2 Effects of Botulinum toxin type A on Embryo-Fetal Development in New Zealand White Rabbits by Intramuscular Administration (14-BP-301)

Conclusion

In conclusion, HU-014 is considered safe in the dosage and administration (20U) based on the animal toxicity studies, because the identified NOAEL is significantly above the dosage of clinical administration.

Module-V

5.3.5 Reports of Efficacy and Safety Studies

5.3.5.1 Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication

5.3.5.1.2 A non-inferiority study of Hutox to Botox® for subject who require improvement of glabellar lines.

Clinical Study	Study #No.	Refference	Purpose	Study design and control	Study drug, Dosage, Administration route	Number of Subject (Safety set)	Subject	Tr du
Safety and Efficacy	HU-014_P1/2	Section 5.3.5.1 5.3.5.2	Evaluation of Safety and Efficacy	A Single center, single arm	4 U/0.1 mL was injected intramuscularly (IM) into each of 5 sites for a total dose of 20 U/0.5 mL	Phase I; 12 subjects (Test group)	Subject with moderate to severe glabellar lines	P S admi and fol
				A Single center, randomized, double-blind, active control		Phase II 54 subjects (Test group; 27, Control group; 27)		Pl S admi and fol
Safety and Efficacy	HU-014_P3	Section 5.3.5.1	Evaluation of Efficacy and Safety	Multi-center, randomized, double-blind, active control	4 U/0.1 mL was injected intramuscularly (IM) into each of 5 sites for a total dose of 20 U/0.5 mL	267 Subjects (Test group; 135, Control group; 132)	Subject with moderate to severe glabellar lines	S admi and fol

Conclusion of Efficacy

From the results of two clinical trials on the improvement of Glabellar lines, the conclusions are as follows.

- Based on the study results, the improvement effect of HU-014 was observed in the recommended dosage and administration (single dose administration of 4 Unit/0.1 mL, 20 Unit/0.4 mL total), and the non-inferiority of HU-014 to Botox® was demonstrated in terms of the glabellar lines improvement rate.

Conclusion of Safety

	From the results of two clinical trials on the safety, the conclusions are as follows. • HU-014 is considered to have favorable drug tolerance and to be safe to administer in recommended dosage and usage (IM, 4 U/0.1 mL in each site, total 20 U/0.5 mL). • HU-014 and Botox® are similar in overall safety.

Remarks:

Sr. No.	Shortcoming	Reply
1	DSL is expired. Provide copy of valid DSL.	The DSL was valid at the time of dossier submission; however, we are now providing the updated valid DSL (Copy enclosed herewith)
2	Long term stability data of API is till 24 months while the product shelf life is 36 months.	Both stability studies are independent. The substance is tested up to 24 months according to the stability protocol. Similarly, for the finished product, stability data up to 24 months has been submitted. The 36-month data is not yet due. We have committed in the dossier to provide the 36-month stability data once it is available, as per the stability protocol.
3	Compatibility studies with container closure systems is not provided.	Since both the product and container closure system comply with Pharmacopeial standards, no novel packaging material is used. Stability data well explained that the product during the shelf life complies with specification therefore the compatibility is not required. Moreover, manufacturer has provided both 3.2.P.2.4.2 Extractable and 3.2.P.2.4.2 Leachable on page 25 and 26 under Module 3.2.P.2.4 Container Closure System for compliance of pharmacopeial standards.
4	Detail of Reference standard or material under Module 2.3.P.6 is not provided.	Detail of reference standard for finished good is provided in 2.3. P.6.
5	Certificate of Reference standard under module 3 2.S.5.2 is not attached in the dossier.	Reference details are mentioned dossier at 3.2.S.5.1. Please refer to the tables 3.2.S.5.1.1, 3.2.S.5.1.2, and 3.2.S.5.1.3 of Module 3.2.S.5. Reference Standards or Materials.
6	The product complies European Pharmacopoeia as mentioned in the dossier, but the manufacturer has used In-House Reference standard instead of using primary reference standard.	For biological products, the pharmacopeial convention doesn't provide specific references but allows manufacturers to create their own reference preparations for testing batches. For our product, the manufacturer has prepared an in-house reference that meets pharmacopeial standards. (See the monograph Ph. Eur. Botulinum toxin type -A monograph under 'manufacturer reference preparation which states that *"'manufacturer reference preparation: [please take four lines from monograph]"*
7	Certificate of analysis of finished product is required along the Pharmacopeial Monograph.	Pharmacopoeia monograph has already been submitted whereas COA of product has been requested from supplier once we receive it, we will submit it.
8	Stability data of three commercial batches at recommended time intervals is required on all stability indicating parameters.	All stability indicating parameter are established by manufacturer in compliance of with ICH-Q5C

		5 - STABILITY INDICATING PROFILE in ICH-Q5C state that: *" Consequently, the manufacturer should propose a stability-indicating profile that provides assurance that changes in the identity, purity and potency of the product will be detected"* All parameters tested at designated time interval are tested according to submitted stability protocol.
9	Adventitious agent safety evaluation under Module 3.2.A.2 is not provided.	According to document no. PE&R/GL/AF/004, Edition 1st. "The submission against this point is optional."
10	TSE, BSE statements for Excipients of human or Animal origin used in drug product is not attached in dossier.	In point no. 2.63 of site master file has been provided and reproduce here for your reference" *"TSE Control of raw materials used by Huons BioPharma complies with European Directorate for the Quality of Medicines (EDQM) regulations.*
11	TSE, BSE free certificates for yeast extract, dextrose and casein used in APl manufacturing is not attached in dossier.	It has been requested from supplier once we received it, we will submit it.

Decision of Previous M-340:
The Registration Board deferred the case for the submission of stability data till claimed shelf life i.e. 24 months.

The firm has submitted reply vide Dy. No. 2906 (R&I) Dated 13-11-2024 which is reproduces as under:

"*Refer to letter No. F. No. 2-2/2024DD(BD)(M-340) dated 6th November, 2024, we are submitting comprehensive stability studies data of Drug substance (3.2.S.7) and Drug Product (3.2.P.8) methodology, results and conclusions demonstrating the product's quality, safety, and efficacy till claimed shelf life.*

	Long Term	***Accelerated***	***Status***	
3.2.S.7 Stability	*0, 3, 6, 9, 12, 18, 24, 36 months*	*0,2,4,6 Months*	*Completed*	
3.2.P.8 Stability	*0, 3, 6, 9, 12, 18, 24, 36 months*	*0,2,4,6 Months*	*Completed*	

The long term and accelerated stability studies for Hutox injection 100 units drug product manufactured in European Pharmacopoeia (EP) standard are completed, and the test results shows that the quality of drug products is stable within the test period. The long term study was conducted upto 36 months which is the proposed shelf life of the drug product. The stability study after reconstitution was performed for 24 hours after saline for injection is added to Hutox Injection 100 Units drug product.

3.2.S.7. Conclusion

Long-term Stability Study

The objective of the long-term stability study is to determine the shelf-life for storage of the Hutox Injection 100 Units drug substance (Clostridium botulinum toxin type A) and to test whether the quality of the drug substance remains stable in the proposed storage condition (≤- 70°C). The long-term stability study of 3 lots (VLD001, VLD002, and VLD003) for drug substance has been performed for 36 months in accordance with the EP specification. The long- term stability study has been performed for the items as mentioned in the long-term stability proposal. The result shows that

	Hutox Injection 100 Units drug substance (Clostridium botulinum toxin type A) is stable within the test period under the proposed storage condition. **Accelerated Stability Study** The purpose of the accelerated stability study is to provide evidence of how the quality of an active pharmaceutical ingredient varies within time under the influence of temperature (5 3°C). The accelerated stability study of drug substance 3 lots (VLD001, VLD002, and VLD003) is completed up to 6 months. **3.2.P.8 Conclusions** **Long-term Stability Study** The long-term stability study of 3 Lots (VL0001, VL0002, and VL0003) for Hutox Injection 100 Units drug product has been performed for 36 months in accordance with EP standard. Every test was conformed to EP specifications. The long-term stability study was performed for the items as mentioned in the long-term stability proposal. The results show that Hutox Injection 100 Units is stable within the test period under the proposed storage condition (2- 8 °C) **Accelerated Stability Study** The accelerated stability study of 3 Lots (VL0001, VL0002, and VL0003) for Hutox Injection 100 Units drug product has been performed for 6 months in accordance with EP standard. The accelerated stability study was performed for the items as mentioned in the accelerated stability proposal. The results show that Hutox Injection 100 Units is stable within the test period under the accelerated storage condition (25 ± 2 ° C , RH (60 ±5)%) . **Stability Study after Reconstitution** Stability study after the addition of saline for injection in the drug product of 3 Lots (VL0001, VL0002, and VL0003) has been performed for 24 hours under refrigerator storage condition (2 - 8 °C) to evaluate the stability profile and to assign a shelf-life of the reconstituted solution. **Evaluator Comments** Previously, the applicant has demanded 24 months shelf life. Now, they have submitted 36 months data without the submission of requisite fee for extension in shelf life.
Decision for 343rd Meeting: Registration Board deferred Hutox Injection 100mg for clarification regarding the clinical indication of the applied molecule along with submission of requisite fee as per S.R.O. 1324(l)12024 for extension of shelf life from 24 months to 36 months.	

11.	**Name, address of Applicant / Importer**	**M/s AstraZeneca Pharmaceuticals Pakistan (Private) Limited, C-50, Block -2, Clifton, Karachi, Pakistan**
	Details of Drug Sale License of importer	**Status:** License to sell drugs by way of Wholesale **License No:** 290 **Address:** C-50 Block -2 Clifton Karachi **Address of Godown:** Plot No 208/1, Sector-23 Korangi Industrial Area Karachi **Validity:** 19-04-2028.
	Name and address of marketing authorization holder (abroad)	**Previous MAH** Daiichi Sankyo Europe GmbH, Zielstattstrasse 48, 81379 Munich, Germany. **Preregistration Variation i.e. Change of MAH** M/s AstraZeneca Pty Ltd , 66 Talavera Road Macquarie Park NSW2113 AUSTRALIA

	Name, address of manufacturer(s)	<table><tr><th>Name of manufacturing site</th><th>Address</th><th>Activity</th></tr><tr><td>Daiichi Sankyo Europe GmbH</td><td>Luitpoldstrasse 1 Pfaffenhofen , 85276, Germany</td><td>- batch release - secondary packaging</td></tr><tr><td>Baxter Oncology GmbH</td><td>Kantstrasse 2, Halle/Westfalen 33790 Germany</td><td>- manufacturing of dosage form Packaging and labelling Manufacture of dosage form Testing chemical and physical Testing sterility Testing microbial</td></tr><tr><td>Charles River Laboratories Germany GmbH</td><td>Max Planck Strasse 15A Erkrath D-40699 Germany</td><td>Manufacturing Steps: Testing biological</td></tr></table>
	Name of exporting country	**Germany**
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	**Previous COPP** **Legalized Valid COPP** Certificate Number: 01/23/003602 Request :94332 Certifying Authority: EMA Is this Product subject to community marketing authorization: Yes, under conditional approval. Is this product actually in the market: Yes **Pre-registration Variation** **Original, Legalized Valid COPP** Certificate Number: 24/0046 Certifying Authority: TGA ls this product licensed to be placed on the market for use in the exporting country?Yes ls this product on the market in the exporting country? YES Issuance Date: 23-01-2024
	Details of letter of authorization / sole agency agreement	**Original Authorization letter** The letter specifies that the AstraZeneca UK Ltd authorize AstraZeneca Pharmaceuticals Pakistan (Private) Limited located at C-50,Block 2, Clifton ,Karachi to conduct the activities for the Marketing Authorization application, post approval, importing and commercializing Enhertu 100mg Powder for concentration for solution for infusion in Pakistan. Dated:09-06-2023. **Pre-registration Variation** **Original Authorization letter** Dated:18-04-2024 We, AstraZeneca Pty Ltd (Australian Company Number (ACN) 009 682 311), a company incorporated under the laws of New South Wales, Australia, with its registered office located at 66 Talavera Road, Macquarie Park, NSW 2113, Australia hereby certify that AstraZeneca Pharmaceuticals Pakistan (Private) Limited, located at G-50, Block 2, Clifton, Karachi. Pakistan is duly authorised to conduct the activities

		for the Marketing Authorisation Application, post approval, importing and commercialising our following product in Pakistan. Brand name: ENHERTU@ trastuzumab deruxtecan 100 mg powder for injection vial Generic name: Trastuzumab deruxtecan AstraZeneca Pty Ltd and AstraZeneca Pharmaceuticals Pakistan (Private) Limited are members of the AstraZeneca Group of Companies.
	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 -5F Dy. No.: 606 Dated:21/09/2023
	Details of fee submitted	PKR 150,000/- Date: 05-Sept-2023 Deposit Slip No: 585341846407
	The proposed proprietary name / brand name	**Enhertu; Powder for Concentrate for Solution for Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each vial contains: Trastuzumab deruxtecan……100mg After reconstitution one vial of 5ml solution contains 20mg/ml of Trastuzumab deruxtecan.
	Dosage form of applied drug	Powder for Concentrate for Solution for Infusion
	Pharmacotherapeutic Group of (API)	Antineoplastic agents HER2 (Human Epidermal Growth Factor Receptor 2) inhibitors ATC code: L01FD04
	Reference to Finished product specifications	Innovator's Specifications
	Proposed Pack size	One Vial
	Proposed unit price	As per SRO.
	Shelf Life	Unopened Vial:4 years Reconstituted Solution:24 hrs at 2°C to 8°C Diluted Solution: Room temperature 4 hrs;24 hrs at 2°C to 8°C
	Storage Conditions	Store in a refrigerator 2°C to 8°C
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	NA
	Module-II (Quality Overall Summary	Firm has submitted QOS. 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	<table><tr><th>Facility</th><th>Address</th><th>Activities</th></tr><tr><td>Daiichi Sankyo Chemical Pharma Co., Ltd., Onahama Plant</td><td>389-4, Izumimachi Shimokawa Aza Otsurugi, Iwaki, Fukushima 971-8183, Japan</td><td>Manufacturing Release testing</td></tr><tr><td>Lonza AG</td><td>Lonzastrasse, Visp, 3930, Switzerland</td><td>Manufacturing Release testing</td></tr></table>
	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)	A 36-month shelf life is proposed for DS-8201a drug substance stored in the proposed container closure systems (EVA copolymer bags) protected from light at −20°C ± 5°C based upon the 48 months long-term and 6 months accelerated stability data provided in Trastuzumab Deruxtecan .
	Module-III Drug Product:	DS-8201a drug product (DP) contains L-histidine and L-histidine hydrochloride monohydrate as buffers, sucrose as a bulking agent, and polysorbate 80 as a surfactant, in addition to the active ingredient, DS-8201a. The employed excipients are commonly used in injectable product formulations. Water for injection is used as a solvent and is removed during the process of lyophilization. Nitrogen gas is used as the backfilling gas during the lyophilization step. DS-8201a is an antibody-drug conjugate (ADC) comprised of monoclonal antibody (MAb) conjugated with a drug-linker (D-L).
	Analytical method validation/verification of product	The following compendial methods have been verified for suitability for trastuzumab deruxtecan (DS-8201a) drug substance (DS) for each intended purpose. The verification results of bacterial endotoxins and bioburden are provided.(Description (Appearance),Osmolality,pH,Bacterial endotoxins,Bioburden The in-house analytical procedures listed in below have been successfully validated for the testing of DS-8201a drug substance.Identiy,Purity,Potency,Drug to antibody ratio, Protein Concentration
	Container closure system of the drug product	Amber borosilicate (Type I) glass vial, 10 mL
	Stability study data of drug product, shelf life and storage conditions	The shelf life for DP is 48 months when labelled "Store refrigerated at 2°C to 8°C". The expiration dating period of 48 months is justified based on the long-term and accelerated primary stability data.
	Module-IV Non-Clinical	In animals, toxicities were observed in lymphatic and haematopoietic organs, intestines, kidneys, lungs, testes and skin following the administration of trastuzumab deruxtecan at exposure levels of the 27 topoisomerase I inhibitor (DXd) below clinical plasma exposure. In these animals, antibody-drug conjugate (ADC) exposure levels were similar or above clinical plasma exposure.
	Module-V Clinical **Summary of Biopharmaceutics and and Associated analytical Methods** The currently approved and marketed Lyo-DP formulation was administered to subjects in Study U303 in support of the current application. All biopharmaceutic studies, comparability assessments,	

and bioanalytical assays to support the use of T-DXd have been previously reported. No new studies or assays have been conducted

Summary of Clinical Safety

Conclusion

The results from Study U303 confirm that T-DXd continues to be tolerable at the targeted dose of 5.4 mg/kg Q3W in the target population of patients with unresectable or metastatic HER2-low BC who had received a prior systemic therapy in the metastatic setting or had developed disease recurrence during or within 6 months of completing adjuvant chemotherapy.

Summary of Clinical Efficacy

Overview of the Clinical Program

Study Number/ Phase / Status[a]	Data Cut-off Date	Study Title	Number of Subjects
DS8201-A-U303 (DESTINY-Breast04) Phase 3 Completed	11 Jan 2022	A Phase 3, Multicenter, Randomized, Open-label, Active-controlled Trial of Trastuzumab Deruxtecan (T-DXd), an Anti-HER2-antibody Drug Conjugate (ADC), versus Treatment of Physician's Choice for HER2-low, Unresectable and/or Metastatic Breast Cancer Subjects	543 subjects treated: 371 T-DXd 5.4 mg/kg 172 TPC
DS8201-A-J101 Phase 1 Completed	01 Aug 2019	Phase 1, Two-part, Multicenter, Non-randomized, Open-label, Multiple-dose, First-in-human Study of DS-8201a, in Subjects with Advanced Solid Malignant Tumors	280 subjects treated with T-DXd ≥5.4 mg/kg: 91 at 5.4 mg/kg 183 at 6.4 mg/kg 6 at 8.0 mg/kg
DS8201-A-U201 (DESTINY-Breast01) Phase 2 Completed	08 Jun 2020	A Phase 2, Multicenter, Open-label Study of DS-8201a, an Anti-HER2-Antibody Drug Conjugate (ADC), for HER2-positive, Unresectable and/or Metastatic Breast Cancer Subjects Previously Treated with T-DM1	253 subjects treated with T-DXd: 184 at 5.4 mg/kg 48 at 6.4 mg/kg 21 at 7.4 mg/kg
DS8201-A-U302 (DESTINY-Breast03) Phase 3 Completed	07 Sept 2021	A Phase 3, Multicenter, Randomized, Open-label, Active-controlled Study of Trastuzumab Deruxtecan (DS-8201a), an Anti-HER2-antibody Drug Conjugate, versus Ado-trastuzumab Emtansine (T-DM1) for HER2-positive, Unresectable and/or Metastatic Breast Cancer Subjects Previously Treated with Trastuzumab and Taxane (DESTINY-Breast03)	518 subjects treated: 257 T-DXd 5.4 mg/kg 261 T-DM1
DS8201-A-J202 (DESTINY-Gastric01) Phase 2 Completed	03 Jun 2020	A Phase 2, Multicenter, Open-label Study of DS-8201a in Subjects with HER2-expressing Advanced Gastric or GEJ Adenocarcinoma (DESTINY-Gastric01)	232 subjects treated: Primary Cohort: 125 T-DXd (all at 6.4 mg/kg) 62 TPC (55 irinotecan, 7 paclitax Exploratory Cohort 1: 21 T-DXd 6.4 mg/kg Exploratory Cohort 2: 24 T-DXd 64 mg/kg
DS8201-A-U204 (DESTINY-Lung01) Phase 2 Completed	03 May 2021	A Phase 2, Multicenter, Open-label, 2-cohort Study of Trastuzumab Deruxtecan (DS-8201a), an Anti-HER2 Antibody Drug Conjugate (ADC), for HER2-over-expressing or -mutated, Unresectable and/or Metastatic Non-small Cell Lung Cancer (NSCLC)	Total: 181 subjects treat Subjects with HER2-over-exp NSCLC treated with T-D 49 at 6.4 mg/kg (Coh 41 at 5.4 mg/kg (Coh Subjects with HER2-mutant N 91 treated with T-DXd 6.4 m (Cohort 2)
DS8201-A-U205 (DESTINY-Gastric02) Phase 2 Completed	09 Apr 2021	A Phase 2, Open-label, Single-arm Trial of Trastuzumab Deruxtecan (DS-8201a) in HER2-positive, Unresectable or Metastatic Gastric or Gastro-esophageal Junction (GEJ) Adenocarcinoma Subjects Who Have Progressed On or After a Trastuzumab-containing Regimen	79 subjects treated with T-DXd 6.4 mg/kg
D9670C00001 (DESTINY-Breast06) Phase 3 Ongoing	Current projection: 1Q2023	A Phase 3, Randomized, Multi-center, Open-label Study of Trastuzumab Deruxtecan Versus Investigator's Choice Chemotherapy in HER2-low, Hormone Receptor-Positive Breast Cancer Patients whose Disease has Progressed on Endocrine Therapy in the Metastatic Setting	Planned subjects: ~850 700 subjects with HER2 IHC IHC 2+/ISH-negative statu 150 with HER2 IHC >0 and expression) Subjects randomized in 1:1 ratio. 353 subjects treated as of 1 Mar 2022

BC = breast cancer; GEJ = gastro-esophageal junction; HER2 = human epidermal growth factor receptor 2; IHC = immunohistochemistry; ISH = in situ hybridization; Q = quarter; T-DXd = trastuzumab deruxtecan; TPC = treatment of physician's choice

[a] Study was defined as completed if the analyses for the primary objective had been performed

Conclusion

The results from Study U303 confirm that T-DXd continues to be tolerable at the targeted dose of 5.4 mg/kg Q3W in the target population of patients with unresectable or metastatic HER2-low BC who

had received a prior systemic therapy in the metastatic setting or had developed disease recurrence during or within 6 months of completing adjuvant chemotherapy.

Remarks of Evaluator

Sr. No	Deficiencies/ Discrepancies	Firms Response
1.	Submit name of exporting country.	Exporting Country - The exporting country for Enhertu is Germany.
2.	The product has been granted conditional approval as per COPP mentioned under section 1.3. Justification/clarification is required.	Conditional Approval - Attached, please find clarification (refer to Annex - 1) regarding the conditional approval granted to Enhertu in EMA CoPP, the EMA CoPP is not associated with this MAA anymore. Additionally, we kindly request you to review the Enhertu registration dossier as per the Australian CoPP and LoA submitted in DRAP on 7th May 2024 (refer to Annex - 2). The Marketing Authorization holder for Enhertu in Pakistan will be AstraZeneca Pty Ltd Australia to align with the CoPP approved Marketing Authorisation Holder
3.	The COPP and Module 3 drug product part section 3.2.P.3.1 mentions three manufacturers with their specific activities, whereas Form 5 F specifies two, clarification is required.	Three Manufacturers in CoPP - The Manufactures of the finished product submitted with the MAA are presented in the Table below. They match the EU CoPP registered details, however Module 3.2.P.3.1 gives the detail of Charles River as Manufacturer for "release testing (cell growth inhibition only)", EU CPP has Charles River as "quality control of the finished medicinal product" this is the same function, as the EU CPP doesn't specify the tests performed at Baxter and Charles River instead, they broadly mention these sites as quality control of the finished medicinal product. CRL performs only one test (cell growth inhibition) which is not performed at Baxter.
4.	The marketing authorization holder in COPP is different than Form 5 F and relationship letter between M/s Daiichi and M/s AstraZeneca.	Markting Authorization Holder in CoPP – For the EU CoPP Daiichi Sankyo is mentioned as the MAH holder in Europe. Daiichi Sankyo Company Ltd Japan and AstraZeneca UK Limited have entered into a Strategic Alliance dated March 29, 2019, to jointly develop and commercialize Enhertu globally, except in Japan where Daiichi Sankyo maintains exclusive rights (Relationship letter attached). Daiichi Sankyo Europe GmBH, with

			a registered office in Germany, is an affiliate of Daiichi Sankyo and is the holder of the European centralized marketing authorization for Enhertu. However, as per the agreement, AstraZeneca is duly authorized to conduct the activities for Marketing Authorization application in other regions, including Pakistan. Therefore, we initially requested approval of AstraZeneca UK Limited as MA holder for Pakistan, but this request was rejected by DRAP because it was in contrast to what is mentioned in EMA CoPP. On May 7th, 2024, we submitted Enhertu CoPP issued by TGA Australia along with LoA issued by Minutes for 340th meeting of Registration Board (1 st October to 2nd October, 2024) | 750 AstraZeneca Pty Ltd Australia so that we can change and have AstraZeneca Australia as MA holder in Pakistan, corresponding to the Australian CoPP. Therefore, we would request you to please review our file as per the CoPP and LoA submitted on 7th May 2024 – (please refer to Annex 2).
	5.	Submit validation of analytical procedures of drug product as you have referred to drug substance part.	Validation of Analytical Procedure – (please refer to Annex 3)
	Decision of 340th Meeting: The Registration Board deferred the case for the submission of the following documents: • Fee for change in Marketing authorization holder as per S.R.O. 1324 (I)/2024. • Undertaking that the provided information/ documents is true. **Firms Response** The firm has submitted following documents vide Dy. NO. 2930 (R&I) DRAP Dated 19-11-2024: • Fee for change in Marketing authorization holder as per S.R.O 1324(I)/2024 of Rs. 150,000 vide slip no. 83510717701dated 13-11-2024 **Original, Legalized Valid COPP** Certificate Number: 24/0046 Certifying Authority: TGA ls this product licensed to be placed on the market for use in the exporting country?Yes ls this product on the market in the exporting country? YES Issuance Date: 23-01-2024 • Undertaking that the provided information is true on stamp paper		
Decision of 343rd Meeting: The Registration Board approved the applied formulation subject to compliance with current import policy of inspection of manufacturer abroad.			

Item No.04: Miscellaneous Matters
Withdrawal of Registration Applications Abrilada 40mg/0.8ml Pre-Filled Pen

Following application of Abrilada 40mg/0.8ml Pre-Filled Pen filed by M/s Pfizer Pakistan Limited, 12, Dockyard Road, West Wharf, Karachi for registration. However, the applicant has now requested for withdrawal of their application.

12.	**Name, address of Applicant / Importer**	M/s Pfizer Pakistan Limited, 12, Dockyard Road, West Wharf, Karachi,
	Details of Drug Sale License of importer	Drug License by Way of Wholesale License No: 035 Address: 12 Dockyard Road West Wharf, Karachi Validity: 19-07-2028
	Name and address of marketing authorization holder (abroad)	**Name:** Pfizer Europe MA EEIG, **Address:** Boulevard de la Plaine 17, Bruxelle 1050, Belgium
	Name, address of manufacturer(s)	**Manufacturing the Bulk Finished Product, Primary Packaging of the dosage Form, Secondary Packaging of the dosage form** **Name:** Catalent Indiana,LLC **Address:** 1300 South Patterson Dr., Bloomington, Indiana IN 47403, USA
	Name of exporting country	USA
	Detail of certificates attached (CoPP, Free Sale certificate, GMP certificate)	**Electronic COPP** Certificate No: 01/23/008763 Request:96603 Certifying Authority: EMA Is this product subject to a Community Marketing Authorization: Yes Is this product strength actually on the market within the jurisdiction of the certifying authority: Yes Issue date:21, August 2023
	Details of letter of authorization / sole agency agreement	**<u>Original Authorization Letter</u>** Pfizer Inc., 66 Hudson Boulevard East, New York, NY 10001-2192 grants authority to Pfizer Pakistan Ltd., to be responsible for all matters pertaining to the regulation of Abrilada in Pakistan. The site details (manufactured, tested and released) as per authorization letter are as follows: Catalent Indiana, LLC[a] — 1300 South Patterson Dr. Bloomington, Indiana (IN) 47403 United States (USA): Drug substance storage; Manufacture; Primary packaging; Release testing (sterility and endotoxin; Assembly of prefilled syringe; Secondary packaging and labeling Pfizer Ireland Pharmaceuticals — Grange Castle Business Park Clondalkin, Dublin 22 Ireland: Release testing; Stability testing
	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 -5F Dy. No.: 1526 Dated:24/11/2023
	Details of fee submitted	Rs: 150,000/-. Deposit Slip No. 729049771970

	The proposed proprietary name / brand name	Abrilada; Solution for Injection
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each pre-filled pen contains: Adalimumab….40mg/0.8ml
	Dosage form of applied drug	Solution for Injection SC injection
	Pharmacotherapeutic Group of (API)	Immunosuppressant Tumor Necrosis factor-alpha (TNF-alpha) inhibitors.
	Reference to Finished product specifications	As per Innovator Specifications
	Proposed Pack size	2 pre-filled pen+2 Alcohol Pads
	Proposed unit price	To be submitted later.
	Shelf Life	36 Months
	Storage Conditions	Store at 2-8°C. Protect from light.
	The status in reference regulatory authorities	EMA Approved.
	For generic drugs (me-too status)	Not Applicable
	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	<table><tr><th>Site</th><th>Responsibility</th></tr><tr><td>Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC One Burtt Road Andover, MA 01810 USA</td><td>Cell bank manufacture and storage Drug substance manufacture Drug substance in-process control, release, and stability testing Drug substance storage</td></tr><tr><td>Pfizer Ireland Pharmaceuticals Grange Castle Business Park Clondalkin, Dublin 22 Ireland</td><td>Cell bank storage</td></tr><tr><td>BioReliance Corporation 9900 Blackwell Road Rockville, MD 20850 - 3349 USA</td><td>In process testing of drug substance [In-Vitro Adventitious Virus, Mouse Minute Virus (MMV), and Mycoplasma]</td></tr></table>
	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)	The PF-06410293 drug substance shelf life claim is 60 months when stored at the recommended temperature of -15 to -25 °C in EVA bags. The shelf life is based on 60 months of stability data on primary stability batches generated at the -20 ± 5 °C long term storage condition in EVA bags. In addition, the data demonstrate the PF-06410293 drug substance stored in EVA bags is stable through: • 9 months at 5 ± 3 °C • 1 month at 25 ± 2 °C/ 60 ± 5% RH • 1 month at -70 ± 10 °C • 3 months at -40 ± 10 °C • Thermal cycling with cumulative storage at -20 ±5 °C for 6 days and 25 ± 2 °C/ 60 ± 5% RH for 9 days followed by storage at -20 ± 5 °C for at least 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.

	Analytical method validation/verification of product	Appearance testing is performed by visual examination of the final assembled PF-06410293 Prefilled Pen. The method was transferred to the relevant manufacturing facilities via training in the visual attributes required for establishing cosmetic and assembly defects against a control. This qualified empirical methodology uses established techniques, therefore analytical validation data are not provided. The functional performance analytical procedures are validated for testing each attribute of the PF-06410293 Prefilled Pen on the Zwick and Instron sets of equipment as described in Section 3.2.P.5.2 Analytical Procedures – Functional Performance (PFP 40 mg). Validation of the functional performance methods met the requirements described in International Conference on Harmonization (ICH) Guidelines on Validation of Analytical Procedures: Text and Methodology Q2 (R1).
	Container closure system of the drug product	The primary container closure system of the PF-06410293 drug product is the 1 mL long Prefilled Syringe.The Prefilled Pen enclosing the syringe is made up of two subassemblies (front subassembly and power pack subassembly), a syringe clip and a label. Secondary Packaging Components Single-dose Prefilled Pens are packaged in paperboard cartons. The cartons are printed with an instruction to keep the contents protected from light.
	Stability study data of drug product, shelf life and storage conditions	Based on the available data, the proposed shelf life for PF-06410293 Prefilled Pen is 36 months when stored at the recommended storage condition of 2 to 8 °C. Expiration dating of each lot of PF-06410293 Prefilled Pens is assigned based on the Prefilled Syringe expiration and is supported by the Prefilled Pen functionality data through to 36 months.
	Module-IV Non-Clinical	**Repeat-dose 1-month toxicity study in cynomolgus monkeys,** PF-06410293 is being developed as a proposed biosimilar mAb to the adalimumab product marketed globally as Humira□. The nonclinical strategy for evaluating the similarity of PF-06410293 to adalimumab-US and adalimumab-EU was designed in accordance with the and with the consideration of the nonclinical information that was available for the reference product. PF-06410293 was evaluated in comparison to licensed products sourced from both the EU (adalimumab-EU) and the US (adalimumab-US) as representative of global supply, in a series of in vitro pharmacology studies, as well as in comparison to adalimumab-EU in an in vivo, **repeat-dose 1-month toxicity study in cynomolgus monkeys,** a species that the originator showed was pharmacologically relevant.
	Module-V Clinical	The PF-06410293 clinical development program consisted of 4 clinical studies: **2 single subcutaneous** (SC) dose PK similarity studies in healthy volunteers**, 1 single SC PF-06410293 dose** PK comparability study using a prefilled syringe (PFS) or a prefilled pen (PFP) in healthy volunteers, and **1 multi-dose comparative safety and efficacy study** in subjects with moderately to severely active RA, which included a device sub study using a PFP (in which participation was optional). The PF-06410293 clinical program summarized herein supports a demonstration of bio similarity. The comparative PK and comparative safety and efficacy studies confirm that no clinically meaningful differences were demonstrated between the proposed biosimilar, PF-06410293, and the reference product, Humira, in terms of the PK, efficacy, immunogenicity, and safety.

Study Identifier (Country/Region)	Study Design	Treatment	Study Population	Number of Subjects	Objectives
B5381005 (US, single center)	Open-label, randomized (1:1), single-dose, parallel-group, 2-arm PK comparability study	Arm A: PF-06410293 PFS Arm B: PF-06410293 PFP Route: Single-use, PFS or PFP for SC injection Dose Regimen: 40 mg [0.8 mL of a 50 mg/mL solution] on Study Day 1	Healthy subjects between 20 to 55 years of age	Randomized: 164 Arm A (PFS): 81 Arm B (PFP): 83	Primary: • To compare the single-dose PK of PF-06410293 administered SC with a PFP device containing the PF-06410293 PFS, as compared to that of the PFS, in healthy adult subjects. Secondary: • To evaluate the safety and tolerability of PF-06410293 administered with the PFP device containing the PFS, compared to the PFS. • To evaluate the full PK profile following a single dose of PF-06410293 administered with the PFP device and the PFS. Exploratory: • To evaluate the immunogenicity of PF-06410293 administered with the PFP device containing the PFS, and with the PFS.
Comparative Safety and Efficacy Study					
B5381002 (WW, 173 centers)	Double-blind randomized (1:1), parallel-group study	**TP1:** PF-06410293 or adalimumab-EU **TP2:** PF-06410293/ PF-06410293 or adalimumab-EU/ adalimumab-EU or	Patients ≥ 18 years of age with moderately to severely active RA disease who had an inadequate response to MTX therapy	**TP1:** Randomized: 597 PF-06410293=297 adalimumab-EU=300 **TP2:** Re-randomized: 552 PF-06410293/ PF-06410293=283 adalimumab-EU/	Primary Objective: • To compare the treatment efficacy between PF-06410293 and adalimumab-EU in subjects with moderately to severely active RA who were treated with adalimumab in combination with MTX. Secondary Objectives: • To evaluate the overall safety and tolerability of PF-06410293 and

Table 1. Summary of Clinical Studies Included in This Submission

Study Identifier (Country/Region)	Study Design	Treatment	Study Population	Number of Subjects	Objectives
Single Dose Pharmacokinetic Studies in Healthy Subjects					
B5381001 (Belgium, US, 2 centers)	Double-blind (Sponsor-open), randomized (1:1:1), parallel-group, single-dose, 3-arm, PK similarity study	PF-06410293 or adalimumab-US or adalimumab-EU Route: Single-use, PFS for SC injection Dose Regimen: 40 mg [0.8 mL of a 50 mg/mL solution] on Study Day 1	Healthy subjects between 18 to 55 years of age	Randomized: 210 PF-06410293=69 adalimumab-US=71 adalimumab-EU=70	• To compare the PK of PF-06410293 to adalimumab-EU, and PF-06410293 to adalimumab-US. • To compare the PK of adalimumab-EU to adalimumab-US. • To evaluate the single-dose immunogenicity, safety and tolerability
B5381007 (US, 4 centers)	Double-blind (Sponsor-open), randomized (1:1:1), parallel-group, 3-arm, single-dose, PK similarity study	PF-06410293 or adalimumab-US or adalimumab-EU Route: Single use PFS for SC injection Dose Regimen: 40 mg [0.8 mL of a 50 mg/mL solution] on Study Day 1	Healthy subjects between 18 to 45 years of age	Randomized: 362 PF-06410293=121 adalimumab-US=119 adalimumab-EU=119	Primary Objective • To compare the PK of PF-06410293 to adalimumab-EU, and of PF-06410293 to adalimumab-US. Secondary Objectives • To compare the PK of adalimumab-EU to adalimumab-US. • To evaluate the single-dose safety and tolerability. • To evaluate immunogenicity.

Study Identifier (Country/Region)	Study Design	Treatment	Study Population	Number of Subjects	Objectives
		adalimumab-EU/ PF-06410293 **TP3:** PF-06410293/ PF-06410293/ PF-06410293 or adalimumab-EU/ adalimumab-EU/ PF-06410293 or adalimumab-EU/ PF-06410293/ PF-06410293 Route: Single-use, PFS for SC injection Dose Regimen: 40 mg [0.8 mL of a 50 mg/mL solution] every other week		adalimumab-EU=135 adalimumab-EU/ PF-06410293=133 **TP3:** Entered: 507 PF-06410293/ PF-06410293/ PF-06410293=259 adalimumab-EU/ adalimumab-EU/ PF-06410293=121 adalimumab-EU/ PF-06410293/ PF-06410293=127	adalimumab-EU. • To evaluate the immunogenicity of PF-06410293 and adalimumab-EU. • To evaluate the multiple composite and individual parameters of clinical response to PF-06410293 and adalimumab-EU. • To evaluate the overall safety, tolerability and immunogenicity of PF-06410293 after treatment transition from adalimumab-EU to PF-06410293. • To evaluate the population PK of PF-06410293 and adalimumab-EU. • To evaluate the PD response to PF-06410293 and adalimumab-EU.
B5381002 Substudy (WW, 19 centers)	Open-label, single arm, PFP substudy in a subset of subjects enrolled in Study B5381002	PF-06410293 Route: single-use, PFP device for SC administration Dose Regimen: 40 mg [0.8 mL of a 50 mg/mL solution] every other week	Patients ≥ 18 years of age with moderately to severely active RA disease who had an inadequate response to MTX therapy	**Enrolled:** PF-06410293=50	Primary Objective: • To evaluate the success of PF-06410293 administration by the subject with RA or their non-healthcare professional caregiver using the PFP device. Secondary Objectives: • To describe the safety of PF-06410293 administration by the
					subject or their non-healthcare professional caregiver using the PFP device. • To determine the correct operation of the PF-06410293 PFP by examination of returned used devices.

Bio similarity Data	Already Approved for PFS in M-320.

Remarks of Evaluator: **a proposed biosimilar to HUMIRA**

Shortcoming	Firms Response
i. Clarification is required for variation in manufacturing site details as provided in COPP, letter of authorization ,Form 5 F and section 3.2.P.3.1 , as the activities specified in section 3.1 of COPP are not in accordance with letter of authorization , Form 5 F and section 3.2.P.3.1 of the drug product part. ii. The authorization letter is between Pfizer, New York instead of Pfizer Europe MA EEIg, Belgium. Clarification is required. iii. Clarification is required for specifications whether inhouse or innovator specs. As section 1.5.6 of Form 5F specifies both.	Reply Awaited.

	iv. Submit justification in the light of international guidelines for not performing stability studies of applied drug in PFP, as mentioned in section in 3.2.P.8.1. v. Submit proposed pack size. vi. The exporting country is USA ,whereas COPP is from EMA.Clarification is required. vii. Submit GMP of manufacturing site i.e. Catalent.		
	Decision of 340th meeting: **The Registration Board deferred the case for the submission of the following documents**: i. Clarification for variation in manufacturing site details, since the activities specified in section 3.1 of COPP are not in line with letter of authorization, Form 5 F and section 3.2.P.3.1 of the drug product part. ii. The authorization letter between Pfizer Europe MA EEIg, Belgium and M/s Pfizer Pakistan Limited, 12, Dockyard Road, West Wharf, Karachi. iii. Clarification for specifications whether in-house or innovator specs. As section 1.5.6 of Form 5F specifies both. iv. Justification in the light of international guidelines for not performing stability studies of applied drug in PFP, as mentioned in section in 3.2. P.8.1. v. Submit proposed pack size. vi. Justification for provision of EMA COPP instead of USFDA. vii. GMP of manufacturing site i.e. Catalent Indiana, LLC ,1300 South Patterson Dr., Bloomington, Indiana IN 47403, USA. **Firms Response** However the firm has submitted application for the withdrawal of registration of ABRILADA , which is reproduced as under: "*Pfizer plans to withdraw the application for registration of Abrilada. The reason for a withdrawal is due solely to a Pfizer business decision and it is not related to any safety, tolerability, efficacy or quality concern.* *Pfizer values its ongoing partnership with the regulatory agency We would link the agency for the continued collaboration* *With this letter, we write to notify (in order to update records) that this application shall now be considered as withdrawn* *Please let us know if you need any further details."*		
Decision of 343rd Meeting: The Registration Board acceded with the firm's request for withdrawal of Abrilada 40mg/0.8ml Pre-Filled Pen and the application is rejected.			

13. <u>Withdrawal Of Initial Marketing Authorization Application Of Ronapreve (Casirivimab + Imdevimab) Solution For Injection/Infusion</u>

M/s Roche Pakistan Limited, Karachi vide dy. No. 2521 (R&I) Dated 30-09-2024 wherein the M/s Roche has requested to hold the registration of their product Ronapreve (Casirivimab + Imdevimad) due to change in global strategy following the end of the Covid-19 pandemic.

Another FR is received vide Dy. No. 2803 (R&I) DRAP Dated 01-11-2024, for the withdrawal of initial Marketing Authorization Application of the said product, which is reproduced as under:

"We are writing regarding the application for the registration of Ronapreve (Casirivimab Imdevimab) 300mg + 300mg Solution for Injection/Infusion and Ronapreve (Casirivimab+ Imdevimab) 120mg/ml + 120mg/ml Solution for Injection/Infusion, reference number 015/2022/SS-DRAP, submitted on April 23. 2022.

Upon thorough review, we have determined that, in the current post-COVID-19 context, there is no longer a clinical need for Ronapreve's registration. With the significant decline in COVID-19 cases globally and within Pakistan, the product's intended use does not align with present therapeutic requirements. In view of this, we believe it appropriate to proceed with the withdrawal of the registration application for Ronapreve at this time."

Placed before the board for consideration

Decision of 343rd Meeting: The Registration Board acceded to the firm's request for withdrawal of Ronapreve (Casirivimab + Imdevimab) Solution and disposed of the application.

4. <u>License Withdrawal Of Verorab (Reg No. 009519) By M/s Sanofi-Aventis Pakistan Limited, Karachi</u>

M/s Sanofi-aventis Pakistan Limited, Karachi vide Dy. No. 2512 (R&) DRAP Dated 27-09-2024 on the subject cited above. Which is reproduced as under:

This is in reference to our letter dated 23 Oct 2023 (copy of letter attached) regarding the availability status of our registered vaccine namely **Verorab (Reg No. 009519)**

We, sanofi-aventis Pakistan limited, would like to inform the competent authority that company has decided to withdraw registration license of Verorab.This is a commercial decision and is not related to safety, quality, and efficacy of the product.Kindly note that following alternate of Verorab is available in market:

Brand Name	Corporation Name
ABHAYRAB	L.C.I

Decision of 343rd Meeting: Registration Board referred the case for views of DRAP's availability committee CALSD regarding therapeutic need of vaccine and availability of alternate products/ brands before decision on the applicant's request for withdrawal.

14. License Withdrawal Of Avaxim 80u Pediatric Vaccine (Reg No. 047525] By Sanofi-Ventis Pakistan Limited, Karachi

M/s Sanofi-aventis Pakistan Limited, Karachi vide Dy. No. 2746(R&) DRAP Dated 24-10-2024 on the subject cited above. Which is reproduced as under:

We, sanofi-aventis Pakistan limited, would like to inform the competent authority that company has decided to withdraw registration license of our vaccine namely **Avaxim 80U Pediatric Vaccine (Reg No. 047525).** This is a commercial decision and is not related to safety, quality, and efficacy of the product.

Decision of 343rd Meeting: Registration Board referred the case for views of DRAP's availability committee CALSD regarding therapeutic need of vaccine and availability of alternate products/ brands before decision on the applicant's request for withdrawal.

(Nafees-ur-Rehman)
(Deputy Director PRVC):

Item No. 01: Post Registration Variations

15. Permission for Import of Shingrix Vaccine in General Export Pack and Printing of Labelling Text Locally

FR is received from M/s GlaxoSmithKline Pakistan Ltd., Karachi where in the company has requested for the permission for local printing of some labelling text in Urdu. The application is reproduced as under:

"*At the very outset we wish to thank you for your kind support in Shingrix Vaccine registration in Pakistan. In this regard, we are also seeking permission of DRA Pakistan for local printing of some labelling text including urdu text, RN, address, price, and barcode on the product for a period of one year* ***at our licensed/ authorized warehouse M/s Connect Logistics (Pvt.), Ltd.*** *which is registered with the product. Copy of registration letter is attached along with DRAP fee challan of Rs. 12000/-. Similar approval granted by the DRAP in past is also enclosed for your reference. We look forward to your kind consideration and concurrence in this regard."*

The details of the product is as under:

Reg.No.	Name of Drug and composition	Packing	MRP	Shelf Life
120555	**Shingrix powder and suspension for suspension for injection** Herpes Zoster Vaccine (recombinant, adjuvanted) After reconstitution, one dose (0.5 mL) contains: Varicella Zoster Virus[1] glycoprotein E antigen[2,3]: 50 µg [1]Varicella Zoster Virus = VZV	1's Vial of Powder (Antigen) 1's Vial of Suspension (Adjuvant)	As per SRO 228(I)/2024 Dated 19-02-2024	3 Year (2°C-8°C)

	[2]adjuvanted with $AS01_B$ containing: plant extract Quillaja saponaria Molina, fraction 21 (QS-21): 50 µg 3-O-desacyl-4'-monophosphoryl lipid A (MPL) from Salmonella minnesota: 50 µg [3]glycoprotein E (gE) produced in Chinese Hamster Ovary (CHO) cells by recombinant DNA technology **As per Innovator's Specifications**			

Marketing Authorization Holder & Batch Release Site: M/s GSK Biologicals S.A. i.e., Rue de I'Institut 89, B-1330 Rixensart, Belgium
Manufacturer: M/s GSK Biologicals SA, Parc de la Noire Empine 20, Avenue Fleming, 1300, Wavre, Belgium.

The case is placed for consideration of the Registration Board.

Decision of 343rd Meeting: To ensure priority availability of product, Registration Board acceded to the firm's request and directed to expeditiously issue letter, without waiting for finalization of mintues of the meeting, for grant of exemption from labeling text as per (Labelling and Packing) Rules, 1986 in general export packs of their already registered product Shingrix Powder for Suspension for Injection with following conditions:

i. **The firm shall locally print MRP, Registration Number, Urdu Text and barcode as per Drugs (Labeling and Packing) Rules, 1986 before sale of drug at DML No. 000233 of M/s GlaxoSmithKline Pakistan Limited, F-268, S.I.T.E, Karachi.**
ii. **This permission shall be valid for one (01) year only.**
iii. **The firm will submit the future plan of import of compliant packs as per Drugs (Labeling and Packing) Rules, 1986 within 03 months.**
iv. **During printing, monitoring of temperature from 2 °C to 8 °C will be responsibility of the MAH.**

The Board also authorized its Chairman to dispose of / approve such cases in future to ensure uninterrupted availability of drug products.

Cases of Deputy Director-II

16. Personal Hearing-M/s Vigilant Lahore and M/s. Inuko, Lahore for the product of Immucox-5 ®

- The subject case is an FR/ complaint lodged by the M/s. Vigilant Veterinary Services (Pvt) Limited, Lahore dated 15th January 2024, wherein they claimed that "the stated product had been already registered in their name, dated 19-10-1994 having registration number "015484". Therefore, the said product cannot be granted as registration to the M/s. Inuko, Lahore. In support of their case, Vigilant Veterinary claimed that the subject product is manufactured by the same manufacturer, i.e., "Ceva Animal Health Inc. Canada".
- The complaint was evaluated and two letters were served to M/s. Vigilant Veterinary Services (Pvt) Limited, Lahore, dated 21-02-2024 and 02-09-2024 respectively that required the complainant to submit/provide sufficient information or documents to prove their claim of

registration of the subject product, i.e., Immucox-5®. The firm submitted the following documents for their justification in support of the claim raised in the FR/ Complaint: -

Table:01

Sr. #.	Documents/ Clarification Required by the DRAP	Firm Submission
i.	Letter of Authorization/ Agreement between Market Authorization Holder and M/s Vigilant Veterinary Services for "Immucox Vaccine".	A photocopy of the document of 1st March 1993, as an evidence of agreement between M/s. Vetech Laboratories Ltd., Wellington, Province of Ontario, Canada and M/s. Vigilant Veterinary Services (Pvt) Limited, Chowk Chauburji, Lahore. The statement of term is as follows: - "The initial term of this agreement shall be from March 1, 1993, to and including February 29, 1996, but it is understood and agreed that if the $300,000.00 target set out in paragraph 2 hereof is met, the agreement shall automatically renew for a further three years to expire February 28, 1999. If the agreement is so renewed, the purchase price for Immucox purchased by Vigilant from Vetech shall be increased by such amount as Vetech and Vigilant may agree upon and a new target for purchase by Vigilant from Vetech during 1996 shall also be agreed upon. If the said target of $100,000.00 is not achieved in 1993, this agreement shall automatically terminate on the 28th day of February, 1994, unless Vetech and Vigilant agree in writing prior to March 1, 1994, to extend this term of the agreement."
ii.	Registration Letter of "Immucox vaccine" issued by DRAP.	Copy of Registration letter issued on 19-10-1994 alongwith copies of renewal submissions, dated as follows: - 28-08-2019; 24-09-2014; 30-09 2009; 29-09-2004; 25-10-1999.
iii.	Complete name of manufacturer and Market Authorization Holder of "Immucox Vaccine".	**-not provided-**
iv.	Any online link to verify registration status of "Immucox Vaccine" in Canada showing Market Authorization Holder or manufacturer also.	**-not provided-**
v.	The detail composition of "Immucox Vaccine" and similarity with "Immucox ® 5 Vaccine" as composition of both seems to be different.	Certificate of analysis of 2013 provided with composition of the product, i.e., 1. E. acervulina; 2. E. maxima; 3. E. necatrix; 4. E. tenella,
vi.	The letter/permission of change of name of manufacturer from M/s Vetech Laboratories Ltd to M/s Ceva Sante Animale Canada (as stated in your letter).	**-not provided-**

vii.	Import record of "Immucox Vaccine".	Import invoices copies dated Dec. 2011 and Dec. 2013.

- The reply submitted by the firm did not suffice its claim that the same product was approved to the name of M/s. Inuko, Lahore. It is pertinent to mention here that the firm M/s. Inuko, Lahore was already in the court for issuance of Registration letter of the product Immucox-5®, that was approved in M-331 of the Registration Board. But its letter was not issued due to above mentioned complaint of M/s. Vigilant Veterinary Services (Pvt) Limited, Lahore. The honourable high court in writ petition-51565 of 2024 has decided the case and directed the DRAP to dispose of the matter in first week of October, 2024, positively.
- The comparison of documents/information submitted by both the parties, is as under;

Table:02

Sr. #.	**Documents provided as an evidence.**	**M/s. Vigilant Veterinary Services (Pvt) Limited, Lahore.**	**M/s. Inuko, Lahore**
i.	**Product Details**	Immucox Vaccine **Each dose of vaccine contains:** **E. acervulina… not provided-** **E. maxima……..not provided-** **E. necatrix not provided-** **E. tenella… not provided-**	Immucox ® 5 Each dose of vaccine contains: Eimeria acervulina.at least…… 151 oocysts/dose Eimeria brunetti…….at least 40 oocysts/dose Eimeria maxima…….at least 50 oocysts/dose Eimeria necartrix……..….at least 51 oocysts/dose Eimeria tenella…….….at least 25 oocysts/dose
ii.	Complete name of manufacturer and Market Authorization Holder of "Immucox-5 Vaccine". As of today.	-no evidence provided for agreement bw M/s. Ceva Sante Animale, Canada,	Sole agency agreement of M/s. Ceva Sante Animale, Canada to the name of M/s. Inuko, Lahore provided, i.e., valid till 31st December, 2024.
iii.	Letter of Authorization/ Agreement	A photocopy of the document of 1st March 1993.	Original, Legalized and valid Sole agency agreement of M/s. Ceva Sante Animale, Canada to the name of M/s. Inuko, Lahore, as an exclusive distributor of Immucox ® 5 provided, i.e., valid till 31st December, 2024.
iv.	Complete name of manufacturer and Market Authorization Holder of "Immucox Vaccine".	**-not provided-**	
v.	Any online link to verify registration status of "Immucox Vaccine" in Canada showing Market Authorization Holder or manufacturer also.	**-not provided-**	Online justification provided by the firm that the subject product is registered with M/s. Ceva Sante Animale, Canada and on free sale in the country of origin.
vi.	The detail composition of	Certificate of analysis of 2013	Each dose of vaccine contains:

	"Immucox Vaccine" and similarity with "Immucox ® 5 Vaccine" as composition of both seems to be different.	provided with composition of the product, i.e., 1. E. acervulina; 2. E. maxima; 3. E. necatrix; 4. E. tenella,	Eimeria acervulina.at least…… 151 oocysts/dose Eimeria brunetti…….at least 40 oocysts/dose Eimeria maxima…….at least 50 oocysts/dose Eimeria necartrix……..….at least 51 oocysts/dose Eimeria tenella…….….at least 25 oocysts/dose
vii.	The letter/permission of change of name of manufacturer from M/s Vetech Laboratories Ltd to M/s Ceva Sante Animale Canada (as stated in your letter).	**-not provided-**	Original, Legalized and valid Sole agency agreement of M/s. Ceva Sante Animale, Canada to the name of M/s. Inuko, Lahore, as an exclusive distributor of Immucox 5® provided, i.e., valid till 31st December, 2024.
viii.	Import record of "Immucox Vaccine".	Import invoices copies dated Dec. 2011 and Dec. 2013.	----------

- In accordance to above case history, both parties were called for personal hearing for defense of their case in 340th meeting of the Board.

Proceeding of the Board in its 340th meeting:

In compliance to letter for personal hearing, Ms. Irum Advocate from M/s. Vigilant Veterinary Services (Pvt) Limited, Lahore requested for an adjournment however, Mr. Umar Hameed Khan being counsel of M/s. Inuko, Lahore presented the case and ensure that all the legal liabilities on M/s. Inuko, Lahore for the grant of registration has been complied, and requested for grant of registration.

Decision of the Registration Board in its 340th meeting:

The Registration Board deliberated the case and acceded the request of M/s. Vigilant Veterinary Services (Pvt.) Limited, Lahore for adjournment along with the direction to appear in the next meeting otherwise case shall be decided, ex-parte.

In light of above decision of the Registration Board, M/s. Vigilant Veterinary Services (Pvt.) Limited, Lahore, was called for personal hearing in 343rd meeting of the Registration Board.

Proceeding of 343rd meeting of the Registration Board:

In compliance to the letter of personal hearing, Ms. Irum Advocate and Dr. Muhammad Azam Chohan, Chief Executive, Vigilant Veterinary Services (Pvt.) Limited, Lahore, appeared before the Board and submitted as under;

> "That Vigilant Veterinary Services (Pvt.) Ltd. is a renowned firm which is offering its services in Pakistan for more than 2 decades. It is pertinent to mention here that the said firm entered in an agreement with VETECH LABORATORIES INC. of 131 Malcolm Road, Guelph, Ontario, Canada N1K 1A8 dated on 01-03-1993.
>
> That vide agreement dated 01-03-1993, Vigilant Veterinary Services (Pvt.) Ltd. were delegated the exclusive rights to sell IMMUCOX vaccine directly or through third party agents throughout Pakistan.
>
> That thereafter, Vigilant Veterinary Services (Pvt.) Ltd. applied for the registration of IMMUCOX vaccine under section 7 of the Drugs Act, 1976 and Rule 30 of the Drugs (registration and advertising) Rules 1976.
>
> That the drug was registered vide Document No. 3-4/94- Reg-I(M-109) bearing Registration No. 015484 dated 19- 10-1994. After registration of IMMUCOX vaccine, Vigilant Veterinary Services (Pvt.) Ltd. imports and sales the said vaccine in Pakistan.
>
> That thereafter VETECH merged with Ceva Animal Health in a new firm named Ceva Animal Health Canada. After merger all the ongoing business of VETECH LABORATORIES INC. was shifted to Ceva Animal Health Canada located at the same premises 131 Malcolm Road, Guelph, Ontario, Canada N1K 1A8. Ceva Animal Health Canada continued to sell the IMMUCOX vaccine to Vigilant Veterinary Services (Pvt.) Ltd. without any objection or any hindrance from any quarter whatsoever. The invoices issued by Ceva Animal Health Canada are also available.

That till today Vigilant Veterinary Services (Pvt.) Ltd. is holding the drug registration and thereby the brand name, intellectual and propriety rights are in its name since 1994 without objection or interference either by CEVA ANIMAL HEALTH OR ANY OTHER AGENCY. It will be not out of place to mention here that the IMMUCOX vaccine is a renowned name in Pakistan due to the 20+ years of effort, cost and risk taken by Vigilant Veterinary Services (Pvt.) Ltd. and now IMMUCOX vaccine is an ICON of Vigilant Veterinary Services (Pvt.) Ltd. And both are recognized as a part and parcel of each other.

That now it comes to the knowledge of Vigilant Veterinary Services (Pvt.) Ltd. that another firm has applied for the same name with a minor change i.e IMMUCOX 5 instead of IMMUCOX for registration, which is against the law and facts available on record.

That we immediately applied for cancellation of registration of Immucox 5. The request of Vigilant Veterinary Services (Pvt.) Ltd. was considered by the Registration Board and they offered an opportunity of hearing.

That the matter under consideration is that IMMUCOX® vaccine is registered in the name of Vigilant Veterinary Services (Pvt.) Ltd. and as per clause 2 of Form No. 5 that design/colour, graphic of label/carton is not copy /counterfeit of any other drug. If we observe the script of IMMUCOX 5 it is similar to IMMUCOX which could not be differentiated by a layman and he could easily be deceived. Even otherwise it is also against the established law. That Inouko Animal Health (Private) Limited. is trying to get IMMUCOX 5 registered, which should not be issued to them BECAUSE IT COULD BE USED IN DECEPTIVE MANNER to grab the market share of IMMUCOX which is established in Pakistan by Vigilant Veterinary Services (Pvt.) Ltd. with 20+ years of effort, cost and risk. It is worth mentioning here that the registration of IMMUCOX vaccine still exists in the name of Vigilant Veterinary Services (Pvt.) Ltd. since 1994 and same has been renewed as per law regularly.

That there is no such data available on net uploaded by Ceva Animal Health. However, names of countries are mentioned at their site with whom they are doing business.

That has already been mentioned that after the merger Ceva Animal Health has accommodated all the clients of VETECH LABORATORIES INC. The agreement was never rescinded or amended in any manner till today and both the parties are abiding terms and conditions till today."

During the hearing, the Board was apprised by Ms. Irum Advocate and Dr. Muhammad Azam Chohan, Chief Executive, Vigilant Veterinary Services (Pvt) Limited, Lahore that the last shipment of the Immucox Vaccine was imported in 2014 and after merger of the VETECH LABORATORIES INC. Canada with Ceva Animal Health, Canada, old distribution agreement dated 01-03-1993 with VETECH LABORATORIES INC. Canada was never revised and submitted to DRAP.

The Board was further apprised by the Division of BE&R that drug registered in the name of M/s Vigilant Veterinary Services (Pvt) Limited, Lahore i.e Immucox Vaccine is tetravalent vaccine while the drug applied for registration by M/s Inouko Animal Health (Private) Limited i.e. Immucox 5 Vaccine, is pentavalent vaccine.

Decision of 343rd meeting of the Registration Board: The Board after hearing M/s. Vigilant Veterinary Services (Pvt) Limited, Lahore and going through the facts, decided to defer the case and directed the Division of Biological Evaluation and Research to write an email to Ceva Animal Health, Canada for confirmation of following information/facts;

i. Registration/Marketing Authorization status of Immucox Vaccine.

ii. Validity/existence of distribution agreement for Pakistan pertaining to Immucox Vaccine & Immucox 5 Vaccine with M/s. Vigilant Veterinary Services (Pvt) Limited, Lahore or M/s Inouko Animal Health (Private) Limited, Lahore.

<u>Minutes of Additional Agenda Items-343rd Meeting of Registration Board</u>

Case No. 1

Imported Human Biological Product from Non-Reference Countries:

4.	Name, address of Applicant / Importer	**M/s Mediflow Pharmaceutical (Pvt) Ltd.,** **Company Address: Plot # ID-100 Sector 30 Korangi Industrial Area** **Site Address: Plot: ID -100, Sector 30 Korangi Industrial Area, Karachi,**

	Details of Drug Sale License of importer	Address 15 & 33, Sec:30 K.I.A Karachi Status: License to sell drugs by way of wholesale. Validity: 10-07-2023. Renewal: NA
	Name and address of marketing authorization holder (abroad)	M/s Suzhou Abogen Biosciences Co. Ltd. Building 19,Area Phase 5, Biomedical Industrial Park, No.21 Chaoqian Road, Suzhou Industrial Park.
	Name, address of manufacturer(s)	Suzhou Abogen Biosciences Co. Ltd. Building 18 No. 218 Sangtian street, Suzhou Industrial Park, Jiangsu, China. **As per Drug Manufacturing Certificate** 2nd Floor, Building 32, No. 218, Sangtian Street, Suzhou Industrial Park, Jiangsu, China: Warehouse Building 18, No. 218, Sangtian Street, Suzhou Industrial Park, Jiangsu, China: Prophylactic biological products (SARS-Co V-2(Variant)mRNA manufacturing Vaccine)
	Name of exporting country	China
	Detail of certificates attached (CoPP, Free sale certificate, GMP certificate)	**Original Legalized and Valid COPP** Not submitted by the applicant. **GMP Compliance Statement** The Chinese drug regulatory authority no longer issues GMP Certificate; however, GMP Compliance Statement is attached. And Drug Manufacturing Certificate is also attached. The GMP compliance statement does not mention the site address.
	Details of letter of authorization / sole agency agreement	**Scanned Copy of Letter of Authorization Issued on 13th November 2024** - We Suzhou Abogen Biosciences Co., Ltd., Building 19, Area C, Phase 5, Biomedical Industrial Park, No. 21 Chaoqian Road, Suzhou Industrial Park, hereby appoint Mediflow Pharmaceutical Pvt. Ltd. Situated at Plot ID 100, Sector 30, Korangi industrial Area, Karachi-74900, Pakistan To apply for the registration of our pharmaceutical product: **Product Name:** SARS-CoV-2 Variant (BA.4/5) mRNA vaccine **Dosage form and strength:** Injection, 0.5ml:15ug **Pack size:** Pre-filled 1ml glass syringe with rubber plunger With the drug regulatory authority in Pakistan on our behalf and Suzhou Abogen Bioscience Co., Ltd., Building 19, Area C, Phase 5, Biomedical Industrial Park, No. 21 Chaoqian Road, Suzhou Industrial Park will be marketing authorization holder of the registration certificate and be responsible for all the matters pertaining to the registration of this product. This letter is valid for 3 years from Nov 13, 2024, unless specifically extended.
	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	Tracking ID:6XM-J4D-G842 Application Number:35198 Receiving Date :25-10-2024
	Details of fee submitted	Challan Number: 7529209634

		Division: Biological Evaluation & Registration Paid Fee: 300000.0 Paid Date: 2024-07-24 Fee Head: DML.
	The proposed proprietary name / brand name	**ARCoVE Pre-filled syringe for Intramuscular Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each vial contains 0.5 mL for one dose:** **Each dose contains 15ug mRNA**
	Dosage form of applied drug	Pre-filled syringe for injection.
	Pharmacotherapeutic Group of (API)	Indicate pharmacological class of the API (drug substance) & WHO ATC code for each distinct therapeutic indication: both are not available, whether they are mandatory and suitable for this vaccine, as it is the first time and there is no relevant guidance either.
	Finished product specifications	**Chinese Pharmacopoeia (Form 5 F)** **(Should be as per innovator)**
	Proposed Pack size	1's vial.
	Proposed unit price	Each vial will be 3000 Rupees.
	Shelf life	12 months
	Storage conditions	2-8°C.
	The status in reference regulatory authorities	The application is for Innovator product, -**AWCorna Produc**t is registered in Indonesia (PICs country). - Trials approved in 4 countries UAE, Philippines, Indonesia (PICs countries) and Pakistan (Annexure 1). 15752 participants were screened, out of which 14138 enrolled however Pakistan nationals mostly in UAE part of trials. Evidence of Trial Approvals UAE, Philippines,Indonesia : A Randomized, Double blind, Placebo controlled Clinical Study to Evaluate the Efficacy , Safety, and Immunogenicity of SARS CoV 2 Variant BA.4 /5 mRNA Vaccine ABO1020 in Healthy Subjects Aged 18 Years and Older Who Have Completed the Full Vaccination Pakistan Title of trial or study: A Randomized, Double-Blind, Controlled Clinical Study to Evaluate the Efficacy, Safety and SARs-CoV-2 Variant @A.4/5) mRNA Vaccine (ABO1020) in Healthy Subjects 18 (1) of Physiological-Saline Years and Older who have full Vaccination".
	For generic drugs (me-too status)	N/a
	Module-II (Quality Overall Summary)	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 and drug product. The firm has also submitted the non-clinical and clinical overviews and summaries.
	Name, address of drug substance manufacturer	M/s Suzhou Abogen Biosciences Co., Ltd. Address: Building 18, No. 218, Sangtian Street, Suzhou Industrial Park, Jiangsu, China
	Module-III Drug Substance:	Firm has submitted information related to nomenclature, structure, general properties, solubility, physical form, manufacturers, description of manufacturing process, Characterization, 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)	Based on the analysis of the completed stability study results, the drug substance is sensitive to temperature, can tolerate some degree of freezethaw, can be stored stably under the currently selected long-term stability conditions (-20 ± 5 °C), and long-term exposure to higher temperature should be avoided during use. The available stability studies support 12 months of storage at -20 ± 5 °C.
	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	The analytical procedures used for ABO1020 testing are compendial analytical procedures or in-house platform test methods. The method qualification of compendial methods such as bacterial endotoxin test and sterility test has been performed, and all other analytical procedures have been fully validated. The analytical method validation is summarized in Table 3.2.P.5.3-1, and the validation results of each analytical procedure are shown in Table 3.2.P.5.3-2 to Table 3.2.P.5.3- 12. The results of the validation parameters in all analytical procedures met the acceptance criteria, indicating that the established analytical method is suitable for the testing of ABO1020.
	Container closure system of the drug product	The container closure system of ABO1020 uses BD's prefilled syringe (1 mL) and rubber plunger, and the primary packaging materials used for this product have been strictly controlled
	Stability study data of drug product	Based on the analysis of the completed stability study results, the finished product can be stored at 5±3 °C. The finished product is sensitive to temperature, and should be protected from light. The available stability study results support the 12-month shelf life of this product when stored at 2-8 °C.

Non-clinical (Module-IV)

	Module 4 (Non-clinical / Safety)		
4.2	Study Reports		
4.2.1	Pharmacology		
	4.2.1.1	Primary Pharmacodynamics	A total of 5 research reports for the primary pharmacodynamic studies of ABO1020 was shown below including the expression analysis in vitro, the evaluation of the humoral and cellular response in Naïve mice, the immunogenicity evaluation based on AWcorna primed mice, and the study of mouse challenge.
	4.2.1.2	Secondary Pharmacodynamics	Not Applicable.
	4.2.1.3	Safety Pharmacology	We refer the safety pharmacology study data of AWcorna to support the safety pharmacology of ABO1020 as both are produced from the same platform technology with the same LNP, albeit the mRNA sequences are different between the two vaccines. Attachment 4.2.1.3-1 AWcorna: 3 cycles of repeated intramuscular administration in Cynomolgus monkeys to recover 2 weeks toxicity with Safety Pharmacology (DT-2016-068).

	4.2.1.4	Pharmacodynamic Drug Interactions	NA
4.2.2	Pharmacokinetics		Vaccines usually do not require pharmacokinetic studies in animals. During the development of the prototype vaccine AWcorna, a series of studies were carried out on the biodistribution of the vaccine and the novel ionizable lipid 9001 in the lipid delivery vector, which can be used as a reference for this product.
4.2.3	Toxicology		ABO1020 is a pharmaceutical basis and technology platform based on the available prototype vaccine AWcorna. Based on this platform technology, a novel coronavirus Omicron BA.1 mRNA vaccine ABO1009-DP has been developed. Toxicology data from AWcorna and ABO1009-DP have important reference significance for ABO1020.
	4.2.3.1	Single-Dose Toxicity (in order by species, by route)	A single-dose toxicity study with a total of 1 study report was conducted with AWcorna, Attachment 4.2.3.1-1 AWcorna: a Single-Dose Intramuscular Toxicity Study in Cynomolgus Monkeys with a 21-Day Recovery Period with an Immunogenicity, Biodistribution Study (DT2016-067
	4.2.3.2	**Repeat-Dose Toxicity (in order by species, by route, by duration; including supportive**	**ABO1020 conducted 1 repeat-dose toxicity study, with reference to the repeat-dose toxicity study with prototype vaccine AWcorna, a total of 2 study reports are shown in Table 4.2.3.2-1.** **Attachment 4.2.3.2-1 ABO1020: 3-Cycle Repeat Dose Toxicity Study via Intramuscular Injection in SD Rats with a 2-Week Recovery Period Accompanied with Immunogenicity Study(DT-2287- 451)** **Attachment 4.2.3.2-2 AWcorna: a 3-Week Repeated Dose Intramuscular Toxicity Study in Cynomolgus Monkeys with a 2-Week Recovery Period with Biodistribution,**
	4.2.3.3	Genotoxicity	AWcorna conducted 2 in vitro genotoxicity assays with a total of 2 study reports. AWcorna conducted an in vivo genotoxicity assay with a total of 1 study report.
	4.2.3.4	Carcinogenicity (including supportive toxicokinetics evaluations)	Not applicable. The mRNA vaccine does not involve relevant studies because it does not need to enter the nucleus to function, does not integrate into the genome, and does not pose a safety risk of insertional mutations.
	4.2.3.5	Reproductive and Developmental Toxicity (including range-finding studies and supportive toxicokinetics evaluations) (If modified study designs are used, the following sub-headings should be modified accordingly.)	An embryo-fetal developmental toxicity in combination with pre- and postnatal toxicity of ABO1020 was performed in Sprague-Dawley rats with a study report, Attachment 4.2.3.5-1 ABO1020: Embryo-Fetal Developmental (EFD) and Pre- and Postnatal Developmental (PPND) toxicity study via intramuscular injection in SD rats(DT-2287-501).
	4.2.3.6	Local Tolerance	A muscle stimulation study was conducted with ABO1020 with 1 study report, Attachment 4.2.3.6-1 ABO1020: Local Muscle Irritation Study in New Zealand Rabbits (DT-2287-482).

Clinical (Module-V)

Sr. No. Name Comments

5.2 Tabular Listing of All Clinical Studies

Table 5.2-1 Listing of Clinical Studies

Study Type	Study Number	Study Objectives	Study Design and Type of Control	Investigational Product: dose Regimen: route of Administration:	Number of subjects	Healthy subjects or patient diagnosis	Immunization duration	Study Status: report Type
Phase 3-Efficacy and Safety	ABO1020-301	Protective efficacy, immunogenicity, and safety	1: 1 randomized, double-blind, multicenter, placebo-controlled	ABO1020; injection (injected intramuscularly into the lateral area of the deltoid muscle of the upper arm); 0.5 ml : 15 µg ; Two vaccinations 28 days apart	14138	Healthy subjects	2 doses	Ongoing, the primary clinical endpoint has been reached and is currently in the long-term efficacy, long-term immunogenicity and long-term safety follow-up; completed protective efficacy, immunogenicity and safety analysis report
Phase 1-Safety	ABO1020-301	Safety	2: 1 Randomized, double-blind, placebo-controlled	ABO1020; injection (injected intramuscularly into the lateral area of the deltoid muscle of the upper arm); 0.5 ml : 15 µg ; Two vaccinations 28 days apart	30	Healthy subjects	2 doses	Ongoing, the primary endpoint has been reached and is currently in the long-term safety follow-up phase; safety and Immunogenicity Analysis Report Completed

5.3 Cl**inical Study Reports**

5.3.1 Reports of Biopharmaceutic Studies

5.3.1.1 Bioavailability (BA) Study Reports

NA

5.3.1.2 Comparative BA and Bioequivalence (BE) Study Reports

NA

5.3.1.3 *In vitro-In vivo* Correlation Study Reports

NA

5.3.1.4 Reports of Bioanalytical and Analytical Methods for Human Studies

A total of 2 sets of bioanalytical and analytical method reports for the Phase 1 study of the novel coronavirus variant (BA.4/5) mRNA vaccine, including detection of live virus neutralizing antibodies and RT-PCR assays, were completed at the G42 laboratory in the United Arab Emirates. A total of 9 sets of bioanalytical and analytical method reports for Phase 3 study were conducted in the G42 laboratory in the United Arab Emirates for all countries (methods were consistent with those used for Phase I); SARS-COV-2 sequencing of the UAE samples was performed at the local G42 laboratory, and the sequencing of the Philippines samples was performed at the local Detoxicare laboratory; RT-PCR testing of UAE samples was performed in the local G42 laboratory (method was consistent with Phase I), and RT-PCR testing of Philippines samples was performed in 4 local laboratories, including Detoxicare, Davao One World, Next Gen, and MJSH; RT-PCR testing of Indonesian samples was performed at the local EBDC laboratory

Test contents	Laboratory Name
Detection of Live Virus Neutralizing Antibodies in Samples from All Countries in Phase 1 and Phase 3	G42 LABORATORY L.L.C
RT-PCR testing of Phase 1 and Phase 3 UAE samples	G42 LABORATORY L.L.C
SARS-COV-2 Sequencing of Phase 3 UAE Samples	G42 LABORATORY L.L.C
Sequencing of SARS-COV-2 in Phase III Philippines Samples	Detoxicare Molecular Diagnostics Laboratory
RT-PCR Detection of Phase III Philippines Samples	Detoxicare Molecular Diagnostics Laboratory
	Next Gen PCR Diagnostic Laboratory Corp.
	Davao One World Diagnostic Center, Inc.
	Manuel J. Santos Hospital molecular Laboratory
RT-PCR Testing of Phase 3 Indonesian Samples	PT. Excellent Beneficial Diagnostic Center (EBDC)

5.3.2 Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials

NA

5.3.3 Reports of Human Pharmacokinetic (PK) Studies

NA

5.3.4 Reports of Human Pharmacodynamic (PD) Studies

NA

5.3.5 Reports of Efficacy and Safety Studies

5.3.5.2 Study Reports of Uncontrolled Clinical Studies

5.3.5.3 Reports of Analyses of Data from More Than One Study

5.3.5.1 Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication

One each report of the Phase I and Phase III Clinical Study Reports of a Novel Coronavirus Variant (BA.4/5) mRNA Vaccine.

Phase I Studies

Name of Study Drug

SARS-CoV-2 Variant (BA.4/5) mRNA Vaccine (ABO1020)

Active Pharmaceutical Ingredient

mRNA encoding for the spike protein (S protein) receptor binding

domains (RBD) of BA.4/5 (BA.4 and BA.5 have identical S protein

sequence)

Study Title

A Randomized, Double-blind, Placebo-controlled Clinical Study to

Evaluate the Efficacy, Safety, and Immunogenicity of SARS-CoV2 Variant (BA.4/5) mRNA Vaccine (ABO1020) in Healthy

Subjects Aged 18 Years and Older Who Have Completed the Full Vaccination

Investigation al Site

AI Kuwait Hospital (AI Baraha Hospital)

Duration

This report only summarizes the safety and immunogenicity results of 30 patients enrolled in

		Phase 1. The data analysis cutoff date is 30 Apr 2023, and long-term safety follow-up is still ongoing. The Phase 3 study results are detailed in a separate Phase 3 Clinical Study Report. Start time of the Phase 1 study (first subject signed the informedconsent form): 28 Nov 2022 The long-term safety follow-up of the study specified in the protocol is still ongoing. The data cutoff date for this Phase 1 analysis: 30 Apr 2023 Study Phase Phase 1. Conclusions The results of this study suggest that the sequential booster study vaccination (ABO1020) is safe and well tolerated, can induce a high level of humoral immune response against Omicron variant BA.5, and has a good cross-neutralizing ability against XBB variant at the same time, highlighting the broad-spectrum advantage that sequential booster vaccination of ABO1020 can provide good vaccine effect against both the strain of the vaccine antigen and the currently major pandemic strains **Phase III Studies** **Study Title A Randomized, Double-blind, Placebo-controlled Clinical Study to Evaluate the Efficacy, Safety, and Immunogenicity of SARS-CoV-2 Variant (BA.4/5) mRNA Vaccine (ABO1020) in Healthy Subjects Aged 18 Years and Older Who Have Completed the Full** Vaccination. Investigational Site: University of the Philippines - Philippine General Hospital Al Kuwait Hospital (Al Baraha Hospital) RSUP Persahabatan Jakarta. **Conclusion** 2 sequential booster doses of ABO1020 in people who had previously received 2 or 3 doses of inactivated COVID-19 vaccine produced high protective efficacy against COVID-19 caused by the currently prevalent variants, with predictable and controllable safety risks and the benefits outweighing the risks upon comprehensive analysis; this further enhances the immune effect for the vaccinated population, thus providing safe and effective protection. Based on the above, ABO1020 presents a safer and more effective and convenient vaccination option for personal protection and public health in the prolonged, repeated outbreaks of COVID-19 **5.3.5.2 Study Reports of Uncontrolled Clinical Studies** NA
	5.3.6 Reports of Post-Marketing Experience.	NA
	5.3.7 Case Report Forms and Individual Patient Listings	The case report forms (CRFs) for the Phase I and Phase III clinical study of the novel coronavirus variant (BA.4/5) mRNA vaccine are available. Individual patient listings for the Phase III clinical studies of the novel coronavirus variant (BA.4/5)

			mRNA vaccine are provided in Module 5.3.7-3 and the individual patient listings for the Phase I clinical studies are provided in Module 5.3.7-4.

Evaluation by BE& R

S. No.	Deficiency	Response	Evaluator Remarks
1.	(Form 5F) The application and fee should be submitted under the head/license category of DSL instead of DML for imported drug products	The submitted application "ARCOVE Pre-filled syringe 15 ug mRNA" and fee were submitted under the division of Biological Evaluation & Registration, payment head was Biological Drugs Registration Fee. By default, DML. No mentioned when we log in e-portal, it is appeared automatically. The category DSL not available on e-portal for submission.	**Submission of fee under the head of DSL is required.**
2.	(a) Original, legalized and valid Certificate of Pharmaceutical Product (CoPP) / Free Sale certificate and valid GMP certificate of the Manufacturer issued by relevant certifying regulatory authority in the country of origin and name of exporting country.	(a) The Chinese drug regulatory authority no longer issues GMP Certificate; however, GMP Compliance Statement is attached. And Drug Manufacturing Certificate is also attached. (b) Letter of authorization is attached.	**Clarification for variation in Building No. mentioned on Drug Manufacturing Certificate i.e. (2nd Floor Building 32) and Form 5 A (Building 18).** **GMP compliance statement doesn't mention the Site address.** Requirements for drug GMP and GSP administration As from December 1, 2019, drug GMP and GSP certifications shall be cancelled, and the corresponding applications / certificates shall be no longer accepted / issued. Certification applications accepted before December 1, 2019 shall be processed in accordance with the relevant provisions of the original drug GMP and GSP certification. To applications with on-site inspection completed and conformance to requirements before December 1, 2019, drug GMP and GSP certificates can be issued. On-site inspection shall be carried out even after December 1, 2019, where the current regulations require it, and the corresponding results shall be notified to the enterprise; non-compliance found in the inspections shall be dealt

				with in accordance with regulations pursuant to the Law/ **Clarification is required for different MAH address on letter of authorization.**
	3.	(1.3.4) Drug Sale License (DSL) issued by relevant licensing authority has expired.	Updated Drug Sale License has been attached.	Submitted.
	4.	(1.5.6) The pharmacopeial reference mentioned in this section is Chinese Pharmacopeia whereas, product general details mention Innovator Specifications.	Refer to the description document for analysis methods, 3.2.S.4 & 3.2.P.5.2	Innovator Specs.
	5.	1.5.9(a) The regulatory status (Approval, Emergency use authorization, under approval/not applied yet) of applied strain (SARS-CoV-2 Omicron variant BA.4/5) in any one of the reference regulatory authority specified by Registration Board in 275th meeting and country of origin 1.5.9(b) Data regarding prevalence of SARS-CoV-2 Omicron variant BA.4/5 in Pakistan.	ABO1020 has been in the process of Pre-NDA review by China Center for Drug Evaluation and its Pre-NDA submission is attached. Regarding the COVID-19 variant prevalence data for Pakistan in 2022-2023, it appears that the information might not be readily available on WHO's website. However, there are national analysis studies that provide insights into the pandemic waves in Pakistan. For instance, a study published in PLOS One analyzed five distinct pandemic waves in Pakistan, detailing the impact of different virus variants on the contours and features of each wave. **Pakistan's National Emergency Operations Centre (NEOC) in Islamabad is a likely source for such data**,	**Applicant has submitted Appointment Consultation Request Form submitted in NPMA.** **No evidence of approval submitted in any one of the reference regulatory authority specified by Registration Board in 275th meeting and country of origin** **Applicant has no data regarding prevalence of variant.**

			as they prepare daily national situation reports (Sitreps). The study mentioned above sourced its data from these reports. I recommend reaching out to the NEOC or similar national public health departments in Pakistan. They would be the most equipped to provide detailed COVID-19 research data, including variant prevalence and epidemiological trends for the years in question. Please note that the data available may not be as detailed as what is required for a comprehensive analysis, and it might be necessary to work directly with these departments to obtain the necessary information.	
	6.	(3.2.S.2.2-2.6) Information on the manufacturing process, starting materials used in the manufacture of the drug substance, Controls of Critical Steps and Intermediates, process validation and manufacturing process development is required.	See 2.3.S.2 Manufacture_ABO1020-20241029	Submitted. Name: Jiangsu GenScript ProBio Biotechology Co., Address (Zhenjiang): Building 50, No. 99 DingmouJingShiwu Road, Zhenjiang, Jiangsu, China ➢ Preparation of ABO1020-MSL, ABO1020- WSL of the strain containing VCABOP-127-2 Name: Suzhou Abogen Biosciences Co., Ltd. Address: Building 18, No. 218, Sangtian Street, Suzhou Industrial Park, Jiangsu, China ➢ Manufacturing and release of bulk purified mRNA (ABO1020-DS) ➢ Stability study
	7.	3.2.S.4.1-4.2(a) Drug substance specifications and analytical procedures used for routine testing of the Drug substance /Active Pharmaceutical Ingredient is required.	See 3.2.S.4 Control of Drug Substance_ABO1020-20241029	Submitted.
		3.2.S.4.1-4.2 (b) Monograph of drug	The drug substance of ABO1020 is an innovator product, and is solely for the	

		substance of Chinese Pharmacopoeia shall be submitted.	production of ABO1020 drug product.	
	8.	(3.2.S.4.3) Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for compendial drug substance shall be submitted	See 3.2.P.5.3 Validation of Analytical Procedures	**The Analytical Method validation studies for drug substance required as provided reports are of drug product..**
	9.	(3.2.S.7) Stability data of drug substance at long term condition till claimed shelf life as provided data is of only 9 months	See 3.2.S.7.2 Stability_ABO1020-20241029	Stability data of drug substance at long term condition till claimed shelf life i.e. 12 months have been provided.
	10.	(3.2.P.2.1) List of all components with their amount on a per unit basis and the function of the components	2.3.P.1 Description and Composition of the Drug Product_ABO1020-20241029	Submitted.
	11.	(3.2.P.3.2) A batch formula should be provided that includes a list of all components of the dosage form to be used in the manufacturing process, their amounts on a per batch basis and a reference to their quality standards.	See 3.2.P.3.2 Batch Formula_ABO1020-20241029	Submitted.
	12.	(3.2.P.4.5) A certificate shall be provided, confirming that the excipient including cholesterol is free from BSE and TSE.	Attachment : 3.2. P.4.9 Cholesterol-TSE BSE statement	Submitted.
	13.	(3.2.P.5.2) Detailed analytical procedures used for testing the drug product shall be provided.	See 3.2.P.5.2 Analytical Procedures	**Not submitted.** **Only method overview has been provided.**
	14.	(3.2.P.5.4) The copies of complete analysis of all batches for which stability data is provided in section 3.2.P.8.3.	See 3.2.P.5.4 Batch Analyses- BN 202209012 & BN 202209014 & BN 202209015	Submitted.
	15.	(a). Submit supporting documents of stability data of drug product like raw data sheets,	Reply not submitted	(a**) Supporting documents of stability data of drug product like raw data sheets, COAs etc. at each time point not submitted, only**

	COAs etc. at each time point		**COA's of initial testing are attached**.
	(b). Record of Digital data longer for temperature and humidity monitoring of stability chambers (real time and accelerated stability (conditions).		(b). Record of Digital data longer for temperature and humidity monitoring of stability chambers (real time and accelerated stability (conditions). Submitted.
16.	Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3.	Reply not submitted.	**Summary protocol for production and testing for COVID-19 mRNA Vaccine has been submitted as an evidence for BMR. Justification is required.**
17.	(Module-4, non-clinical data) Complete non-clinical studies as per ICH safety guidelines and proper justification with evidence of reference guidelines were "Not applicable" has been mentioned for non-clinical study reports.	ABO1020 has completed all non-clinical study content in accordance with the WHO vaccine guidelines	**The applicant has provided WHO guidelines on nonclinical evaluation of vaccines, instead of providing justification for not applicable against each section.** The guidelines have been reviewed and submitted data is in line WHO requirements which includes following studies: Characterization of candidate vaccines. • Immunogenicity and other pharmacodynamics studies • Toxicity assessment • Basic toxicity assessment • Additional toxicity assessments
18.	(a) Complete Phase 2 clinical studies as per ICH efficacy guidelines or scientific justification with evidence of reference guidelines for it. (b) Complete clinical trial data of Phase 1 and Phase 2 is required as per ICH efficacy guidelines (c) Submit evidence of Guidelines for the Development and Evaluation of Prophylactic Vaccines Against SARS-CoV2 Variant issued by CDE in November 2021.	**INC-E8: GENERAL CONSIDERATIONS FOR CLINICAL STUDIES** 4.3 Clinical Studies Clinical drug development, defined as studying the drug in humans, is conducted in a sequence that builds on knowledge accumulated from non-clinical and previous clinical studies. The structure of the drug development programme will be shaped by many considerations and comprised of studies with different objectives, different designs, and different	a) Justification for not performing phase II has been provided. b) Study reports for Phase 1 and Phase III submitted by the applicant. **c)** Guidelines for the Development and Evaluation of Prophylactic Vaccines Against SARS-CoV2 Variant issued by CDE in November 2021 has been submitted. **d) Clinical study Protocols not submitted, only reports are provided.** **e) Regulatory status of trails applicant has submitted approvals of Clinical Trials.**

		(d) Clinical study protocol, clinical study sites, summary results of Phase 1 and 3 along with regulatory status of these trails in relevant NRA (e)Proper justification with evidence of reference guidelines were "Not applicable" has been mentioned for clinical study reports. (f) Adverse Events Following Immunization (AEFIs) data of the vaccine in country of origin or any other NRAs.	dependencies. Although clinical drug development is often described as consisting of four temporal phases (phases 1-4), **it is important to appreciate that the phase concept is a description and not a requirement, and that the phases of drug development may overlap or be combined. Phase II Clinical Trials: After the safety and dosage of the drug have been established in Phase I trials, Phase II trials further evaluate the drug's efficacy and safety, as well as determine the optimal dosage.** ABO1020, which is developed using the same platform technology as the first-generation vaccine (AWcorna) that has already received EUA in Indonesia, has a formulation specification of 15μg, the same as Acrona. Therefore, a conventional Phase II study is not required. After Phase I safety exploration, it can directly proceed to Phase III clinical trials to verify its protective efficacy, immunogenicity, and safety in a large population. ABO1020-301_Phase I_CSR_V2.0-20231013 (attached with CSR Phase III, Section d) Guidelines for the Development and Evaluation of COVID-19 Variant Preventive Vaccines	**Indonesia(PICS member), Philippines and UAE.** f) Data on Adverse Events Following Immunization (AEFIs) data of the vaccine in country of origin or any other NRAs. g) Immunization (AEFIs) data of the vaccine of following countries have been provided: Philippines, UAE and Indonesia.

202109 Guiding Principles for the Development and Evaluation of Vaccines for Preventive Use of New Coronavirus Variant Strain (Trial)

1. Clinical study report "ABO1020-301_PhaseI_ CSR_V2.0-20231013"
2. Clinical study report "ABO1020-301_Phase III_CSR_V2. 0-20231013"
3. Regulatory approvals from UAE-MOH, CTA Philippines, and Indonesia

Guideline attached (Section c)

Adverse Events Following Immunization (AEFIs) data for ABO1020—— 20241031

Adverse Events Following Immunization (AEFIs) data for ABO1020

Stage	Country	Site	Number of enrolled subjects	Number of AE	Incidence of AE	Number of ≥G3 AE	Incidence of ≥G3 AE	Number of SAE	Inci SAE
Phase I	UAE	801	30	11	36.70%	2	6.70%	0	
Phase III	Philippines	301	1717	313	18.20%	60	3.50%	0	
		302	800	328	**41.00%**	74	9.30%	10	
		303	904	133	14.70%	13	1.40%	1	
		304	600	87	14.50%	14	2.30%	1	
		305	620	77	12.40%	4	0.60%	0	
		305A	807	191	23.70%	16	2.00%	2	
		306	621	129	20.80%	14	2.30%	3	
		307	739	244	33.00%	46	6.20%	2	
	UAE	401	**4338**	744	17.40%	61	1.40%	3	
		404	889	283	31.90%	26	2.90%	8	
		405	103	61	**59.80%**	2	2.00%	0	
	Indoenesia	101	928	630	**68.20%**	106	**11.50%**	22	
		102	86	65	**75.60%**	12	**14.00%**	0	
		104	132	89	**67.40%**	10	7.60%	3	
		105	571	363	**63.70%**	69	**12.10%**	3	
		106	283	179	**63.50%**	26	9.20%	7	
Total			**14138**	**3916**	**27.84%**	**553**	**3.93%**	**65**	

Decision of 343rd Meeting: The Registration Board deferred the applied formulation for submission of the following documents:

- The fee should be submitted under the head of DSL instead of DML.
- Clarification for variation in Building No. mentioned on Drug Manufacturing Certificate i.e. (2nd Floor Building 32) and Form 5 A (Building 18).
- GMP compliance statement doesn't mention the Site address.
- Clarification is required for different MAH address on letter of authorization.
- Evidence of approval submitted in any one of the reference regulatory authority specified by Registration Board in 275th meeting and country of origin

- Data regarding prevalence of omicron variant.
- The Analytical Method validation studies for drug substance required as provided reports are of drug product.
- Stability data of drug substance at long term condition till claimed shelf life,as 12 months stability analysis have been provided.
- Detailed analytical procedures used for testing the drug product shall be provided as only method overview has been submitted.
- Supporting documents of stability data of drug product like raw data sheets, COAs etc. at each time point not submitted, only COA's of initial testing are attached.
- Copy of Batch Manufacturing Record (BMR) for all the batches of drug product for which stability studies data is provided in Module 3.
- Clinical study Protocols as only study reports are provided.
- Evidence of published clinical studies.
- Complete listing/classification of ADRs and organ systems most commonly involved in ADRs.

Case no. 02

Registration Applications for Local Manufacturing of Human Biological Drugs
Semaglutide
New Section- Tablet (Biotech)

The CLB in its 294th meeting held on 27th December, 2023 has approved the following 01 additional section of M/s Hilton Pharma Pvt., Ltd.

- Tablet(Biotech)Section- New

The Board decided that following comments be forwarded to Drug Registration Board, for consideration and further necessary action at their end.

"Semaglutide is a peptide and therefore vulnerable to inactivation by the gastric HCl and proteolytic enzymes. The drug therefore, is formulated in combination with a permeation enhancer, Salcaprozate Sodium not only facilitates its absorption but also protects it from degradation in stomach. Any discrepancy in formulation of the tablet is likely to affect bioavailability of the active drug seriously. It is therefore strongly recommended that prior to registration, the firm may be asked to produce a test batch of the drug and get bio-equivalence studies performed from any accredited laboratory to ensure efficacy and safety of the drug in patients."

5.	Name, address of Applicant / Importer	**M/s Hilton Pharma (Pvt) Limited.** **Company Address: Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area, Karachi** **Site Address: Plot No. 13-14 & 43, Sector 15, Korangi Industrial Area, Karachi**
	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 Hilton Pharma (Pvt) Limited. Plot No. 13-14 & 43, Sector 15, Korangi Industrial Area, Karachi
	GMP of manufacturer & Evidence of Section	DML No. 000136 Grant of Additional Section –Tablet (Biotech) Section-New
	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

	Dy. No. and Date of submission	Tracking ID: 1YT-GTG-42GT Application Number: 2561 Date of Receiving: 29-11-2014
	Details of fee submitted	Challan Number: 0138946564 Division: Biological Evaluation & Registration Paid Fee: 30000.0 Paid Date: 08-11-2023
	The proposed proprietary name / brand name	**Semhil Tablets 3mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each tablet contains:** **Semaglutide..... 3mg**
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Glucagon-like peptide-1 (GLP-1) analogues ATC Code: A10BJ06
	Reference to Finished product specifications	As per Innovator's Specifications
	Proposed Pack size	7's,10's,14's,20's,28's,30's ,Alu- Alu blister
	Proposed unit price	As per DPC
	Shelf Life	24 Months
	Storage Condition	Store in a refrigerator (2 -8 °C), Do not freeze. Protect from heat and light.
	The status in reference regulatory authorities	Novo Nordisk A/S, DK-2880 Bagsvaerd, Denmark
	For generic drugs (me-too status)	Rybelsus by Novo Nordisk
	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	**M/s Sinopep-Allsino Biopharmaceutical CO., Ltd No. 28,Linpu Road, Economic & Technological Development Zone, Lianyungang, Jiangsu Province.**
	Module-III Drug Substance:	3.2.S.2: In various sections applicant have referred to DMF instead of providing documents in relevant sections. 3.2.S.4.2 and 3.2.S.4.3: Analytical Test method and validation of both drug substance and drug product manufacturer is required. 3.2.S.4.5: Justification of Specification not provided. 3.2.S.5: Justification for use of working standard instead of reference standard is required. 3.2.S.7.3: Stability data of drug substance till claimed shelf life.
	Module-III Drug Product:	The pharmaceutical Equivalence and CDP is of 14 mg tablet. 3.2. P.5.5 Characterization of impurities not performed.
	Pharmaceutical Equivalence	Pharmaceutical Equivalence and CDP is of 14mg strength.

	And CDP			
	Module IV	NA.		
	Module V	NA.		
	Sameness Evaluation data	As per USFDA is required. **Primary Sequence & Physicochemical properties:** • Complete peptide sequence analysis by Mass spectrometry • Molecular weight determination by Tris Tricine SDS-PAGE **Secondary Structure** • By circular Di-Chroism • By Capillary Iso-electric focusing **Oligomeric states** • High molecular weight proteins by Size exclusion chromatography (SEC) **Biological activities** • Determination of specific activity by in-vitro Bioassay •Protein content by ELISA		
	Bioequivalence Studies	**We commit that we will submit the Bioequivalence studies in 4-5 months.**		
	STABILITY STUDY DATA			
	Manufacturer of API	M/s Sinopep-Allsino Biopharmaceutical CO., Ltd No. 28,Linpu Road, Economic & Technological Development Zone, Lianyungang, Jiangsu Province.		
	API Lot No.	S1033201101-3		
	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, 9, 12, 18, 24 (Months)		
	Batch No.	SEM-350-01/22	SEM-351-02/22	SEM-352-03/22
	Batch Size	1247 Tablets	1247 Tablets	1247 Tablets
	Manufacturing Date	06-2022	06-2022	06-2022
	Date of Initiation	06-2022	02-2022	02-2022
	No. of Batches	03		

Administrative Portion		
1.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The provided GMP is of Bulk drug Octreotide Acetate.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Commercial Invoice is not ADC attested. Date: April 2, 2022 Semaglutide Invoice No.:34131 Batch No. S1033201101-3 Quantity of Semaglutide: 100g Mfg Date:13-10-2021 Expiry Date: 12-10-2023 Salcaprozate Sodium

		Qty. 4000 g
3.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
4.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
5.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of the Evaluator:

Sr. No.	Observation	Hilton Response
1.	**Clarification/Justification is required for manufacturing of biological product before the grant of additional section.**	**Trial batches have been manufactured in our approved R&D Lab.**
2.	3.2. A: List of analytical equipment is required along with evidence of RP UHPLC.	Supporting documents have been provided by the applicant.
3.	Drug substance Part	M/s Sinopep-Allsino Biopharmaceutical CO., Ltd No. 28,Linpu Road, Economic & Technological Development Zone, Lianyungang, Jiangsu Province.
4.	**3.2. S.2: The data should be submitted in relevant sections instead of referring to DMF.**	**It is restricted part of the DMF, however we have recently communicated with the DS manufacturer and data will be submitted shortly.**
5.	**3.2. S.4.2 and 3.2.S.4.3: Analytical Test method and validation of both drug substance and drug product manufacturer is required**	**We hereby commit that we will perform verification studies before manufacturing commercial batches.**
6.	**3.2. S.4.5: Justification of Specification is not provided.**	**It is restricted part of the DMF, however we have recently communicated with the DS manufacturer and data will be submitted shortly.**
7.	3.2. S.5. Justification for use of working standard instead of reference standard is required.	Working standard has been standardized against the manufacturer's provided standard.
8.	3.2. S.7.3: Stability data of drug substance till claimed shelf life is required	We have submitted 18 months of real-time stability data and commit to providing the complete stability data for the drug substance (DS) prior to the manufacture of commercial batches. Storage Condition: -20C
9.	**3.2. P.2.2.1: The pharmaceutical Equivalence and CDP is of 14 mg tablet instead of applied strength**	**Our formulation of all the three strengths (3mg, 7mg & 14mg) are same with respect to same excipient quantities and the difference is only in the API quantity.**

	10.	**3.2. P.5.1: The water content, peptide mapping, high molecular weight protein, hydrophilic impurities, hydrophobic impurities 1, hydrophobic impurities 2 is not performed as per innovator specifications. Justification is required.**	**Peptide Mapping:** **It is not the part of our specification, however Amino acid ratio was checked / performed by API manufacturer. COA Provided.** **High Molecular Weight /hydrophilic impurities/ hydrophobic impurities 1/ hydrophobic impurities 2:** **These are not the part of our's as well as manufacturer's specifications**
	11.	**3.2. P.5.3: The analytical method validation reports of all the analytical tests are required**	**Complete Analytical method validation will be submitted prior to manufacturing the commercial batches.**
	12.	3.2. P.5.5 Characterization of impurities has not been performed	SPC054-Z60 SPC054-Z69 SPC054-Z76 Above degradation impurities have been characterized with known impurity standard in finished product and relative retention times (RRT) are mentioned in Finished product specification, Chromatogram are provided
	13.	**3.2.P.8.3: Stability of specification should include water content, peptide mapping, high molecular weight protein, hydrophilic impurities, hydrophobic impurities 1, hydrophobic impurities 2 is not performed as per innovator specifications. Justification is required**	**Water content:** **LOD has been checked after drying of granules.** **Peptide Mapping:** **It is not the part of our specification, however Amino acid ratio was checked / performed by API manufacturer. COA Provided** **High Molecular Weight /hydrophilic impurities/ hydrophobic impurities 1/ hydrophobic impurities 2:** **These are not the part of our 's as well as manufacturer's specifications.**
	14.	3.2.P.8.3: The chromatograms of six-month time point are not submitted	Provided But audit trail report not clear. Assessor Remarks PSI will be done.
	15.	Module IV and Module V or Bio-similarity Studies.	Sameness Evaluation Studies provided by the firm of drug substance manufacturer. Reference Listed Product. Ozempic ® (semaglutide) injection (0.5mg/1mg) in pre-filled single-patient-use pen device.
	16.	**The Bioequivalence Studies are required**	**We commit that we will submit the Bioequivalence studies in 4-5 months.**
	17.	**Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin**	**GMP certificate is of Octreotide.**
	18.	The ADC attested commercial invoices needs to be submitted	Invoice is not ADC attested. Shipment Document
	19.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

	Previous Decision of 340th Meeting of Registration Board Pertinent to Semaglutide Tablets Approval: Keeping in view the above mentioned facts and after thorough deliberations, Registration Board decided to approve Semaglutide 3mg, 7mg and 14mg tablets in name of M/s Weather Folds Pharmaceuticals, Plot No 69/2, Phase 2, Industrial Estate Hattar, Pakistan and in name of M/s. Jupiter Pharma, Plot No. 25, Street No. S-6, National Industrial Zone (RCCI) Rawat, Rawalpindi to be manufactured on contract basis by M/s Weather Folds' Pharmaceuticals, Plot No 69/2, Phase 2, Industrial estate Hattar subject to following: a. Product Specific Inspection (PSI) by the below mentioned panel: 1. Dr. Ali Jan, Member Registration Board/Director, Director Drug Testing Laboratory, Quetta. 2. Mr. Atiq ul Bari, Federal Inspector of Drugs, DRAP Peshawar b. The firm will perform the post marketing surveillance studies. c. The firm will make arrangements for the ADR reporting as per Rules. d. The firm will submit the quarterly safety Reports to the Registration Board. e. The manufacturer shall perform identification test for peptide mapping for finished product from any of Government Drug Testing Laboratory for every batch and during the aforesaid period the manufacturer shall install LC/MS in their own facility and in form Registration Board. f. The manufacturer shall perform Bioequivalence Studies within six months. The Registration Board also decided to conduct the Product Specific Inspection (PSI) of the manufacturers holding registrations of Semaglutide containing products. Furthermore, the Board also decided to conduct Product Specific Inspection (PSI) for all future applications for grant of registration of Semaglutide containing products/ dosage forms.

Proceedings of the Board

Keeping in view the previously granted registrations and on the basis of already well eastblished principles for grant of registeration to semaglutide tablets and considering the guidelines on "ANDAs for Certain Highly Purified Synthetic Peptide Drug Products that refer to listed drugs of rDNA Origin" by USFDA 2021 (CDER), the Board was apprised that the drug substance manufacturer has established sameness of synthetically produced active ingredient through physicochemical characterization and biological evaluation against reference listed drug, Ozempic ® (semaglutide) injection (0.5mg/1mg) in pre-filled single-patient-use pen device.

The Board was further apprised with the following facts of the instant case for deliberation and final decision:

- The drug substance and drug product manufacturer have not clearly identified/segregated the peptide related impurities and new specified impurities, if any. But as the level of each impurity is <0.1% therefore, it can be asserted that the active ingredient in Semahil Tablets 3mg, 7mg and 14mg is same as of innovator product.
- The Board was further acquainted that the trial batches were manufactured in research and development laboratory in 2022 whereas, the section was granted in 2024. This means that when the product was developed, the manufacturer did not have the requisite approved manufacturing facility /section.
- Moreover, the drug product manufacturer did not perform the identification test i.e., peptide mapping by UHPLC-HRMS, analytical method validation report of both drug substance and drug product by the applicant, pharmaceutical equivalence, and CDP of 3mg and 7mg and bioequivalence of all the three strength 3mg, 7mg and 14mg.

In the light of the above findings, the Board unanimously was of the view that aforementioned deficiencies must be fulfilled by the applicant before the issuance of Registration letter.

Decision of 343rd Meeting: Approved "as per innovator's specifications".

Registration Board decided that registration letter will be issued subject to the following conditions:

a. **Submission of the following documents by the manufacturer:**
   - **3.2.S.2: Drug substance manufacturer's data in the relevant sections instead of referring to DMF.**
   - **3.2.S.4.2 and 3.2.S.4.3: Analytical Test method and its validation performed by drug product manufacturer.**
   - **3.2.S.4.5: Justification of Specifications.**

- **Conducting of Pharmaceutical equivalence and CDP of Semaglutide Tablet 3 mg and 7mg.**
- **Revision of Finished Product specifications to include identification test through Peptide mapping along with evidence of test performance from any of Government Drug Testing Laboratory for every batch till the time the manufacturer installs LC/MS in their own facility and inform Registration Board.**
- **Identification and quantification of peptide related impurities including High Molecular Weight Proteins (HMWP).**
- **3.2.P.5.3: Analytical method validation report.**

b. PSI by under mentioned panel to verify the authenticity of stability data along with inspection of research and development laboratory to ensure facilities and controls used for the manufacture, processing, and packing of the stability batches were adequate to assure and preserve their identity, strength, quality, and purity.

- **Dr. Ali Jan, Member Registration Board/Director, Director Drug Testing Laboratory, Quetta.**
- **Mr. Sajjad Ahmed Abbassi, Deputy Director, CDL, DRAP, Karachi.**

Additionally, after registration the applicant is responsible to perform and submit the following:

Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.
Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.

- **PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. (Timeline may be discussed with Reg Board)**

2.	Name, address of Applicant / Importer	**M/s Hilton Pharma (Pvt) Limited.** **Company Address: Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area** **Site Address: Plot No. 13-14 & 43, Sector 15, Korangi Industrial Area**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Bulk Import and Local Repack ☐ Is involved in none of the above
	Name, address of manufacturer(s)	Plot No. 13-14 & 43, Sector 15, Korangi Industrial Area
	GMP of manufacturer & Evidence of Section	DML No. 000136 Grant of Additional Section – Tablet (Biotech) Section-New
	Status of application	x 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
	Dy. No. and Date of submission	Tracking ID: VX1-7TZ-6NJ2 Application Number: 2580 Date of Receiving: 29-11-2014
	Details of fee submitted	Challan Number: 77752245 Division: Biological Evaluation & Registration Paid Fee: 30000.0 Paid Date: 25-11-2023 Differential Fee: Rs 45000/-
	The proposed proprietary name / brand name	**Semhil Tablets 7mg**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each tablet contains:** **Semaglutide..... 7mg**
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Glucagon-like peptide-1 (GLP-1) analogues ATC Code: A10BJ06
	Reference to Finished product specifications	As per Innovator's Specifications
	Proposed Pack size	7's,10's,14's,20's,28's,30's ,Alu- Alu blister
	Proposed unit price	As per DPC
	Shelf Life	24 Months
	Storage Condition	Store in a refrigerator (2 -8 °C), Do not freeze. Protect from heat and light.
	The status in reference regulatory authorities	Novo Nordisk A/S, DK-2880 Bagsvaerd, Denmark
	For generic drugs (me-too status)	Rybelsus by Novo Nordisk
	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	M/s Sinopep-Allsino Biopharmaceutical CO., Ltd No. 28,Linpu Road, Economic & Technological Development Zone, Lianyungang, Jiangsu Province.
	Module-III Drug Substance:	3.2.S.2: In various sections applicant have referred to DMF instead of providing documents in relevant sections. 3.2.S.4.2 and 3.2.S.4.3: Analytical Test method and validation of both drug substance and drug product manufacturer is required. 3.2.S.4.5: Justification of Specification not provided. 3.2.S.5: Justification for use of working standard instead of reference standard is required. 3.2.S.7.3: Stability data of drug substance till claimed shelf life.
	Module-III Drug Product:	The pharmaceutical Equivalence and CDP is of 14 mg tablet. 3.2.P.5.5 Characterization of impurities not performed
	Pharmaceutical Equivalence And CDP	Pharmaceutical Equivalence and CDP is of 14mg strength.
	Module IV	NA
	Module V	NA
	Or Sameness Evaluation data	As per USFDA is required. **Primary Sequence & Physicochemical properties:** • Complete peptide sequence analysis by Mass spectrometry • Molecular weight determination by Tris Tricine SDS-PAGE **Secondary Structure** • By circular Di-Chroism • By Capillary Iso-electric focusing

		Oligomeric states • High molecular weight proteins by Size exclusion chromatography (SEC) **Biological activities** • Determination of specific activity by in-vitro Bioassay •Protein content by ELISA		
	STABILITY STUDY DATA			
	Manufacturer of API	M/s Sinopep-Allsino Biopharmaceutical CO., Ltd No. 28,Linpu Road, Economic & Technological Development Zone, Lianyungang, Jiangsu Province.		
	API Lot No.	S1033201101-3		
	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, 9, 12, 18, 24 (Months)		
	Batch No.	SEM-347-01/22	SEM-348-02/22	SEM-349-03/22
	Batch Size	1235 Tablets	1235 Tablets	1235 Tablets
	Manufacturing Date	06-2022	06-2022	06-2022
	Date of Initiation	06-2022	02-2022	02-2022
	No. of Batches	03		
Administrative Portion				
1.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	The provided GMP is of Bulk drug Octreotide Acetate.		
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Commercial Invoice is not ADC attested. Date: April 2, 2022 Semaglutide Invoice No.:34131 Batch No. S1033201101-3 Quantity of Semaglutide: 100g Mfg Date:13-10-2021 Expiry Date: 12-10-2023 Salcaprozate Sodium Qty. 4000 g		
3.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.		
4.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted		
5.	Record of Digital data logger for temperature and humidity	Submitted.		

	monitoring of stability chambers (real time and accelerated)	

Remarks of Deputy Director IV:

Sr. No.	Observation	Hilton Response
1.	**Clarification/Justification is required for manufacturing of biological product before the grant of additional section.**	**Trial batches have been manufactured in our approved R&D Lab.**
2.	3.2. A: List of analytical equipment is required along with evidence of RP UHPLC.	Supporting documents have been provided by the applicant.
3.	Drug substance Part	M/s Sinopep-Allsino Biopharmaceutical CO., Ltd No. 28,Linpu Road, Economic & Technological Development Zone, Lianyungang, Jiangsu Province.
4.	**3.2. S.2: The data should be submitted in relevant sections instead of referring to DMF.**	**It is restricted part of the DMF, however we have recently communicated with the DS manufacturer and data will be submitted shortly.**
5.	**3.2. S.4.2 and 3.2.S.4.3: Analytical Test method and validation of both drug substance and drug product manufacturer is required**	**We hereby commit that we will perform verification studies before manufacturing commercial batches.**
6.	**3.2. S.4.5: Justification of Specification is not provided.**	**It is restricted part of the DMF, however we have recently communicated with the DS manufacturer and data will be submitted shortly.**
7.	3.2. S.5. Justification for use of working standard instead of reference standard is required.	Working standard has been standardized against the manufacturer's provided standard.
8.	3.2. S.7.3: Stability data of drug substance till claimed shelf life is required	We have submitted 18 months of real-time stability data and commit to providing the complete stability data for the drug substance (DS) prior to the manufacture of commercial batches. Storage Condition: -20C
9.	**3.2. P.2.2.1: The pharmaceutical Equivalence and CDP is of 14 mg tablet instead of applied strength**	**Our formulation of all the three strengths (3mg, 7mg & 14mg) are same with respect to same excipient quantities and the difference is only in the API quantity.**
10.	**3.2. P.5.1: The water content, peptide mapping, high molecular weight protein, hydrophilic impurities, hydrophobic impurities 1, hydrophobic impurities 2 is not performed as per innovator specifications. Justification is required.**	**Peptide Mapping:** **It is not the part of our specification, however Amino acid ratio was checked / performed by API manufacturer. COA Provided.** **High Molecular Weight /hydrophilic impurities/ hydrophobic impurities 1/ hydrophobic impurities 2:** **These are not the part of our's as well as manufacturer's specifications**
11.	**3.2. P.5.3: The analytical method validation reports of all the analytical tests are required**	**Complete Analytical method validation will be submitted prior to**

		manufacturing the commercial batches.
12.	3.2. P.5.5 Characterization of impurities has not been performed	SPC054-Z60 SPC054-Z69 SPC054-Z76 Above degradation impurities have been characterized with known impurity standard in finished product and relative retention times (RRT) are mentioned in Finished product specification, Chromatogram are provided
13.	**3.2.P.8.3: Stability of specification should include water content, peptide mapping, high molecular weight protein, hydrophilic impurities, hydrophobic impurities 1, hydrophobic impurities 2 is not performed as per innovator specifications. Justification is required**	**Water content:** **LOD has been checked after drying of granules** **Peptide Mapping:** **It is not the part of our specification, however Amino acid ratio was checked / performed by API manufacturer. COA Provided** **High Molecular Weight /hydrophilic impurities/ hydrophobic impurities 1/ hydrophobic impurities 2:** **These are not the part of our 's as well as manufacturer's specifications**
14.	3.2.P.8.3: The chromatograms of six-month time point are not submitted	Provided But audit trail report not clear.
15.	Module IV and Module V or Bio-similarity Studies.	Sameness Evaluation Studies provided by the firm of drug substance manufacturer. Reference Listed Product. Ozempic ® (semaglutide) injection (0.5mg/1mg) in pre-filled single-patient-use pen device.
16.	**The Bioequivalence Studies are required**	**We commit that we will submit the Bioequivalence studies in 4-5 months**
17.	**Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin**	**GMP certificate is of Octreotide.**
18.	The ADC attested commercial invoices needs to be submitted	Invoice is not ADC attested. Shipment Document
19.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Previous Decisions of Registration Board Pertinent to Semaglutide Tablets Approval:

Keeping in view the above mentioned facts and after thorough deliberations, Registration Board decided to approve Semaglutide 3mg, 7mg and 14mg tablets in name of M/s Weather Folds Pharmaceuticals, Plot No 69/2, Phase 2, Industrial Estate Hattar, Pakistan and in name of M/s. Jupiter Pharma, Plot No. 25, Street No. S-6, National Industrial Zone (RCCI) Rawat, Rawalpindi to be manufactured on contract basis by M/s Weather Folds' Pharmaceuticals, Plot No 69/2, Phase 2, Industrial estate Hattar subject to following:

a. Product Specific Inspection (PSI) by the below mentioned panel:
   1. Dr. Ali Jan, Member Registration Board/Director, Director Drug Testing Laboratory, Quetta.
   2. Mr. Atiq ul Bari, Federal Inspector of Drugs, DRAP Peshawar

b. The firm will perform the post marketing surveillance studies.

c. The firm will make arrangements for the ADR reporting as per Rules.

d. The firm will submit the quarterly safety Reports to the Registration Board.

e. The manufacturer shall perform identification test for peptide mapping for finished product from any of Government Drug Testing Laboratory for every batch and during the aforesaid period the manufacturer shall install LC/MS in their own facility and in form Registration Board.
f. The manufacturer shall perform Bioequivalence Studies within six months.
The Registration Board also decided to conduct the Product Specific Inspection (PSI) of the manufacturers holding registrations of Semaglutide containing products.
Furthermore, the Board also decided to conduct Product Specific Inspection (PSI) for all future applications for grant of registration of Semaglutide containing products/ dosage forms.

Proceedings of the Board

Keeping in view the previously granted registrations to semaglutide tablets and considering the guidelines on "ANDAs for Certain Highly Purified Synthetic Peptide Drug Products that refer to listed drugs of rDNA Origin" by USFDA 2021 (CDER), the Board was apprised that the drug substance manufacturer has established sameness of synthetically produced active ingredient through physicochemical characterization and biological evaluation against reference listed drug, Ozempic ® (semaglutide) injection (0.5mg/1mg) in pre-filled single-patient-use pen device.

The Board was further apprised with the following facts of the instant case for deliberation and final decision:

- The drug substance and drug product manufacturer have not clearly identified/segregated the peptide related impurities and new specified impurities, if any. But as the level of each impurity is <0.1% therefore, it can be asserted that the active ingredient in Semahil Tablets 3mg, 7mg and 14mg is same as of innovator product.
- The Board was further acquainted that the trial batches were manufactured in research and development laboratory in 2022 whereas, the section was granted in 2024. This means that when the product was developed, the manufacturer did not have the requisite approved manufacturing facility /section.
- Moreover, the drug product manufacturer did not perform the identification test i.e., peptide mapping by UHPLC-HRMS, analytical method validation report of both drug substance and drug product by the applicant, pharmaceutical equivalence, and CDP of 3mg and 7mg and bioequivalence of all the three strength 3mg, 7mg and 14mg.

In the light of the above findings, the Board unanimously was of the view that aforementioned deficiencies must be fulfilled by the applicant before the issuance of Registration letter.

Decision of 343rd Meeting: Approved "as per innovator's specifications".

Registration Board decided that registration letter will be issued subject to the following conditions:

a. **Submission of the following documents by the manufacturer:**
   - **3.2.S.2: Drug substance manufacturer's data in the relevant sections instead of referring to DMF.**
   - **3.2.S.4.2 and 3.2.S.4.3: Analytical Test method and its validation performed by drug product manufacturer.**
   - **3.2.S.4.5: Justification of Specifications.**
   - **Conducting of Pharmaceutical equivalence and CDP of Semaglutide Tablet 3 mg and 7mg.**
   - **Revision of Finished Product specifications to include identification test through Peptide mapping along with evidence of test performance from any of Government Drug Testing Laboratory for every batch till the time the manufacturer installs LC/MS in their own facility and inform Registration Board.**
   - **Identification and quantification of peptide related impurities including High Molecular Weight Proteins (HMWP).**
   - **3.2.P.5.3: Analytical method validation report.**
b. **PSI by under mentioned panel to verify the authenticity of stability data along with inspection of research and development laboratory to ensure facilities and controls used for the manufacture, processing, and packing of the stability batches were adequate to assure and preserve their identity, strength, quality, and purity.**
   - **Dr. Ali Jan, Member Registration Board/Director, Director Drug Testing Laboratory, Quetta.**
   - **Mr. Sajjad Ahmed Abbassi, Deputy Director, CDL, DRAP, Karachi.**

Additionally, after registration the applicant is responsible to perform and submit the following:

	Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022. **PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. (Timeline may be discussed with Reg Board)**	
3.	Name, address of Applicant / Importer	**M/s Hilton Pharma (Pvt) Limited.** **Company Address: Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area** **Site Address: Plot No. 13-14 & 43, Sector 15, Korangi Industrial Area**
	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 Hilton Pharma (Pvt) Limited. Plot No. 13-14 & 43, Sector 15, Korangi Industrial Area
	GMP of manufacturer & Evidence of Section	DML No. 000136 Grant of Additional Section – Tablet (Biotech) Section-New
	Status of application	x 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
	Dy. No. and Date of submission	Tracking ID: N7S-DG9-165J Application Number: 2581 Date of Receiving: 29-11-2014
	Details of fee submitted	Challan Number:957177839216 Division: Biological Evaluation & Registration Paid Fee: 30000.0 Challan Number:1678822544 Paid Date: 22-11-2023 Differential Fee: Rs 45000/-
	The proposed proprietary name / brand name	Semhil Tablets 14mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each tablet contains: Semaglutide..... 14mg
	Pharmaceutical form of applied drug	Tablet
	Pharmacotherapeutic Group of (API)	Glucagon-like peptide-1 (GLP-1) analogues ATC Code: A10BJ06
	Reference to Finished product specifications	As per Innovator's Specifications.
	Proposed Pack size	7's,10's,14's,20's,28's,30's ,Alu- Alu blister
	Proposed unit price	As per DPC
	Shelf Life	24 Months
	Storage Condition	Store in a refrigerator (2 -8 °C), Do not freeze. Protect from heat and light.

	The status in reference regulatory authorities	Novo Nordisk A/S, DK-2880 Bagsvaerd, Denmark
	For generic drugs (me-too status)	Rybelsus by Novo Nordisk
	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	M/s Sinopep-Allsino Biopharmaceutical CO., Ltd No. 28,Linpu Road, Economic & Technological Development Zone, Lianyungang, Jiangsu Province.
	Module-III Drug Substance:	3.2.S.2: In various sections applicant have referred to DMF instead of providing documents in relevant sections. 3.2.S.4.2 and 3.2.S.4.3: Analytical Test method and validation of both drug subs. and drug product manufacturer is required. 3.2.S.4.4: COA of Batch No: S1033201101-3 is submitted. 3.2.S.4.5: Justification of Specification not provided. 3.2.S.5: Justification for use of working standard instead of reference standard.is required. 3.2.S.7.3 : Stability data of drug substance till claimed shelf life is required.
	Module-III Drug Product:	The pharmaceutical Equivalence and CDP is of 14 mg tablet. 3.2.P.5.5 Characterization of impurities not performed
	Pharmaceutical Equivalence And CDP	Pharmaceutical Equivalence and CDP is of 14mg strength.
	Module IV	NA
	Module V	NA
	Or Sameness Evaluation data	As per USFDA is required. **Primary Sequence & Physicochemical properties:** • Complete peptide sequence analysis by Mass spectrometry • Molecular weight determination by Tris Tricine SDS-PAGE **Secondary Structure** • By circular Di-Chroism • By Capillary Iso-electric focusing **Oligomeric states** • High molecular weight proteins by Size exclusion chromatography (SEC) **Biological activities** • Determination of specific activity by in-vitro Bioassay •Protein content by ELISA
	Bioequivalence Studies	**We commit that we will submit the Bioequivalence studies in 4-5 months.**
STABILITY STUDY DATA		
	Manufacturer of API	M/s Sinopep-Allsino Biopharmaceutical CO., Ltd No. 28,Linpu Road, Economic & Technological Development Zone, Lianyungang, Jiangsu Province.

	API Lot No.	S1033201101-3		
	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, 9, 12, 18, 24 (Months)		
	Batch No.	SEM-340-04/22	SEM-342-05/22	SEM-343-06/22
	Batch Size	1214 Tablets	1214 Tablets	1214 Tablets
	Manufacturing Date	06-2022	06-2022	06-2022
	Date of Initiation	06-2022	02-2022	02-2022
	No. of Batches	03		

Administrative Portion		
1.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.	Not Submitted. The provided GMP is of Bulk drug Octreotide Acetate.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Commercial Invoice is not ADC attested. Date: April 2, 2022 Semaglutide Invoice No.:34131 Batch No. S1033201101-3 Quantity of Semaglutide: 100g Mfg Date:13-10-2021 Expiry Date: 12-10-2023 Salcaprozate Sodium Qty. 4000 g
3.	Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc.	Submitted.
4.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing	Submitted
5.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Submitted.

Remarks of Deputy Director IV:

Sr. No.	Observation	Hilton Response
1.	**Clarification/Justification is required for manufacturing of biological product before the grant of additional section.**	**Trial batches have been manufactured in our approved R&D Lab.**
2.	3.2. A: List of analytical equipment is required along with evidence of RP UHPLC.	Supporting documents have been provided by the applicant.
3.	Drug substance Part	M/s Sinopep-Allsino Biopharmaceutical CO., Ltd No. 28,Linpu Road, Economic & Technological Development Zone, Lianyungang, Jiangsu Province.

4.	**3.2. S.2: The data should be submitted in relevant sections instead of referring to DMF.**	**It is restricted part of the DMF, however we have recently communicated with the DS manufacturer and data will be submitted shortly.**
5.	**3.2. S.4.2 and 3.2.S.4.3: Analytical Test method and validation of both drug substance and drug product manufacturer is required**	**We hereby commit that we will perform verification studies before manufacturing commercial batches.**
6.	**3.2. S.4.5: Justification of Specification is not provided.**	**It is restricted part of the DMF, however we have recently communicated with the DS manufacturer and data will be submitted shortly.**
7.	3.2. S.5. Justification for use of working standard instead of reference standard is required.	Working standard has been standardized against the manufacturer's provided standard.
8.	3.2. S.7.3: Stability data of drug substance till claimed shelf life is required	We have submitted 18 months of real-time stability data and commit to providing the complete stability data for the drug substance (DS) prior to the manufacture of commercial batches. Storage Condition: -20C
9.	**3.2. P.5.1: The water content, peptide mapping, high molecular weight protein, hydrophilic impurities, hydrophobic impurities 1, hydrophobic impurities 2 is not performed as per innovator specifications. Justification is required.**	**Peptide Mapping:** **It is not the part of our specification, however Amino acid ratio was checked / performed by API manufacturer. COA Provided.** **High Molecular Weight /hydrophilic impurities/ hydrophobic impurities 1/ hydrophobic impurities 2:** **These are not the part of our's as well as manufacturer's specifications**
10.	**3.2. P.5.3: The analytical method validation reports of all the analytical tests are required**	**Complete Analytical method validation will be submitted prior to manufacturing the commercial batches.**
11.	3.2. P.5.5 Characterization of impurities has not been performed	SPC054-Z60 SPC054-Z69 SPC054-Z76 Above degradation impurities have been characterized with known impurity standard in finished product and relative retention times (RRT) are mentioned in Finished product specification, Chromatogram are provided
12.	**3.2.P.8.3: Stability of specification should include water content, peptide mapping, high molecular weight protein, hydrophilic impurities, hydrophobic impurities 1, hydrophobic impurities 2 is not performed as per innovator specifications. Justification is required**	**Water content:** **LOD has been checked after drying of granules** **Peptide Mapping:** **It is not the part of our specification, however Amino acid ratio was checked / performed by API manufacturer. COA Provided** **High Molecular Weight /hydrophilic impurities/ hydrophobic impurities 1/ hydrophobic impurities 2:** **These are not the part of our 's as well as manufacturer's specifications**
13.	3.2.P.8.3: The chromatograms of six-month time point are not submitted	Provided But audit trail report not clear.

14.	Module IV and Module V or Bio-similarity Studies.	Sameness Evaluation Studies provided by the firm of drug substance manufacturer. Reference Listed Product. Ozempic ® (semaglutide) injection (0.5mg/1mg) in pre-filled single-patient-use pen device.
15.	**The Bioequivalence Studies are required**	**We commit that we will submit the Bioequivalence studies in 4-5 months.**
16.	**Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin**	**GMP certificate is of Octreotide.**
17.	The ADC attested commercial invoices needs to be submitted	Invoice is not ADC attested. Shipment Document
18.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Provided

Previous Decisions of Registration Board Pertinent to Semaglutide Tablets Approval:

Keeping in view the above mentioned facts and after thorough deliberations, Registration Board decided to approve Semaglutide 3mg, 7mg and 14mg tablets in name of M/s Weather Folds Pharmaceuticals, Plot No 69/2, Phase 2, Industrial Estate Hattar, Pakistan and in name of M/s. Jupiter Pharma, Plot No. 25, Street No. S-6, National Industrial Zone (RCCI) Rawat, Rawalpindi to be manufactured on contract basis by M/s Weather Folds' Pharmaceuticals, Plot No 69/2, Phase 2, Industrial estate Hattar subject to following:

a. Product Specific Inspection (PSI) by the below mentioned panel:
   1. Dr. Ali Jan, Member Registration Board/Director, Director Drug Testing Laboratory, Quetta.
   2. Mr. Atiq ul Bari, Federal Inspector of Drugs, DRAP Peshawar

b. The firm will perform the post marketing surveillance studies.
c. The firm will make arrangements for the ADR reporting as per Rules.
d. The firm will submit the quarterly safety Reports to the Registration Board.
e. The manufacturer shall perform identification test for peptide mapping for finished product from any of Government Drug Testing Laboratory for every batch and during the aforesaid period the manufacturer shall install LC/MS in their own facility and in form Registration Board.
f. The manufacturer shall perform Bioequivalence Studies within six months.

The Registration Board also decided to conduct the Product Specific Inspection (PSI) of the manufacturers holding registrations of Semaglutide containing products.

Furthermore, the Board also decided to conduct Product Specific Inspection (PSI) for all future applications for grant of registration of Semaglutide containing products/ dosage forms.

Proceedings of the Board

Keeping in view the previously granted registrations to semaglutide tablets and considering the guidelines on "ANDAs for Certain Highly Purified Synthetic Peptide Drug Products that refer to listed drugs of rDNA Origin" by USFDA 2021 (CDER), the Board was apprised that the drug substance manufacturer has established sameness of synthetically produced active ingredient through physicochemical characterization and biological evaluation against reference listed drug, Ozempic ® (semaglutide) injection (0.5mg/1mg) in pre-filled single-patient-use pen device.

The Board was further apprised with the following facts of the instant case for deliberation and final decision:

- The drug substance and drug product manufacturer have not clearly identified/segregated the peptide related impurities and new specified impurities, if any. But as the level of each impurity is <0.1% therefore, it can be asserted that the active ingredient in Semahil Tablets 3mg, 7mg and 14mg is same as of innovator product.
- The Board was further acquainted that the trial batches were manufactured in research and development laboratory in 2022 whereas, the section was granted in 2024. This means that when the product was developed, the manufacturer did not have the requisite approved manufacturing facility /section.

- Moreover, the drug product manufacturer did not perform the identification test i.e., peptide mapping by UHPLC-HRMS, analytical method validation report of both drug substance and drug product by the applicant, pharmaceutical equivalence, and CDP of 3mg and 7mg and bioequivalence of all the three strength 3mg, 7mg and 14mg.

In the light of the above findings, the Board unanimously was of the view that aforementioned deficiencies must be fulfilled by the applicant before the issuance of Registration letter.

Decision of 343rd Meeting: Approved "as per innovator's specifications".
Registration Board decided that registration letter will be issued subject to the following conditions:

a. **Submission of the following documents by the manufacturer:**
   - **3.2.S.2: Drug substance manufacturer's data in the relevant sections instead of referring to DMF.**
   - **3.2.S.4.2 and 3.2.S.4.3: Analytical Test method and its validation performed by drug product manufacturer.**
   - **3.2.S.4.5: Justification of Specifications.**
   - **Conducting of Pharmaceutical equivalence and CDP of Semaglutide Tablet 3 mg and 7mg.**
   - **Revision of Finished Product specifications to include identification test through Peptide mapping along with evidence of test performance from any of Government Drug Testing Laboratory for every batch till the time the manufacturer installs LC/MS in their own facility and inform Registration Board.**
   - **Identification and quantification of peptide related impurities including High Molecular Weight Proteins (HMWP).**
   - **3.2.P.5.3: Analytical method validation report.**

b. **PSI by under mentioned panel to verify the authenticity of stability data along with inspection of research and development laboratory to ensure facilities and controls used for the manufacture, processing, and packing of the stability batches were adequate to assure and preserve their identity, strength, quality, and purity.**
   - **Dr. Ali Jan, Member Registration Board/Director, Director Drug Testing Laboratory, Quetta.**
   - **Mr. Sajjad Ahmed Abbassi, Deputy Director, CDL, DRAP, Karachi.**

Additionally, after registration the applicant is responsible to perform and submit the following:

Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.

Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.

PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. (Timeline may be discussed with Reg Board)

Case No. 3: Deferred Cases of Imported Human Biological Products:

4.	**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:** 0375 **Address:** Roche Pakistan Limited, 1st floor, 37-B, Block 6, PECHS, Karachi. **Address of Godown:** • R-PI, Plot no. 56, sector 15, K.I.A, Karachi **Validity:** 07/11/2028. **Status:** Drug License by way of wholesale **Renewal:** N/A
	Name and address of marketing authorization holder (abroad)	Genentech, Inc. (A member of the Roche Group), 1 DNA Way, PDRO Building 35, MS 355J, South San Francisco, CA 94080, United States Of America **As per Form 5 F.**
	Name, address of manufacturer(s)	**Manufacture of Drug Product (including primary packaging)** Genentech, Inc.

		1 DNA Way South San Francisco, CA 94080 United States **Secondary Packaging Site** Name of Manufacturing Site Address Activity F. Hoffmann-La Roche Ltd Wurmisweg, Kaiseraugst, Argovia CH-4303 SWITZERLAND
	Name of exporting country	Switzerland
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**Firm has submitted valid eCOPP.** **Certificate Number: HDAB-GJS5** **Certificate Issued Date: October 15, 2024** **Certificate Expiration Date: October 15, 2026** **Marketing authorization holder (name and address):** Genentech, Inc. (A Member of the Roche Group), 1 DNA Way, PDRO Building 35, MS 355J, South San Francisco, CA 94080 United States of America, U.S. License Number: 1048 **Manufacturer name & address:** Genentech, Inc., 1 DNA Way, South San Francisco, CA 94080 United States of America **Packager** Name of Manufacturing Site Address Activity F. Hoffmann-La Roche Ltd Wurmisweg, Kaiseraugst, Argovia CH-4303 SWITZERLAND
	Details of letter of authorization / sole agency agreement	• **Product Specific authorization letter** The M/s F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, CH-4070 Basel Switzerland in name of M/s Roche Pakistan Limited, Karachi dated 13-07-2023. • **Relationship letter** M/s F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, CH-4070 Basel Switzerland,a Swiss Stock Corporation is the operational headquarter company of the Roche group.
	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. 397 dated:11, September 2023.
	Details of fee submitted	**Deposit Slip no**. 8963946807, **PKR** 75,000, **Dated:** 20-07-2023
	The proposed proprietary name / brand name	**Columvi 2.5mg/2.5ml** **Concentrate for Solution for Infusion**
	Strength / concentration of drug of Active	**Each single dose vial contains** Glofitamab…2.5mg

	Pharmaceutical ingredient (API) per unit	
	Dosage form of applied drug	Intravenous Use (Concentrate for solution for infusion)
	Pharmacotherapeutic Group of (API) and Indication	Antineoplastic (Monoclonal Antibodies) ATC code: L01FX28 Columvi is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy.
	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	USFDA Accelerated Approval. EMA Conditional Marketing Authorization. TGA Provisional Approval.
	For generic drugs (me-too status)	N/A
	Module-II (Quality Overall Summary)	Firm has submitted QOS. 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	Roche Diagnostics GmbH, Nonnenwald 2, 82377 Penzberg, Germany
	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)	• 36 months' real time stability data at -40°C of 04 batches(PPQ) • 06 month accelerated stability data 5°C of 03 batches(PPQ).
	Module-III Drug Product:	Complete drug product needs to be submitted, as some sections have been skipped like 3.2.P.5,3.2.P.7.
	Analytical method validation/verification of product	Submitted.
	Container closure system of the drug product	6 mL, USP/Ph. Eur./JP Type I glass, borosilicate, colorless
	Stability study data of drug product, shelf life and storage conditions	• 30 months long-term stability data at 5°C of PPQ • 06 month accelerated stability data 25°C of 03 batches

	Module-IV Non-Clinical	A comprehensive nonclinical testing strategy, consistent with ICH guidelines, was designed to demonstrate and characterize the following: • Pharmacology, • PK/toxicokinetic (TK) profile, • Toxicology **249. <u>Pharmacology</u>** Glofitamab's activity and specificity was characterized in a wide range of **nonclinical models:** • **in vitro models:** consisted of co-cultures of DLBCL tumor target cell lines expressing various levels of CD20 antigen and healthy donor peripheral blood mononuclear cells (PBMCs) • **ex vivo models:** consisted of primary tumor samples derived from freshly isolated or previously frozen bone marrow samples from patients with non-Hodgkin's lymphoma (NHL) • **in vivo nonclinical pharmacology studies**: consisted of the use of both non-tumor bearing human hematopoietic stem cell (HSC)-engrafted NOD/Shi scid/IL-2Rγnull (HSC-NOG) mice [Hayakawa et al. 2009], and tumor-bearing HSC-NOG and HSC-engrafted NOD.Cg-PrkdcscidIl2rgtm1Wjl/SzJ [HSC-NSG] ([1084556], [1077638]) mice. The two DLBCL tumor cell line models utilized for in vivo studies were WSU-DLCL2 and OCI-Ly18. **Pharmacology Conclusion** Data from the in vitro, ex vivo, and in vivo pharmacology studies provide a comprehensive and robust characterization of glofitamab's biological activity and MoA and substantiate the rationale for its use as a therapeutic agent in patients with R/R DLBCL. **250. <u>Pharmacokinetics</u>** The PK/TK and PK/pharmacodynamic (PD) properties of glofitamab were assessed in **single- and multiple-dose studies in cynomolgus monkeys.** Additional information on the PK properties was obtained in single-dose studies in the non-responder species C57BL/6J mice, human FcRn (huFcRn) transgenic mice, and minipigs. **Pharmacokinetics Conclusion** In summary, the PK and PK/PD properties of glofitamab were characterized in animal species to support the nonclinical safety assessment as well as the clinical development of glofitamab. **251. <u>Toxicology</u>** <u>Single dose and repeat dose</u>

Table 2 Overview of Single- and Repeat-Dose Toxicity Studies with Glofitamab in Cynomolgus Monkeys

Study Type (Reference)	Treatment	GLP Status	Dose (µg/kg)	HNSTD	Immunogenicity (ADA Incidence)
Combined MTD/ DRF single- and repeat-dose IV (bolus) toxicity study [1063381]	Single Ascending Dose	Non-GLP	0.3,1.0, 3.0, 10, 30, 100, and 300	100 µg/kg	100% (14 days after single dose)
	Repeat Dose Day 1, 8, and 15[a]	Non-GLP	0, 10, 30, and 100	100 µg/kg	100%
Single-dose IV (bolus) toxicity study with or without Gpt [1066284]	Single Dose (Gpt Day1 / glofitamab Day 5)	Non-GLP	0/0 0/100 Gpt/100 Gpt/300 Gpt/1000	1000 µg/kg (with Gpt)	8/24 (168 h) 7/8 (336 h)
2-week repeat-dose IV (bolus) toxicity study [1067414]	Repeat Dose Day 1 and 8	GLP	0/0 10/10 30/30 100/100[b] 100/NA[b] 30/100[b]	30/100 µg/kg (Day 1/ Day 8)	0/13 10/10 10/10 4/4 NA 10/10
4-week repeat-dose IV and SC toxicity study [1083213]	Step-up dosing Day 1, 2, 3 followed by EOD dosing through Day 27	GLP	IV/SC 0/0/0[c] IV 30/100/100[c] SC 30/100/100[c] SC 30/100/300[c]	not defined	1[d]/10 9/10 10/10 10/10

Toxicology Conclusion

Collectively, data from the toxicity studies provide a comprehensive characterization of the safety profile of glofitamab. All nonclinical in vitro and in vivo safety findings were related to the MoA of glofitamab (attributed to cytokine release). Gpt improved the tolerability. Together with the clinical safety and efficacy data, glofitamab demonstrated a positive benefit-risk profile as a therapeutic agent in patients with R/R DLBCL.

Module-V Clinical

Study Number	Overall Design	Patient Population	Objectives and Endpoints	Number of Patients	Dosing Schedule
NP39488	Phase Ib open-label, multicenter study of glofitamab in combination with atezolizumab or polatuzumab vedotin	R/R NHL	Primary Objectives: MTD and/or RP2D in combination with 1) atezolizumab and 2) polatuzumab vedotin Secondary Objectives: Safety, tolerability, anti-tumor activity, PK, mode of action	Planned N up to 250 Enrolled N=177	Glofitamab: Q3W Cycles 1-8. Starting dose in atezolizumab arm is 70 µg; starting dose in polatuzumab vedotin arm is 4 mg. Atezolizumab: 1200 mg Q3W on D1 starting fro Cycle 2 onwards Polatuzumab vedotin: 1.8 mg/kg Q3W starting c C1D2, then on D1 for C2-6 Obinutuzumab: 1000 mg, 7 days before first glofitamab dose
NP40126	Phase Ib study evaluating glofitamab in combination with rituximab/ obinutuzumab + CHOP In combination with R-CHOP and with R-CHP-polatuzumab	R/R NHL and 1L DLBCL	Primary Objectives: 1. MTD and/or OBD and schedule for combination with G/R-CHOP in R/R NHL and maintenance treatment with glofitamab in patients achieving CR, PR, or SD at EOInd 2. MTD and/or OBD and schedule for combination with G/R-CHOP, R-CHOP or CHOP in untreated DLBCL Secondary Objectives: Anti-tumor activity, safety and tolerability	Planned N=up to 172 Enrolled N=98	Glofitamab: C2D8, C2D15, then Q3W Cycles 3- Maintenance D1 every other cycle Obinutuzumab: 1000 mg on C1D1 Rituximab: 375 mg/m2 Q3W CHOP: Q3W for 6 cycles All cycles are 21 days duration

Study Number	Overall Design	Patient Population	Objectives and Endpoints	Number of Patients	Dosing Schedule
GO43075	Phase II study of glofitamab in combination with R-CHOP in circulating tumor (ct)DNA high-risk patients	ctDNA high risk 1L DLBCL	Primary Objective: EOT CR Rate Secondary Objectives: ORR, PFS, OS, and Safety, efficacy	Planned N=40 Enrolled N=5	Glofitamab IV: 2.5mg on C3D8, 10mg, C3D15, 30mg, C4D8, 30mg on D1 of Cycles 5-10 Rituximab IV: 375 mg/m2 on Day 8 of Cycles 5-6; Da 1 of Cycles 7-10; Cyclophosphamide IV: 750 mg/m2 on Day 1 of Cycles 1-6; Doxorubicin50 mg/m2 on Da 1 of Cycles 1-6; Vincristine IV: 1.4 mg/m2 on Day 1 c Cycles 1-6; Prednisone: 100 mg/day orally on Days 1 5 of Cycles 1-6
BP43015	Phase Ib study of subcutaneous glofitamab following obinutuzumab pretreatment	R/R NHL	Primary Objective: Safety and tolerability of glofitamab SC administration Secondary Objectives: 1. PK profile of glofitamab SC administration 2. Immune response to glofitamab	Planned N = 18-36 Enrolled N = 16	Obinutuzumab: 1000 mg pre-treatment on D1 of Cycle 1 Glofitamab SC: 2.5 mg on D8 of Cycle 1; 10 mg on Day 15 of Cycle 1; 30 mg on Day 1 of Cycle 5 Glofitamab IV: 16 mg IV Q3W in Cycle 2; 30 mg IV Q3W in Cycles 3-12 (except Cycle 5)
YO42610 [a]	Phase I, open-label, multicenter, single-arm study of glofitamab IV infusion in Chinese patients	R/R DLBCL	To evaluate the PK, safety, tolerability, and efficacy of glofitamab, as a single agent following a fixed single dose of Gpt in Chinese patients with R/R DLBCL	Planned N=12 (PK cohort); N=18 (Expansion cohort) Enrolled N=30	Glofitamab: Cycle 1 step-up dose schedule (2.5/10/30 mg) Q3W, IV Obinutuzumab: 1000 mg, 7 days before first glofitamab dose
JO41190 [a]	Phase I open-label, multicenter dose-escalation study of glofitamab as single agent in Japanese patients	R/R NHL	To evaluate the safety, tolerability and PK of glofitamab in patients with R/R NHL To determine the MTD and DLTs of glofitamab in patients with R/R NHL	Planned N=6-12 Enrolled N=8	Glofitamab: Cycle 1 step-up dose schedule (2.5/10/16 mg or 2.5/10/30 mg) Q3W, IV Obinutuzumab: 1000 mg, 7 days before first glofitamab dose
BP41072 [a]	Phase I open-label, study of RO7227166 (CD19 targeted 4-1BB ligand) in combination with obinutuzumab or glofitamab	R/R NHL	Primary Objectives: Part I/II - MTD in combination with obinutuzumab and glofitamab Safety/tolerability in combination with obinutuzumab and glofitamab Part III - efficacy in combination with glofitamab (expansion) Secondary Objectives: Part I/II - PK, efficacy (ORR, DCR, DOR, PFS, OS), biomarkers /PD (in combination with obinutuzumab and glofitamab). Part III - safety, PK, biomarkers/PD (in combination with glofitamab - expansion)	Planned N=207 Enrolled N=88)	Obinutuzumab: 1000mg pre-treatment between 3 and 7-days before glofitamab treatment begins in Parts I-III. In Part I, obinutuzumab is given in combination with RO Q3W. In Parts II and III, glofitamab is given in combination with RO Q3W (Part III is expansion).
CO43810	Phase I/II study of glofitamab in combination with R-ICE in relapsed/refractory mature B-NHL	Pediatric and young adult with R/R B-NHL	Primary Objective: evaluate safety, tolerability, PK, and anti-tumor activity; Secondary Objectives: ORR, DOCR, PFS, EFS, OS, Percentage proceed to HSCT, ADA prevelance, DOR	Total Planned: 65 patients; Enrolled: 0	Glofitamab: IV starting at 2.5mg on C1D8, 10mg C1D15, 30mg C2D1, 30 mg C3D1 and Cohort B: day 1 of each cycle up to cycle 12, Rituximab- 375mg/m2 on C2D5 and C3D5, ICE begins on C1D3 for 2 or 3 21 day cycles
GO43693	A Phase Ib study evaluation glofitamab in combination with rituximab plus ifosfamide, carboplatin, and etoposide phosphate	R/R transplant or CAR-T therapy eligible diffuse B-cell lymphoma	Primary objective: ORR Secondary objectives: EFS, PFS, efficacy and safety	Study has not started yet (projected October 2022)	Cycle 1: obinutuzumab (Gazyva) pretreatment (Gpt) on Day 1 plus ifosfamide, carboplatin, and etoposide on Days 1−3, followed by step up dosing of glofitamab 2.5 mg on Day 8 and 10 mg on Day 15. During Cycles 2 and 3, participants will receive R-ICE between Days 1−3 and glofitamab 30 mg on Day 8.

Remarks of the Evaluator

<u>USFDA: Accelerated Approval</u>

It is approved under **accelerated approval pursuant to section 506(c) of the Federal Food, Drug, and Cosmetic Act (FDCA) and 21 CFR 601.41,** effective on the date of this letter, for use as recommended in the enclosed agreed-upon approved labeling. This BLA provides for the use of Columvi for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy. Marketing of this drug product and related activities must adhere to the substance and procedures of the accelerated approval statutory provisions and regulations.

Accelerated approval requirements

Pursuant to section 506(c) of the FDCA and 21 CFR 601.41, you are required to conduct further adequate and well-controlled clinical trial intended to verify and describe clinical benefit. You are required to conduct such clinical trial with due diligence. If required postmarketing clinical trial fails to verify clinical benefit or is not conducted with due diligence, including with respect to the conditions set forth below, we may, withdraw this approval. We remind you of your postmarketing requirement specified in your submission dated June 6, 2023. This requirement is listed below. 4464-1 Complete a randomized clinical trial that evaluates the clinical benefit of glofitamab in patients with diffuse large B-cell lymphoma. The trial should compare glofitamab in combination with gemcitabine and oxaliplatin (GemOx) to rituximab in

combination with GemOx for patients with relapsed or refractory diffuse large B-cell lymphoma. The primary endpoint should be overall survival with secondary endpoints that include progression-free survival and response rate. The timetable you submitted on June 6, 2023, states that you will conduct this trial according to the following schedule: Trial Completion: 03/2024 Final Report Submission: 09/2024 Submit clinical protocols to your IND 138178 for this product. FDA considers the term final to mean that the applicant has submitted a protocol, the FDA review team has sent comments to the applicant, and the protocol has been revised as needed to meet the goal of the study or clinical trial.

EMA: Conditional Marketing Authorization

Additional monitoring

This medicine is under additional monitoring, meaning that it is monitored even more intensively than other medicines. For more information, see Medicines under additional monitoring.

Conditional approval

This medicine received a conditional marketing authorisation. This was granted in the interest of public health because the medicine addresses an unmet medical need and the benefit of immediate availability outweighs the risk from less comprehensive data than normally required. For more information, see Conditional marketing authorisation.

Orphan

This medicine was designated an orphan medicine. This means that it was developed for use against a rare, life-threatening or chronically debilitating condition or, for economic reasons, it would be unlikely to have been developed without incentives. For more information, see Orphan designation.

TGA:

Black triangle scheme

Yes. As a provisionally registered product, this medicine will remain in the Black Triangle Scheme for the duration of its provisional registration

The sponsor must conduct studies as described in the clinical study plan in version 1.0 (dated 27 May 2022) of the Australia specific annex. The following study reports should be submitted to TGA within 6 months of completion:

Study GO41944 by first quarter of 2024

Study NP30179 by second quarter of 2023

Further data from cohort D5 should be submitted in any application for review of provisional registration.

Firms Response Against Observations by Evaluator

Sr. No.	Observations	Firms Response
1.	Submit separate applications / dossiers for both strengths instead of applying both in one dossier.	We have submitted separate fees and Form-5F for each strength, 2.5 mg and 10 mg. Globally, our practice is to provide an integrated dossier for all strengths to avoid data duplication and ensure optimal use of tangible and intangible resources. Accordingly, we have submitted a combined dossier for both strengths, as received from our principal, and this approach is consistently followed in all countries, including those under stringent regulatory authorities (SRAs). In the past as well, DRAP has approved our products with two strengths on a single dossier e.g. Lunsumio 1 mg and 30 mg. (DRB 329).

		Evaluator Comments Firm has submitted separate fees and Form-5F for each strength, 2.5 mg and 10 mg in a single dossier. Even in USFDA both the strengths have been provided separate approvals.
2.	Submit original, legalized, and valid COPP.	Using the Reliance Pathway, we have provided the BLA approval letter of the US FDA, which can be seen on the following link: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/761309Orig1s000ltr.pdf. **Evaluator Comments** As per 240 Registration Board meeting, : For imported products: Original , Legalized and Valid COPP is required. Variation is sites mentioned on Form 5 F,Section 3.2.P.3.1 and BLA **Manufacture of Drug Product (including primary packaging)** As per form 5 F and section 3.2.P.3.2. Genentech, Inc. 1 DNA Way South San Francisco, CA 94080 United States **As per BLA** The final formulated product will be manufactured and filled at Genentech, Inc., San Francisco, California and labeled, secondary packaged, and stored at F. Hoffman-La Roche AG, Wurmisweg 4303 Kaiseraugst, Switzerland.
4.	The relationship letter mentions the manufacturing sites and release sites; provide the relationship letter w.r.t. MAH.	The relationship letter is attached.
5.	The approved generic of Columvi in USFDA is Glofitamab-gxbm, whereas you have applied for Glofitamab. Clarification is required.	The four-alphabet suffix '-gxbm' in Glofitamab-gxbm is a designation assigned by the USAN Council to identify the manufacturer of the biological product. It is neither a part of the molecule's name nor alters the active ingredient's chemical structure or pharmacological properties, but rather provides additional information from an administrative perspective. Reference USFDA doc link: https://www.fda.gov/files/drugs/published/Nonproprietary-Naming-of-Biological-Products-Guidance-for-Industry.pdf Evaluator Comments Same product is applied for registration with different non-propropriety name. Nonproprietary Name: means a name unprotected by trademark rights that is in the public domain. It may be used by the public at large, both lay and professional.

6.	The product has been granted accelerated approval in USFDA, conditional approval in EMA, and provisional approval in TGA. Justification is required for submission of the applied product in Pakistan considering the safety and efficacy of the biological product.	Conditional/Accelerated authorization is granted for medicines that fulfill an unmet medical need to treat serious diseases and when the benefits of having them available earlier outweigh any risks associated with using the medicines. Columvi is applied in Pakistan and the other countries of the world based on Roche's alignment with global regulatory decisions from SRAs, including US FDA, EMA, and TGA, which have deemed the product safe and efficacious. The product is registered and marketed in these regions, and any changes in their decisions will be implemented locally. In Pakistan, healthcare professionals and patients eagerly await Columvi, as it addresses the unmet medical needs of diffuse large B-cell lymphoma (DLBCL) patients. Moreover, our local Pharmacovigilance function in Pakistan, under Roche Global PV supervision, ensures compliance with the Risk Management Plan (RMP), with additional risk minimisation measures (aRMMs) in place, such as Educational Materials for prescribers and patients to address important risks and adverse events. RMP table is attached.
10.	Submit the stability data of applied strength i.e., both 2.5 mg and 10 mg of commercial batches supporting shelf life.	The complete 30 months' shelf-life data is attached. We have also enclosed p.3.1 "composition" section, where on pg.2 it is mentioned that F04-01 and F04-02 are referring to Columvi 10mg and 2.5mg, respectively. Hence, the data of batch no. 3441754, 3361840, 3361842 and 3361848 belongs to Columvi 10mg vial while of batch no. 3441757, 3441762, 3441764 and GLO_ER1 belongs to Columvi 2.5mg vial. Evaluator Comments As per BLA DATING PERIOD The dating period for Columvi shall be 24 months from the date of manufacture when stored at 2°C to 8°C.
11.	Submit in-use stability studies for infusion solution supporting "72 hours at 2°C–8°C, protected from light, followed by 24 hours at 30°C with exposure to ambient light."	The data is attached. It is present as a part of module 3, section ***P.2.6 Pharmaceutical Development, Compatibility and Physicochemical Stability.***

Decision of M-340

The Registration Board deferred for expert opinion by at least three Haematologists regarding therapeutic use and need of applied formulation , submission of original , legalized and valid COPP, separate applications for both strengths 2.5mg and 10mg and stability data of applied strengths till claimed shelf life.

Remarks of Deputy Director IV:

a) Expert Opinions

- ✓ **Expert Opinion of Prof. Dr. Qasim Buttar, Pakitan Institute of Medical Sciences (PIMS)**

As per decision of Registration Board letter, No. 3-41/2014-DDC(BD)(Vol-VII)-P-001(M-340) dated 22nd November, 2024 was written to Prof. Dr. Qasim Buttar, Pakitan Institute of Medical Sciences (PIMS), Brig. Dr. Raheel Iftikhar, AFBMTC, Combined Military Hospital (CMH) Rawalpindi and Mr.Ayaz Mir, Shifa International Hospital, Islamabad for the expert opinon on registration of Columvi 2.5mg and 10mg of M/s Roche Pakistan Limited, Karachi.

In this regards reply of Pakistan Institute of Medical Sciences (PIMS), Islamabad is received dated 02-12-2024 which is reproduced as under:

"*With reference to your letter no. 3-41/2014-DDC(BD) (Vol-VII)-P-001 (M-340)the request for expert opinion from the DRAP, I wish to highlight the critical therapeutic gap faced by patients with relapsed or refractory Diffuse Large B- Cell Lymphoma (DLBCL) after two lines of therapy. The lack of any effective third-line treatment options in Pakistan leaves these patients with dismal prognoses and minimal hope.*

Columvi offers a promising solution, with clinical trials demonstrating a significant 40% complete response rate and substantial improvements in overall survival. Its accelerated approval by the USFDA and inclusion in the NCCN Guidelines as a preferred regimen highlight its potential to address this urgent need.

Given the high unmet need and strong clinical evidence supporting its efficacy, I recommend the registration of Columvi to ensure that patients in Pakistan have access to this life-saving therapy"

- ✓ **Expert Opinion of Brig. Dr. Raheel Iftikhar (AFBMTC) CMH, Rawalpindi.**

And following reply has been received from Brig. Dr. Raheel Iftikhar (AFBMTC) CMH, Rawalpindi:

In response to the letter no.3-41/2014-DDC(BD)(VOL-VII)-P-001(M-340) received from the Drug Regulatory Authority of Pakistan regarding the registration of Columvi (Glofitamab), it is pertinent to highlight the critical unmet need for effective therapies for patients with relapsed or refractory Diffuse Large B-Cell Lymphoma (DLBCL) who have undergone two prior lines of therapy. Such patients face an extremely poor prognosis and very limited survival options.

Based on available data, Columvi has demonstrated robust clinical efficacy, achieving a complete rrate of approximately 40% and providing a long-term survival benefit to over 80% of patients in clinical trials. Considering the lack of alternative treatment options and the compelling clinical evidence, I strongly recommend that Columvi be registered for use in Pakistan to improve patient outcomes significantly.

- ✓ **Expert Opinion of Dr.Ayaz Mir, (Shifa International Hospital) Islamabad**

Glofitamab will be a great addition to fight Cancer / Lymphoma in Pakistan as 1st in class approved BiTe Therapy and will save many lives.

I fully support it.

b) <u>Submission of eCOPP 2.5mg and 10mg</u>

Separate applications have been submitted for both strengths on eAPP.

<u>Firm has submitted valid eCOPP.</u>
Certificate Number: HDAB-GJS5
Certificate Issued Date: October 15, 2024
Certificate Expiration Date: October 15, 2026
Marketing authorization holder (name and address): Genentech, Inc. (A Member of the Roche Group), 1 DNA Way, PDRO Building 35, MS 355J, South San Francisco, CA 94080 United States of America, U.S. License Number: 1048
Manufacturer name & address: Genentech, Inc., 1 DNA Way, South San Francisco, CA 94080 United States of America
Packager
Name of Manufacturing Site Address Activity F. Hoffmann-La Roche Ltd Wurmisweg, Kaiseraugst, Argovia CH-4303 SWITZERLAND

	As per form 5 F and section 3.2. P.3.1. **Manufacture of Drug Product (including primary packaging)** Genentech, Inc. 1 DNA Way South San Francisco, CA 94080 United States c) ***Submission of applications for both strengths*** Separate applications for both strengths 1.2mg and 10mg have been submitted on eAPP. d) ***Submission of stability data*** Stability data of applied strengths till claimed shelf life i.e. 24 months have been submitted.	
Decision of 343rd Meeting: The Registration Board approved the formulation with shelf life of 24 months as per current policy for inspection of manufacturers abroad notified vide Letter No.3-2/2005-Reg-I /Vol-II dated July 6, 2022.		
5.	**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:** 0375 **Address:** Roche Pakistan Limited, 1st floor, 37-B, Block 6, PECHS, Karachi. **Address of Godown:** • R-PI, Plot no. 56, sector 15, K.I.A, Karachi **Validity:** 07/11/2028. **Status:** Drug License by way of wholesale **Renewal:** N/A
	Name and address of marketing authorization holder (abroad)	Genentech, Inc. (A Member of the Roche Group), 1 DNA Way, PDRO Building 35, MS 355J, South San Francisco, CA 94080 United States of America, U.S. License Number: 1048
	Name, address of manufacturer(s)	**Manufacture of Drug Product (including primary packaging)** Genentech, Inc. 1 DNA Way South San Francisco, CA 94080 United States **Secondary Packaging Site** Name of Manufacturing Site Address Activity F. Hoffmann-La Roche Ltd Wurmisweg, Kaiseraugst, Argovia CH-4303 SWITZERLAND
	Name of exporting country	Switzerland
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**Firm has submitted valid eCOPP.** **Certificate Number:** : : MKMH-DGDU **Certificate Issued Date: October 04, 2024** **Certificate Expiration Date: October 04, 2026** **Marketing authorization holder (name and address):** Genentech, Inc. (A Member of the Roche Group), 1 DNA Way, PDRO Building 35, MS 355J, South San Francisco, CA 94080 United States of America, U.S. License Number: 1048 **Manufacturer name & address:** Genentech, Inc., 1 DNA Way, South San Francisco, CA 94080 United States of America **Packager** Name of Manufacturing Site Address Activity F. Hoffmann-La Roche Ltd Wurmisweg, Kaiseraugst, Argovia CH-4303 SWITZERLAND.

	Details of letter of authorization / sole agency agreement	• **Product Specific authorization letter** The M/s F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, CH-4070 Basel Switzerland in name of M/s Roche Pakistan Limited, Karachi dated 13-07-2023. • **Relationship letter** M/s F. Hoffmann-La Roche Ltd., Grenzacherstrasse 124, CH-4070 Basel Switzerland,a Swiss Stock Corporation is the operational headquarter company of the Roche group.
	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. 397 dated:11, September 2023.
	Details of fee submitted	**Deposit Slip no**. 2650114618, **PKR** 75,000, **Dated:** 20-07-2023
	The proposed proprietary name / brand name	**Columvi 10mg/10ml** **Concentrate for Solution for Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each single dose vial contains** Glofitamab…10mg
	Dosage form of applied drug	Intravenous Use (Concentrate for solution for infusion)
	Pharmacotherapeutic Group of (API) and Indication	Antineoplastic (Monoclonal Antibodies) ATC code: L01FX28 Columvi is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy.
	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	USFDA Accelerated Approval. EMA Conditional Marketing Authorization. TGA Provisional Approval.
	For generic drugs (me-too status)	N/A

	Module-II (Quality Overall Summary)	Firm has submitted QOS. 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	Roche Diagnostics GmbH, Nonnenwald 2, 82377 Penzberg, Germany
	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)	• 36 months real time stability data at -40°C of 04 batches(PPQ) • 06 month accelerated stability data 5°C of 03 batches(PPQ).
	Module-III Drug Product:	Complete drug product needs to be submitted,as some sections have been skipped like 3.2.P.5,3.2.P.7.
	Analytical method validation/verification of product	Submitted.
	Container closure system of the drug product	15 mL, USP/Ph. Eur./JP Type I glass,borosilicate, colorless
	Stability study data of drug product, shelf life and storage conditions	• 24 months long-term stability data at 2°C-8°C • 06 month accelerated stability data 25°C
	Module-IV Non-Clinical	A comprehensive nonclinical testing strategy, consistent with ICH guidelines, was designed to demonstrate and characterize the following: • Pharmacology, • PK/toxicokinetic (TK) profile, • Toxicology **252. <u>Pharmacology</u>** Glofitamab's activity and specificity was characterized in a wide range of **nonclinical models:** • **in vitro models:** consisted of co-cultures of DLBCL tumor target cell lines expressing various levels of CD20 antigen and healthy donor peripheral blood mononuclear cells (PBMCs) • **ex vivo models:** consisted of primary tumor samples derived from freshly isolated or previously frozen bone marrow samples from patients with non-Hodgkin's lymphoma (NHL) • **in vivo nonclinical pharmacology studies**: consisted of the use of both non-tumor bearing human hematopoietic stem cell (HSC)-engrafted NOD/Shi scid/IL-2Rγnull (HSC-NOG) mice [Hayakawa et al. 2009], and tumor-bearing HSC-NOG and HSC-engrafted NOD.Cg-PrkdcscidIl2rgtm1Wjl/SzJ [HSC-NSG] ([1084556], [1077638]) mice. The two DLBCL tumor cell line models utilized for in vivo studies were WSU-DLCL2 and OCI-Ly18. **Pharmacology Conclusion**

Data from the in vitro, ex vivo, and in vivo pharmacology studies provide a comprehensive and robust characterization of glofitamab's biological activity and MoA and substantiate the rationale for its use as a therapeutic agent in patients with R/R DLBCL.

253. Pharmacokinetics

The PK/TK and PK/pharmacodynamic (PD) properties of glofitamab were assessed in **single- and multiple-dose studies in cynomolgus monkeys.** Additional information on the PK properties was obtained in single-dose studies in the non-responder species C57BL/6J mice, human FcRn (huFcRn) transgenic mice, and minipigs.

Pharmacokinetics Conlusion

In summary, the PK and PK/PD properties of glofitamab were characterized in animal species to support the nonclinical safety assessment as well as the clinical development of glofitamab.

254. Toxicology

Single dose and repeat dose

Table 2 Overview of Single- and Repeat-Dose Toxicity Studies with Glofitamab in Cynomolgus Monkeys

Study Type (Reference)	Treatment	GLP Status	Dose (µg/kg)	HNSTD	Immunogenicity (ADA Incidence)
Combined MTD/ DRF single- and repeat-dose IV (bolus) toxicity study [1063381]	Single Ascending Dose	Non-GLP	0.3,1.0, 3.0, 10, 30, 100, and 300	100 µg/kg	100% (14 days after single dose)
	Repeat Dose Day 1, 8, and 15[a]	Non-GLP	0, 10, 30, and 100	100 µg/kg	100%
Single-dose IV (bolus) toxicity study with or without Gpt [1066284]	Single Dose (Gpt Day1 / glofitamab Day 5)	Non-GLP	0/0 0/100 Gpt/100 Gpt/300 Gpt/1000	1000 µg/kg (with Gpt)	8/24 (168 h) 7/8 (336 h)
2-week repeat-dose IV (bolus) toxicity study [1067414]	Repeat Dose Day 1 and 8	GLP	0/0 10/10 30/30 100/100[b] 100/NA[b] 30/100[b]	30/100 µg/kg (Day 1/ Day 8)	0/13 10/10 10/10 4/4 NA 10/10
4-week repeat-dose IV and SC toxicity study [1083213]	Step-up dosing Day 1, 2, 3 followed by EOD dosing through Day 27	GLP	IV/SC 0/0/0[c] IV 30/100/100[c] SC 30/100/100[c] SC 30/100/300[c]	not defined	1[d]/10 9/10 10/10 10/10

Toxicology Conclusion

Collectively, data from the toxicity studies provide a comprehensive characterization of the safety profile of glofitamab. All nonclinical in vitro and in vivo safety findings were related to the MoA of glofitamab (attributed to cytokine release). Gpt improved the tolerability. Together with the clinical safety and efficacy data, glofitamab demonstrated a positive benefit-risk profile as a therapeutic agent in patients with R/R DLBCL.

Module-V Clinical

Appendix 1 Overview of Glofitamab Clinical Development Plan in R/R NHL (as of 23 August 2022)

Study Number	Overall Design	Patient Population	Objectives and Endpoints	Number of Patients	Dosing Schedule
Ongoing Studies					
NP30179	Phase I/II study evaluating glofitamab as single agent and in combination with obinutuzumab	Relapsed / refractory (R/R) NHL	Primary Objectives: Safety, tolerability, PK, MTD and efficacy by CR rate, DOCR and DOR (Part III only) Secondary Objectives: Safety, incidence of ADAs, PD biomarkers, patient reported outcomes (Part III only)	Parts I and II: Planned N=300, Enrolled N=301 Part III overall: Planned N= 560, Enrolled N=257 Part III SUDa R/R DLBCL monotherapy (Cohort D3): Planned ~N=100, Enrolled N=109	Part I: Glofitamab monotherapy Q2W. Dosing initiated at 5 µg (flat dose), followed by 15 and 45 µg. Obinutuzumab: 1000 mg, 7 days before first glofitamab dose; Double pre-treatment may be tested Part II: Glofitamab administered with fixed dosing or step-up dosing either as monotherapy (Q2W) following Gpt; monotherapy Q3W following Gpt; or in combination with obinutuzumab Q3W. Part III: Glofitamab administered with fixed dosing or step-up dosing either as monotherapy Q3W following Gpt; or in combination with obinutuzumab Q3W following Gpt.
GO41944	Phase III, open-label, 2:1 randomized study of glofitamab + gemcitabine + oxaliplatin vs. rituximab + gemcitabine + oxaliplatin	R/R DLBCL	Primary Objective: OS Secondary Objectives: PFS, CR, ORR, DOR, DOCR, Safety and tolerability, PRO	Planned: 270 patients 2:1 randomization Enrolled N=218	Obinutuzumab: 1000 mg pre-treatment, 7 days before first glofitamab dose Glofitamab: 2.5 mg on C1D8; 10 mg on C1D15; 30 mg on D1 of Cycles 2–12 Rituximab: 375mg/m^2 on D1 of Cycle 1-8 Gemcitabine, 1000 mg/m^2 on C1D2 and then D1 of Cycles 2–8 Oxaliplatin: 100 mg/m^2 on C1D2 and then D1 of Cycles 2–8 All cycles are 21 days duration

Study Number	Overall Design	Patient Population	Objectives and Endpoints	Number of Patients	Dosing Schedule
NP39488	Phase Ib open-label, multicenter study of glofitamab in combination with atezolizumab or polatuzumab vedotin	R/R NHL	Primary Objectives: MTD and/or RP2D in combination with 1) atezolizumab and 2) polatuzumab vedotin Secondary Objectives: Safety, tolerability, anti-tumor activity, PK, mode of action	Planned N up to 250 Enrolled N=177	Glofitamab: Q3W Cycles 1-8. Starting dose in atezolizumab arm is 70 µg; starting dose in polatuzumab vedotin arm is 4 mg. Atezolizumab: 1200 mg Q3W on D1 starting from Cycle 2 onwards Polatuzumab vedotin: 1.8 mg/kg Q3W starting on C1D2, then on D1 for C2-6 Obinutuzumab: 1000 mg, 7 days before first glofitamab dose
NP40126	Phase Ib study evaluating glofitamab in combination with rituximab/ obinutuzumab + CHOP In combination with R-CHOP and with R-CHP-polatuzumab	R/R NHL and 1L DLBCL	Primary Objectives: 1. MTD and/or OBD and schedule for combination with G/R-CHOP in R/R NHL and maintenance treatment with glofitamab in patients achieving CR, PR, or SD at EOInd 2. MTD and/or OBD and schedule for combination with G/R-CHOP, R-CHOP or CHOP in untreated DLBCL Secondary Objectives: Anti-tumor activity, safety and tolerability	Planned N=up to 172 Enrolled N=98	Glofitamab: C2D8, C2D15, then Q3W Cycles 3-6; Maintenance D1 every other cycle Obinutuzumab: 1000 mg on C1D1 Rituximab: 375 mg/m2 Q3W CHOP: Q3W for 6 cycles All cycles are 21 days duration

Study Number	Overall Design	Patient Population	Objectives and Endpoints	Number of Patients	Dosing Schedule
GO43075	Phase II study of glofitamab in combination with R-CHOP in circulating tumor (ct)DNA high-risk patients	ctDNA high risk 1L DLBCL	Primary Objective: EOT CR Rate Secondary Objectives: ORR, PFS, OS, and Safety, efficacy	Planned N=40 Enrolled N=5	Glofitamab IV: 2.5mg on C3D8, 10mg, C3D15, 30mg, C4D8, 30mg on D1 of Cycles 5-10 Rituximab IV: 375 mg/m2 on Day 8 of Cycles 5-6; Da 1 of Cycles 7-10; Cyclophosphamide IV: 750 mg/m2 on Day 1 of Cycles 1-6; Doxorubicin50 mg/m2 on Da 1 of Cycles 1-6; Vincristine IV: 1.4 mg/m2 on Day 1 Cycles 1-6; Prednisone: 100 mg/day orally on Days 5 of Cycles 1-6
BP43015	Phase Ib study of subcutaneous glofitamab following obinutuzumab pretreatment	R/R NHL	Primary Objective: Safety and tolerability of glofitamab SC administration Secondary Objectives: 1. PK profile of glofitamab SC administration 2. Immune response to glofitamab	Planned N = 18-36 Enrolled N = 16	Obinutuzumab: 1000 mg pre-treatment on D1 of Cycle 1 Glofitamab SC: 2.5 mg on D8 of Cycle 1; 10 mg on Day 15 of Cycle 1; 30 mg on Day 1 of Cycle 5 Glofitamab IV: 16 mg IV Q3W in Cycle 2; 30 mg IV Q3W in Cycles 3-12 (except Cycle 5)
YO42610 [a]	Phase I, open-label, multicenter, single-arm study of glofitamab IV infusion in Chinese patients	R/R DLBCL	To evaluate the PK, safety, tolerability, and efficacy of glofitamab, as a single agent following a fixed single dose of Gpt in Chinese patients with R/R DLBCL	Planned N=12 (PK cohort); N=18 (Expansion cohort) Enrolled N=30	Glofitamab: Cycle 1 step-up dose schedule (2.5/10/30 mg) Q3W, IV Obinutuzumab: 1000 mg, 7 days before first glofitamab dose

JO41190 [a]	Phase I open-label, multicenter dose-escalation study of glofitamab as single agent in Japanese patients	R/R NHL	To evaluate the safety, tolerability and PK of glofitamab in patients with R/R NHL To determine the MTD and DLTs of glofitamab in patients with R/R NHL	Planned N=6-12 Enrolled N=8	Glofitamab: Cycle 1 step-up dose schedule (2.5/10/16 mg or 2.5/10/30 mg) Q3W, IV Obinutuzumab: 1000 mg, 7 days before first glofitamab dose
BP41072 [a]	Phase I open-label, study of RO7227166 (CD19 targeted 4-1BB ligand) in combination with obinutuzumab or glofitamab	R/R NHL	Primary Objectives: Part I/II - MTD in combination with obinutuzumab and glofitamab Safety/tolerability in combination with obinutuzumab and glofitamab Part III - efficacy in combination with glofitamab (expansion) Secondary Objectives: Part I/II - PK, efficacy (ORR, DCR, DOR, PFS, OS), biomarkers /PD (in combination with obinutuzumab and glofitamab). Part III - safety, PK, biomarkers/PD (in combination with glofitamab - expansion)	Planned N=207 Enrolled N=88)	Obinutuzumab: 1000mg pre-treatment between 3 and 7-days before glofitamab treatment begins in Parts I-III. In Part I, obinutuzumab is given in combination with RO Q3W. In Parts II and III, glofitamab is given in combination with RO Q3W (Part III is expansion).
CO43810	Phase I/II study of glofitamab in combination with R-ICE in relapsed/refractory mature B-NHL	Pediatric and young adult with R/R B-NHL	Primary Objective: evaluate safety, tolerability, PK, and anti-tumor activity; Secondary Objectives: ORR, DOCR, PFS, EFS, OS, Percentage proceed to HSCT, ADA prevelance, DOR	Total Planned: 65 patients; Enrolled: 0	Glofitamab: IV starting at 2.5mg on C1D8, 10mg C1D15, 30mg C2D1, 30 mg C3D1 and Cohort B: day 1 of each cycle up to cycle 12, Rituximab- 375mg/m2 on C2D5 and C3D5, ICE begins on C1D3 for 2 or 3 21 day cycles
GO43693	A Phase Ib study evaluation glofitamab in combination with rituximab plus ifosfamide, carboplatin, and etoposide phosphate	R/R transplant or CAR-T therapy eligible diffuse B-cell lymphoma	Primary objective: ORR Secondary objectives: EFS, PFS, efficacy and safety	Study has not started yet (projected October 2022)	Cycle 1: obinutuzumab (Gazyva) pretreatment (Gpt) on Day 1 plus ifosfamide, carboplatin, and etoposide on Days 1−3, followed by step up dosing of glofitamab 2.5 mg on Day 8 and 10 mg on Day 15. During Cycles 2 and 3, participants will receive R-ICE between Days 1−3 and glofitamab 30 mg on Day 8.

Remarks of the Evaluator

<u>USFDA: Accelerated Approval</u>

It is approved under **accelerated approval pursuant to section 506(c) of the Federal Food, Drug, and Cosmetic Act (FDCA) and 21 CFR 601.41,** effective on the date of this letter, for use as recommended in the enclosed agreed-upon approved labeling. This BLA provides for the use of Columvi for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy. Marketing of this drug product and related activities must adhere to the substance and procedures of the accelerated approval statutory provisions and regulations.

Accelerated approval requirements

Pursuant to section 506(c) of the FDCA and 21 CFR 601.41, you are required to conduct further adequate and well-controlled clinical trial intended to verify and describe clinical benefit. You are required to conduct such clinical trial with due diligence. If required postmarketing clinical trial fails to verify clinical benefit or is not conducted with due diligence, including with respect to the conditions set forth below, we may, withdraw this approval. We remind you of your postmarketing requirement specified in your submission dated June 6, 2023. This requirement is listed below. 4464-1 Complete a randomized clinical trial that evaluates the clinical benefit of glofitamab in patients with diffuse large B-cell lymphoma. The trial should compare glofitamab in combination with gemcitabine and oxaliplatin (GemOx) to rituximab in combination with GemOx for patients with relapsed or refractory diffuse large B-cell lymphoma. The primary endpoint should be overall survival with secondary endpoints that include progression-free survival and response rate. The timetable you submitted on June 6, 2023, states that you will conduct this trial according to the following schedule: Trial Completion: 03/2024 Final Report Submission: 09/2024 Submit clinical protocols to your IND 138178 for this product. FDA considers the term final to mean that the applicant has submitted a protocol, the FDA review team has sent comments to the applicant, and the protocol has been revised as needed to meet the goal of the study or clinical trial.

<u>EMA: Conditional Marketing Authorization</u>

Additional monitoring

		This medicine is under additional monitoring, meaning that it is monitored even more intensively than other medicines. For more information, see Medicines under additional monitoring. **Conditional approval** This medicine received a conditional marketing authorisation. This was granted in the interest of public health because the medicine addresses an unmet medical need and the benefit of immediate availability outweighs the risk from less comprehensive data than normally required. For more information, see Conditional marketing authorisation. **Orphan** This medicine was designated an orphan medicine. This means that it was developed for use against a rare, life-threatening or chronically debilitating condition or, for economic reasons, it would be unlikely to have been developed without incentives. For more information, see Orphan designation. TGA: **Black triangle scheme** Yes. As a provisionally registered product, this medicine will remain in the Black Triangle Scheme for the duration of its provisional registration The sponsor must conduct studies as described in the clinical study plan in version 1.0 (dated 27 May 2022) of the Australia specific annex. The following study reports should be submitted to TGA within 6 months of completion: Study GO41944 by first quarter of 2024 Study NP30179 by second quarter of 2023 Further data from cohort D5 should be submitted in any application for review of provisional registration.

Sr. No.	Observations	Firms Response
1.	Submit separate applications / dossiers for both strengths instead of applying both in one dossier.	We have submitted separate fees and Form-5F for each strength, 2.5 mg and 10 mg. Globally, our practice is to provide an integrated dossier for all strengths to avoid data duplication and ensure optimal use of tangible and intangible resources. Accordingly, we have submitted a combined dossier for both strengths, as received from our principal, and this approach is consistently followed in all countries, including those under stringent regulatory authorities (SRAs). In the past as well, DRAP has approved our products with two strengths on a single dossier e.g. Lunsumio 1 mg and 30 mg. (DRB 329). **Evaluator Comments** Firm has submitted separate fees and Form-5F for each strength, 2.5 mg and 10 mg in a single dossier. Even in USFDA both the strengths have been provided separate NDC. One 2.5 mg/2.5 mL (1 mg/mL) single-dose vial NDC 50242-125-01 One 10 mg/10 mL (1 mg/mL) single-dose vial NDC 50242-127-01
2.	Submit original, legalized, and valid COPP.	Using the Reliance Pathway, we have provided the BLA approval letter of the US FDA, which can be seen on the following link: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/761309Orig1s000ltr.pdf. **Evaluator Comments** As per 240 Registration Board meeting, :

			For imported products: Original, Legalized and Valid COPP is required. Variation is sites mentioned on Form 5 Section 3.2.P.3.1 and BLA **Manufacture of Drug Product (including primary packaging)** As per form 5 F and section 3.2.P.3.2. Genentech, Inc. 1 DNA Way South San Francisco, CA 94080 United States **As per BLA** The final formulated product will be manufactured and filled at Genentech, Inc., San Francisco, California and labeled, secondary packaged, and stored at F. Hoffman-La Roche AG, Wurmisweg 4303 Kaiseraugst, Switzerland.
	4.	The relationship letter mentions the manufacturing sites and release sites; provide the relationship letter w.r.t. MAH.	The relationship letter is attached.
	5.	The approved generic of Columvi in USFDA is Glofitamab-gxbm, whereas you have applied for Glofitamab. Clarification is required.	The four-alphabet suffix '-gxbm' in Glofitamab-gxbm is a designation assigned by the USAN Council to identify the manufacturer of the biological product. It is neither a part of the molecule's name nor alters the active ingredient's chemical structure or pharmacological properties, but rather provides additional information from an administrative perspective. Reference USFDA doc link: https://www.fda.gov/files/drugs/published/Nonproprietary-Naming-of-Biological-Products-Guidance-for-Industry.pdf **Evaluator Comments** Same product is applied for registration with different non-propropriety name. Nonproprietary Name :means a name unprotected by trademark rights that is in the public domain. It may be used by the public at large, both lay and professional.

	6.	The product has been granted accelerated approval in USFDA, conditional approval in EMA, and provisional approval in TGA. Justification is required for submission of the applied product in Pakistan considering the safety and efficacy of the biological product.	Conditional/Accelerated authorization is granted for medicines that fulfill an unmet medical need to treat serious diseases and when the benefits of having them available earlier outweigh any risks associated with using the medicines. Columvi is applied in Pakistan and the other countries of the world based on Roche's alignment with global regulatory decisions from SRAs, including US FDA, EMA, and TGA, which have deemed the product safe and efficacious. The product is registered and marketed in these regions, and any changes in their decisions will be implemented locally. In Pakistan, healthcare professionals and patients eagerly await Columvi, as it addresses the unmet medical needs of diffuse large B-cell lymphoma (DLBCL) patients. Moreover, our local Pharmacovigilance function in Pakistan, under Roche Global PV supervision, ensures compliance with the Risk Management Plan (RMP), with additional risk minimisation measures (aRMMs) in place, such as Educational Materials for prescribers and patients to address important risks and adverse events. RMP table is attached.
	10.	Submit the stability data of applied strength i.e., both 2.5 mg and 10 mg of commercial batches supporting shelf life.	The complete 30 months shelf-life data is attached. We have also enclosed p.3.1 "composition" section, where on pg.2 it is mentioned that F04-01 and F04-02 are referring to Columvi 10mg and 2.5mg, respectively. Hence, the data of batch no. 3441754, 3361840, 3361842 and 3361848 belongs to Columvi 10mg vial while of batch no. 3441757, 3441762, 3441764 and GLO_ER1 belongs to Columvi 2.5mg vial. **Evaluator Comments** As per BLA DATING PERIOD The dating period for Columvi shall be 24 months from the date of manufacture when stored at 2°C to 8°C.
	11.	Submit in-use stability studies for infusion solution supporting "72 hours at 2°C–8°C, protected from light, followed by 24 hours at 30°C with exposure to ambient light."	The data is attached. It is present as a part of module 3, section ***P.2.6 Pharmaceutical Development, Compatibility and Physicochemical Stability.***

Decision of M-340

The Registration Board deferred for expert opinion by at least three Haematologists regarding therapeutic use and need of applied formulation , submission of original , legalized and valid COPP, separate applications for both strengths 2.5mg and 10mg and stability data of applied strengths till claimed shelf life.

<u>Remarks of Deputy Director IV</u>:

e) <u>Expert Opinions</u>

- ✓ **Expert Opinion of Prof. Dr. Qasim Buttar, Pakitan Institute of Medical Sciences (PIMS)**

As per decision of Registration Board letter, No. 3-41/2014-DDC(BD)(Vol-VII)-P-001(M-340) dated 22nd November, 2024 was written to Prof. Dr. Qasim Buttar, Pakitan Institute of Medical Sciences (PIMS), Brig. Dr. Raheel Iftikhar, AFBMTC, Combined Military Hospital

(CMH) Rawalpindi and Mr.Ayaz Mir, Shifa International Hospital, Islamabad for the expert opinon on registration of Columvi 2.5mg and 10mg of M/s Roche Pakistan Limited, Karachi.

In this regards reply of Pakistan Institute of Medical Sciences (PIMS), Islamabad is received dated 02-12-2024 which is reproduced as under:

"*With reference to your letter no. 3-41/2014-DDC(BD) (Vol-VII)-P-001 (M-340)the request for expert opinion from the DRAP, I wish to highlight the critical therapeutic gap faced by patients with relapsed or refractory Diffuse Large B- Cell Lymphoma (DLBCL) after two lines of therapy. The lack of any effective third-line treatment options in Pakistan leaves these patients with dismal prognoses and minimal hope.*

Columvi offers a promising solution, with clinical trials demonstrating a significant 40% complete response rate and substantial improvements in overall survival. Its accelerated approval by the USFDA and inclusion in the NCCN Guidelines as a preferred regimen highlight its potential to address this urgent need.

Given the high unmet need and strong clinical evidence supporting its efficacy, I recommend the registration of Columvi to ensure that patients in Pakistan have access to this life-saving therapy"

- ✓ **Expert Opinion of Brig. Dr. Raheel Iftikhar (AFBMTC) CMH, Rawalpindi.**

And following reply has been received from Brig. Dr. Raheel Iftikhar (AFBMTC) CMH, Rawalpindi:

In response to the letter no.3-41/2014-DDC(BD)(VOL-VII)-P-001(M-340) received from the Drug Regulatory Authority of Pakistan regarding the registration of Columvi (Glofitamab), it is pertinent to highlight the critical unmet need for effective therapies for patients with relapsed or refractory Diffuse Large B-Cell Lymphoma (DLBCL) who have undergone two prior lines of therapy. Such patients face an extremely poor prognosis and very limited survival options.

Based on available data, Columvi has demonstrated robust clinical efficacy, achieving a complete rrate of approximately 40% and providing a long-term survival benefit to over 80% of patients in clinical trials. Considering the lack of alternative treatment options and the compelling clinical evidence, I strongly recommend that Columvi be registered for use in Pakistan to improve patient outcomes significantly.

- ✓ **Expert Opinion of Dr.Ayaz Mir, (Shifa International Hospital) Islamabad**

Glofitamab will be a great addition to fight Cancer / Lymphoma in Pakistan as 1st in class approved BiTe Therapy and will save many lives.

I fully support it.

f) <u>Submission of eCOPP 2.5mg and 10mg</u>

Separate applications have been submitted for both strengths on eAPP.

<u>Firm has submitted valid eCOPP.</u>

Certificate Number: : : MKMH-DGDU

Certificate Issued Date: October 04, 2024

Certificate Expiration Date: October 04, 2026

Marketing authorization holder (name and address): Genentech, Inc. (A Member of the Roche Group), 1 DNA Way, PDRO Building 35, MS 355J, South San Francisco, CA 94080 United States of America, U.S. License Number: 1048

Manufacturer name & address: Genentech, Inc., 1 DNA Way, South San Francisco, CA 94080 United States of America

Packager

	Name of Manufacturing Site Address Activity F. Hoffmann-La Roche Ltd Wurmisweg, Kaiseraugst, Argovia CH-4303 SWITZERLAND. g) ***Submission of applications for both strengths*** Separate applications for both strengths 2.5mg and 10mg have been submitted on eAPP. h) ***Submission of eCOPP*** Stability data of applied strengths till claimed shelf life i.e. 24 months have been submitted.
Decision of 343rd Meeting: The Registration Board approved the formulation with shelf life of 24 months as per current policy for inspection of manufacturers abroad notified vide Letter No.3-2/2005-Reg-I /Vol-II dated July 6, 2022.	

Case No. 02. Registration of Locally Manufacturing of Veterinary Biological Products.

6.	**Name and address of product manufacturer (Applicant)**	**OTTOMAN PHARMA** 10 km Raiwind Road Lahore
	Brand Name +Dosage Form + Strength	**AVIAN FLU COMBO**
	Type of Form, Diary No. Date of R& I & fee	Form-5; Dy. No.65 R&I Date:18-Aug-2023; F. No.F.3-7/2024-DD- (Bio); Fee Challan no. 661338150; Rs.30,000/- Date: 11-07-2023
	Composition	Each 0.3ml of dose contains: Inactivated AIV H9N2 containing not < 64HAU and EID50 not < 10^7/ml Inactivated AIV H5N8 containing not < 64HAU and EID50 not < 10^7/ml
	Description	Inactivated vaccine against AIV H5N8 and AIV H9N2
	Pharmacological Group	Biologicals (Vaccine for poultry use)
	Finished Product Specification	Each 0.3ml dose of finished product contains:
		25 parts active ingredient A 25 parts active ingredient B **50 parts of mineral oil excipient**
	Shelf Life & Storage conditions	**12-months; Store at +2oC to +8oC;**
	Document Details	• **DML No. 00502; Renewed on 05-08-2022.**
		• **Inactivated Viral Vaccine Section approval 03rd April, 2023.**
	Pack size & Demanded Price	**300ml; De-Controlled**
	Already registered in Pakistan	**GPVAC FLU (5+9); AI Oil Plus**
	Remarks of Evaluator	• **Product applied for both veterinary/ poultry products in the application form, i.e., Form-5; But dose for administration in veterinary and poultry subjects is not mentioned clearly, clarification is required.** • **Dose for different population/ species among poultry (Breeder, Layer, Broiler) is need to be clarified.** • **What is the justification of mentioning dose range (0.2ml – 0.5ml) in the application form, i.e., Form-5. (Give its compendial evidence or justification).** • **Long term and accelerated stability studies data to support the shelf life of applied products is not provided.** • **Give the preference with regard to multiple pack sizes mentioned in the application form, i.e., Form-5, as only one pack size can be granted with one application.**

		• **Which agents or type of antibodies are used for mixing with WSV as mentioned in manufacturing process in the document. (Give its compendial evidence or justification)** • **Justify the parameters to specify the Grade B conditions applied during the manufacturing process and the flow maintained according to the grading of the surfaces used.** • **What are the justifications for choosing the first two and last two products for quality control testing? (Give its compendial evidence or justification).** • **Give the details of originating of master seed and its source in line with the reference documents.** • **The storage conditions mentioned at label is 4-8 0C, while the product storage is 2-8, please clarify the difference;** • **Label parameters are different from the application form, like. So it is advised to submit the correct version of the label and revised the application form, i.e., Form-5, alongwith applicable fee as per new** **S.R.O 1324(I)2024.**

Decision of 340th meeting of the Registration Board:
Registration Board deliberated the case and deferred for submission/ clarification of followings: -

- Label parameters are different from the application form, like. So it is advised to submit the correct version of the label and revised the application form, i.e., Form-5, alongwith applicable fee as per new S.R.O 1324(I)2024.
- Product applied for both veterinary/ poultry products in the application form, i.e., Form-5; But dose for administration in veterinary and poultry subjects is not mentioned clearly, clarification is required.
- Dose for different population/ species among poultry (Breeder, Layer, Broiler) is need to be clarified.
- What is the justification of mentioning dose range (0.2ml – 0.5ml) in the application form, i.e., Form-5. (Give its compendial evidence or justification).
- Long term and accelerated stability studies data to support the shelf life of applied products is not provided.
- Give the preference with regard to multiple pack sizes mentioned in the application form, i.e., Form-5, as only one pack size can be granted with one application.
- Which agents or type of antibodies are used for mixing with WSV as mentioned in manufacturing process in the document. (Give its compendial evidence or justification).
- Justify the parameters to specify the Grade B conditions applied during the manufacturing process and the flow maintained according to the grading of the surfaces used.
- What are the justifications for choosing the first two and last two products for quality control testing? (Give its compendial evidence or justification).
- Give the details of originating of master seed and its source in line with the reference documents.
- The storage conditions mentioned at label is 4-8 ^{0}C, while the product storage is 2-8, please clarify the difference.

The manufacturer has responded to deficinces as under;

Deficiency	**Response of the firm**
1. Label parameters are different from the application form, like. So it is advised to	Label parameters and dossier will be kept as 2 – 8^{o}C which seems to be desire of evaluator.

	submit the correct version of the label and revised the application form, i.e., Form-5, alongwith applicable fee as per new S.R.O 1324(I)2024.	Drugs Registration Board has the authority to amend such things. However, technically speaking there would be nothing wrong if the storage limits are kept within the WHO Guidelines for maintaining vaccine cold chain" https://cdn.who.int/media/docs/default-source/searo/india/publications/immunization-handbook-107-198-part2.pdf
	2. Product applied for both veterinary/ poultry products in the application form, i.e., Form-5; But dose for administration in veterinary and poultry subjects is not mentioned clearly, clarification is required.	Ottoman Pharma is a Poultry Inactivated Vaccine producing unit, therefore in Form-5, the dose of 0.3ml per bird has been indicated in accordance with the Bible on the subject i.e. "COBB Vaccination Procedure Guide" https://www.cobbgenetics.com/assets/Cobb-Files/Cobb_Vaccination_Guide.pdf and FAO "Technology Review Chapter 3 Vaccination. https://www.fao.org/4/y5162e/y5162e00.htm#Contents
	3. Dose for different population/ species among poultry (Breeder, Layer, Broiler) is need to be clarified.	Breeder, Broiler and Layer all fall in the category of Poultry, therefore 0.3ml dose per bird has been given in the Form-5 in accordance with "COBB Vaccination Procedure Guide" and FAO "Technology Review Chapter 3 Vaccination. https://www.cobbgenetics.com/assets/Cobb-Files/Cobb_Vaccination_Guide.pdf and https://www.fao.org/4/y5162e/y5162e00.htm#Contents
	4. What is the justification of mentioning dose range (0.2ml – 0.5ml) in the application form, i.e., Form-5. (Give its compendial evidence or justification).	Ottoman Pharma's recommended dose of 0.3ml per bird is rightly mentioned in Form 5. The statement *"Day-old vaccination is generally accomplished by giving 0.2 to 0.5 ml of vaccine subcutaneously under the skin at the back of the neck or intramuscularly in the leg".* (COBB Vaccination Procedure Guide). https://www.cobbgenetics.com/assets/Cobb-Files/Cobb_Vaccination_Guide.pdf
	5. Long term and accelerated stability studies data to support the shelf life of applied products is not provided.	According to WHO "Guidelines on stability evaluation of vaccines" accelerated or stressed stability studies are not mandatory for killed viral vaccines. However, long term stability data will be shared after the registration is allowed as per practice. https://cdn.who.int/media/docs/default-source/biologicals/vaccine-quality/guidelines-on-stability-evaluation-of-vaccinesec802a21-dc04-455b-b09c-b7ff76c4d160.pdf?sfvrsn=9a3a8dcb_1
	6. Give the preference with regard to multiple pack sizes mentioned in the application form, i.e., Form-5, as only one pack size can be granted with one application.	It is requested that for all applied products registration, a pack of 300ml may be approved.
	7. Which agents or type of antibodies are used for mixing with WSV as mentioned in manufacturing process in the document. (Give its compendial evidence or justification).	Vaccines are composed of specific purified proteins derived from whole viruses. During production, no **antibodies** or biological agents are mixed with the vaccine.
	8. Justify the parameters to specify the Grade B conditions applied during the manufacturing process and the flow maintained according to the grading of the surfaces used.	The Inoculation process is done in aseptic condition under laminar air flow (LAF) and Heating Ventilating Air Conditioning (HVAC) system in a clean room (Grade B) which is in accordance with the WHO "Environmental

		Monitoring of Clean Rooms in Vaccine Manufacturing Facilities" Table 1. Recommended clean room grades for general activities in the manufacture of prequalified vaccines." Section B "Egg Based Vaccines" clearly mentioned that inoculation process can be done in Unidirectional Air Flow (UDAF) in C. * *https://dcvmn.org/wp-content/uploads/2016/03/who_env_monitoring_cleanrooms_final_2_.pdf
	9. What are the justifications for choosing the first two and last two products for quality control testing? (Give its compendial evidence or justification).	We are using USP procedure, according to pilot scale project of this product, minimum 4 containers are to be tested as per USP sterility testing "10% or 4 containers, whichever is the greater" should be collected for testing. After registration of the product, sample size would be increased.
	10. Give the details of originating of master seed and its source in line with the reference documents.	Ottoman Pharma is using indigenous isolates which have been submitted to National Center for Biotechnology Information (NCBI) USA and granted accession by Gene Bank. This data has been published under the name of Ottoman Pharma. https://www.ncbi.nlm.nih.gov/
	11. The storage conditions mentioned at label is 4-8 ^{0}C, while the product storage is 2-8, please clarify the difference.	Same as already explained against Sr. NO. 1

Decision of 343rd meeting of the Registration Board:
The Registration Board approved the product for local manufacturing with a pack size of 300ml.

7.	**Name and address of product manufacturer (Applicant)**	**OTTOMAN PHARMA** 10 km Raiwind Road Lahore
	Brand Name +Dosage Form + Strength	**AVIAN VAC H9**
	Type of Form, Diary No. Date of R& I & fee	Form-5; R&I Date:18-Aug-2023; F. No.F.3-7/2024-DD-(Bio) Rs. 30,000 Date: 11-July-2023
	Composition	Each 0.3ml of dose contains: Inactivated AIV H9N2 Containing EID50 not < 10^6/ml and HAU not < of 128 HAU
	Description	Inactivated vaccine against Avian Influenza Virus (AIV), H9N2
	Pharmacological Group	Biologicals (Vaccine for veterinary/poultry use)
	Finished Product Specification	Each 0.3ml finished product contains: 0.12 active ingredient 0.18 mineral oil excipient
	Shelf Life & Storage conditions	One year & Store at +2ºC to +8ºC
	Document Details	• DML No. 00502; Renewed on 05-08-2022. • Inactivated Viral Vaccine Section approval 03rd April, 2023.
	Pack size & Demanded Price	50ml; 100ml; 150ml; 300ml; 500ml MRP are De-Controlled
	Products already registered in Pakistan	*Intervac-H9* *Intervac-H9 Oil Emulsion*
	Remarks of Evaluator	• Product applied for both veterinary/ poultry products in the application form, i.e., Form-5; But dose for administration in veterinary and poultry

		subjects is not mentioned clearly, clarification is required. • Dose for different population/ species among poultry (Breeder, Layer, Broiler) is need to be clarified. • Long term and accelerated stability studies data to support the shelf life of applied products is not provided. • What are the tools and ways through which health status of the subjects will be accessed? • Give the preference with regard to multiple pack sizes mentioned in the application form, i.e., Form-5, as only one pack size can be granted with one application. • Which agents or type of antibodies are used for mixing with WSV as mentioned in manufacturing process in the document. (Give its compendial evidence or justification) • What are the parameters/methods adapted for pouring the antigen at a constant rate during the manufacturing process? • Give the details of originating of master seed and its source in line with the reference documents. • The storage conditions mentioned at label is 4-8 ^{0}C, while the product storage is 2-8, please clarify the difference; Label parameters are different from the application form, like. So it is advised to submit the correct version of the label and revised the application form, i.e., Form-5, alongwith applicable fee as per new • S.R.O 1324(I)2024.
	Decision of 340th meeting of the Registration Board: **Registration Board deliberated the case and deferred for submission/ clarification of followings: -** • Label parameters are different from the application form, like. So it is advised to submit the correct version of the label and revised the application form, i.e., Form-5, alongwith applicable fee as per new S.R.O 1324(I)2024. • Product applied for both veterinary/ poultry products in the application form, i.e., Form-5; But dose for administration in veterinary and poultry subjects is not mentioned clearly, clarification is required. • Dose for different population/ species among poultry (Breeder, Layer, Broiler) is need to be clarified. • Long term and accelerated stability studies data to support the shelf life of applied products is not provided. • What are the tools and ways through which health status of the subjects will be accessed? • Give the preference with regard to multiple pack sizes mentioned in the application form, i.e., Form-5, as only one pack size can be granted with one application. • Which agents or type of antibodies are used for mixing with WSV as mentioned in manufacturing process in the document. (Give its compendial evidence or justification) • What are the parameters/methods adapted for pouring the antigen at a constant rate during the manufacturing process? • Give the details of originating of master seed and its source in line with the reference documents. • The storage conditions mentioned at label is 4-8 ^{0}C, while the product storage is 2-8, please clarify the difference.	

The manufacturer has responded to deficinces as under;

Deficiency	Response of the firm
1. Label parameters are different from the application form, like. So, it is advised to submit the correct version of the label and revised the application form, i.e., Form-5, along with applicable fee as per new S.R.O 1324(I)2024.	Label parameters and dossier will be kept as 2 – 8°C which seems to be desire of evaluator. Drugs Registration Board has the authority to amend such things. However, technically speaking there would be nothing wrong if the storage limits are kept within the WHO Guidelines for maintaining vaccine cold chain" https://cdn.who.int/media/docs/default-source/searo/india/publications/immunization-handbook-107-198-part2.pdf
2. Product applied for both veterinary/ poultry products in the application form, i.e., Form-5; But dose for administration in veterinary and poultry subjects is not mentioned clearly, clarification is required.	Ottoman Pharma is a Poultry Inactivated Vaccine producing unit, therefore in Form-5, the dose of 0.3ml per bird has been indicated in accordance with the Bible on the subject i.e. "COBB Vaccination Procedure Guide" https://www.cobbgenetics.com/assets/Cobb-Files/Cobb_Vaccination_Guide.pdf and FAO "Technology Review Chapter 3 Vaccination. https://www.fao.org/4/y5162e/y5162e00.htm#Contents
3. Dose for different population/ species among poultry (Breeder, Layer, Broiler) is need to be clarified.	Breeder, Broiler and Layer all fall in the category of Poultry, therefore 0.3ml dose per bird has been given in the Form-5 in accordance with "COBB Vaccination Procedure Guide" and FAO "Technology Review Chapter 3 Vaccination. https://www.cobbgenetics.com/assets/Cobb-Files/Cobb_Vaccination_Guide.pdf and

		https://www.fao.org/4/y5162e/y5162e00.htm#Contents
	4. Long term and accelerated stability studies data to support the shelf life of applied products is not provided.	According to WHO "Guidelines on stability evaluation of vaccines" accelerated or stressed stability studies are not mandatory for killed viral vaccines. However, long term stability data will be shared after the registration is allowed as per practice. https://cdn.who.int/media/docs/default-source/biologicals/vaccine-quality/guidelines-on-stability-evaluation-of-vaccinesec802a21-dc04-455b-b09c-b7ff76c4d160.pdf?sfvrsn=9a3a8dcb_1
	5. What are the tools and ways through which health status of the subjects will be accessed?	We are using British Pharmacopeia procedure for safety testing, when recommended dose is injected, the birds are to be monitored for any toxic or untoward reactions at the site of injection and vaccinated birds are also to be monitored through feed intake and water intake are to be observed for 14 days.
	6. Give the preference with regard to multiple pack sizes mentioned in the application form, i.e., Form-5, as only one pack size can be granted with one application.	It is requested that for all applied products registration, a pack of 300ml may be approved.
	7. Which agents or type of antibodies are used for mixing with WSV as mentioned in manufacturing process in the document. (Give its compendial evidence or justification)	Vaccines are composed of specific purified proteins derived from whole viruses. During production, no **antibodies** or biological agents are mixed with the vaccine.
	8. What are the parameters/methods adapted for pouring the antigen at a constant rate during the manufacturing process?	This is done through aspiration technique by using constat rate aspirator.
	9. Give the details of originating of master seed and its source in line with the reference documents.	Ottoman Pharma is using indigenous isolates which have been submitted to National Center for Biotechnology Information (NCBI) USA and granted accession by Gene Bank. This data has been published under the name of Ottoman Pharma. https://www.ncbi.nlm.nih.gov/
	10. The storage conditions mentioned at label is 4-8 ^{0}C, while the product storage is 2-8, please clarify the difference.	Same as already explained against Sr. NO. 1
	Decision of 343rd meeting of the Registration Board: **The Registration Board approved the product for local manufacturing with a pack size of 300ml.**	
8. .	**Name and address of product manufacturer (Applicant)**	**OTTOMAN PHARMA** 10 km Raiwind Road Lahore

	Brand Name +Dosage Form + Strength	**GENO FLU VAC**
	Type of Form, Diary No. Date of R& I & fee	Form-5; R&I Date:18-Aug-2023; F. No.F.3-7/2024-DD-(Bio) Rs. 30,000 Date: 11-July-2023
	Composition	Each 0.3ml of dose contains: Inactivated NDV Genotype -VII containing not < 64 HAU and EID_{50} not < 10^7/ml Inactivated AIV H9N2 containing not < 64 HAU and EID_{50} not < 10^7/ml
	Description	Inactivated vaccine against Newcastle Disease Virus Genotype – VII and Avian Influenza Virus (AIV) H9N2
	Pharmacological Group	Biologicals (Vaccine for veterinary/poultry use)
	Finished Product Specification	Each 0.3ml finished product contains: 25 parts active ingredient A 25 parts active ingredient B 0.0005ml preservativ e 50 parts mineral oil excipient
	Shelf Life & Storage conditions	One year & Store at +2°C to +8°C
	Document Details	• DML No. 00502; Renewed on 05-08-2022.
		• Inactivated Viral Vaccine Section approval 03rd April, 2023.
	Pack size & Demanded Price	100ml; 300ml; 500ml; MRP are De-Controlled
	Registered in Pakistan	*GPVAC ND+FLU*
	Remarks of Evaluator	• Dose for different population/ species among poultry (Breeder, Layer, Broiler) is need to be clarified. • What is the justification of mentioning dose range (0.2ml – 0.5ml) in the application form, i.e., Form-5 (Give its compendial evidence or justification). • Long term and accelerated stability studies data to support the shelf life of applied products is not provided. • What are the tools and ways through which health status of the subjects will be accessed? • Give the preference with regard to multiple pack sizes mentioned in the application form, i.e., Form-5, as only one pack size can be granted with one application. • What are the parameters/methods adapted for pouring the antigen at a constant rate during the manufacturing process? • What are the justifications for choosing the first two and last two products for quality control testing? (Give its compendial evidence or justification). • Give the details of originating of master seed and its source in line with the reference documents. • The storage conditions mentioned at label is 4-8 ^{0}C, while the product storage is 2-8, please clarify the difference; • Label parameters are different from the application

		form, like. So it is advised to submit the correct version of the label and revised the application form, i.e., Form-5, alongwith applicable fee as per new S.R.O 1324(I)2024.

9. **Decision of 340th meeting of the Registration Board:**

Registration Board deliberated the case and deferred for submission/ clarification of followings: -

- Label parameters are different from the application form, like. So it is advised to submit the correct version of the label and revised the application form, i.e., Form-5, alongwith applicable fee as per new S.R.O 1324(I)2024.
- Dose for different population/ species among poultry (Breeder, Layer, Broiler) is need to be clarified.
- What is the justification of mentioning dose range (0.2ml – 0.5ml) in the application form, i.e., Form-5 (Give its compendial evidence or justification).
- Long term and accelerated stability studies data to support the shelf life of applied products is not provided.
- What are the tools and ways through which health status of the subjects will be accessed?
- Give the preference with regard to multiple pack sizes mentioned in the application form, i.e., Form-5, as only one pack size can be granted with one application.
- What are the parameters/methods adapted for pouring the antigen at a constant rate during the manufacturing process?
- What are the justifications for choosing the first two and last two products for quality control testing? (Give its compendial evidence or justification).
- Give the details of originating of master seed and its source in line with the reference documents.
- The storage conditions mentioned at label is 4-8 ^{0}C, while the product storage is 2-8, please clarify the difference.

The manufacturer has responded to deficinces as under;

Deficiency	**Response of the firm**
1. Label parameters are different from the application form, like. So, it is advised to submit the correct version of the label and revised the application form, i.e., Form-5, along with applicable fee as per new S.R.O 1324(I)2024.	Label parameters and dossier will be kept as 2 – 8^{o}C which seems to be desire of evaluator. Drugs Registration Board has the authority to amend such things. However, technically speaking there would be nothing wrong if the storage limits are kept within the WHO Guidelines for maintaining vaccine cold chain" https://cdn.who.int/media/docs/default-source/searo/india/publications/immunization-handbook-107-198-part2.pdf
2. Dose for different population/ species among poultry (Breeder, Layer, Broiler) is need to be clarified.	Breeder, Broiler and Layer all fall in the category of Poultry, therefore 0.3ml dose per bird has been given in the Form-5 in accordance with "COBB Vaccination Procedure Guide" and FAO "Technology Review Chapter 3 Vaccination. https://www.cobbgenetics.com/assets/Cobb-Files/Cobb_Vaccination_Guide.pdf and https://www.fao.org/4/y5162e/y5162e00.htm#Contents

	3. What is the justification of mentioning dose range (0.2ml – 0.5ml) in the application form, i.e., Form-5 (Give its compendial evidence or justification).	Ottoman Pharma's recommended dose of 0.3ml per bird is rightly mentioned in Form 5. The statement *"Day-old vaccination is generally accomplished by giving 0.2 to 0.5 ml of vaccine subcutaneously under the skin at the back of the neck or intramuscularly in the leg".* (COBB Vaccination Procedure Guide). https://www.cobbgenetics.com/assets/Cobb-Files/Cobb_Vaccination_Guide.pdf
	4. Long term and accelerated stability studies data to support the shelf life of applied products is not provided.	According to WHO "Guidelines on stability evaluation of vaccines" accelerated or stressed stability studies are not mandatory for killed viral vaccines. However, long term stability data will be shared after the registration is allowed as per practice. https://cdn.who.int/media/docs/default-source/biologicals/vaccine-quality/guidelines-on-stability-evaluation-of-vaccinesec802a21-dc04-455b-b09c-b7ff76c4d160.pdf?sfvrsn=9a3a8dcb_1
	5. What are the tools and ways through which health status of the subjects will be accessed?	We are using British Pharmacopeia procedure for safety testing, when recommended dose is injected, the birds are to be monitored for any toxic or untoward reactions at the site of injection and vaccinated birds are also to be monitored through feed intake and water intake are to be observed for 14 days.
	6. Give the preference with regard to multiple pack sizes mentioned in the application form, i.e., Form-5, as only one pack size can be granted with one application.	It is requested that for all applied products registration, a pack of 300ml may be approved.
	7. What are the parameters/methods adapted for pouring the antigen at a constant rate during the manufacturing process?	This is done through aspiration technique by using constat rate aspirator.
	8. What are the justifications for choosing the first two and last two products for quality control testing? (Give its compendial evidence or justification).	We are using USP procedure, according to pilot scale project of this product, minimum 4 containers are to be tested as per USP sterility testing "10% or 4 containers, whichever is the greater" should be collected for testing. After registration of the product, sample size would be increased.
	9. Give the details of originating of master seed and its source in line with the reference documents.	Ottoman Pharma is using indigenous isolates which have been submitted to National Center for Biotechnology Information (NCBI) USA and granted accession by Gene Bank. This data has been published under the name of Ottoman Pharma. https://www.ncbi.nlm.nih.gov/

	10. The storage conditions mentioned at label is 4-8 0C, while the product storage is 2-8, please clarify the difference.	Same as already explained against Sr. NO. 1

Decision of 343rd meeting of the Registration Board:
The Registration Board approved the product for local manufacturing with a pack size of 300ml.

10. .	**Name and address of product manufacturer (Applicant)**	**OTTOMAN PHARMA** 10 km Raiwind Road Lahore
	Brand Name +Dosage Form + Strength	**BIRD FLU VAC**
	Type of Form, Diary No. Date of R& I & fee	Form-5; R&I Date:18-Aug-2023; F. No.F.3-7/2024-DD-(Bio) Rs. 30,000 Date: 11-July-2023
	Composition	Each dose of 0.3ml contains: Inactivated AIV H5N8 containing not < 128 HAU and EID50 not < 10^8/ml
	Description	Inactivated vaccine against Avian Influenza Virus (AIV), H5N8
	Pharmacological Group	Biologicals (Vaccine for veterinary/poultry use)
	Finished Product Specification	Each 0.3ml finished product contains: 50 parts active ingredient 2mg/ml Gentamycin 0.005% Preservative 50 parts mineral oil excipient
	Shelf Life & Storage conditions	One year & Store at +2ºC to +8ºC
	Document Details	• DML No. 00502; Renewed on 05-08-2022. • Inactivated Viral Vaccine Section approval 03rd April, 2023.
	Pack size & Demanded Price	50ml;100ml;150 ml;300ml; 500ml MRP are De-Controlled
	Already registered in Pakistan	*GPVAC FLU-5; AI Oil H5*

	Remarks of Evaluator	• What is the justification of mentioning dose range (0.2ml – 0.5ml) in the application form, i.e., Form-5 (Give its compendial evidence or justification). • Long term and accelerated stability studies data to support the shelf life of applied products is not provided. • Give the preference with regard to multiple pack sizes mentioned in the application form, i.e., Form-5, as only one pack size can be granted with one application. • Which agents or type of antibodies are used for mixing with WSV as mentioned in manufacturing process in the document. (Give its compendial evidence or justification) • What are the justifications for choosing the first two and last two products for quality control testing? (Give its compendial evidence or justification). • Give the details of originating of master seed and its source in line with the reference documents. • The storage conditions mentioned at label is 4-8 ^{0}C, while the product storage is 2-8, please clarify the difference; • Label parameters are different from the application form, like. So it is advised to submit the correct version of the label and revised the application form, i.e., Form-5, alongwith applicable fee as per new S.R.O 1324(I)2024.

Decision of 340th meeting of the Registration Board:

Registration Board deliberated the case and deferred for submission/ clarification of followings: -

- Label parameters are different from the application form, like. So it is advised to submit the correct version of the label and revised the application form, i.e., Form-5, alongwith applicable fee as per new S.R.O 1324(I)2024;
- What is the justification of mentioning dose range (0.2ml – 0.5ml) in the application form, i.e., Form-5 (Give its compendial evidence or justification).
- Long term and accelerated stability studies data to support the shelf life of applied products is not provided.
- Give the preference with regard to multiple pack sizes mentioned in the application form, i.e., Form-5, as only one pack size can be granted with one application.
- Which agents or type of antibodies are used for mixing with WSV as mentioned in manufacturing process in the document. (Give its compendial evidence or justification)
- What are the justifications for choosing the first two and last two products for quality control testing? (Give its compendial evidence or justification).
- Give the details of originating of master seed and its source in line with the reference documents.
- The storage conditions mentioned at label is 4-8 ^{0}C, while the product storage is 2-8, please clarify the difference.

The manufacturer has responded to deficinces as under;

Deficiency	**Response of the firm**

	1. Label parameters are different from the application form, like. So, it is advised to submit the correct version of the label and revised the application form, i.e., Form-5, along with applicable fee as per new S.R.O 1324(I)2024;	1. Label parameters and dossier will be kept as 2 – 8oC which seems to be desire of evaluator. Drugs Registration Board has the authority to amend such things. However, technically speaking there would be nothing wrong if the storage limits are kept within the WHO Guidelines for maintaining vaccine cold chain" https://cdn.who.int/media/docs/default-source/searo/india/publications/immunization-handbook-107-198-part2.pdf
	2. What is the justification of mentioning dose range (0.2ml – 0.5ml) in the application form, i.e., Form-5 (Give its compendial evidence or justification).	2. Ottoman Pharma's recommended dose of 0.3ml per bird is rightly mentioned in Form 5. The statement *"Day-old vaccination is generally accomplished by giving 0.2 to 0.5 ml of vaccine subcutaneously under the skin at the back of the neck or intramuscularly in the leg".* (COBB Vaccination Procedure Guide). https://www.cobbgenetics.com/assets/Cobb-Files/Cobb_Vaccination_Guide.pdf
	3. Long term and accelerated stability studies data to support the shelf life of applied products is not provided.	3. According to WHO "Guidelines on stability evaluation of vaccines" accelerated or stressed stability studies are not mandatory for killed viral vaccines. However, long term stability data will be shared after the registration is allowed as per practice. https://cdn.who.int/media/docs/default-source/biologicals/vaccine-quality/guidelines-on-stability-evaluation-of-vaccinesec802a21-dc04-455b-b09c-b7ff76c4d160.pdf?sfvrsn=9a3a8dcb_1
	4. Give the preference with regard to multiple pack sizes mentioned in the application form, i.e., Form-5, as only one pack size can be granted with one application.	4. It is requested that for all applied products registration, a pack of 300ml may be approved.
	5. Which agents or type of antibodies are used for mixing with WSV as mentioned in manufacturing process in the document. (Give its compendial evidence or justification)	5. Vaccines are composed of specific purified proteins derived from whole viruses. During production, no **antibodies** or biological agents are mixed with the vaccine.
	6. What are the justifications for choosing the first two and last two products for quality control testing? (Give its compendial evidence or justification).	6. We are using USP procedure, according to pilot scale project of this product, minimum 4 containers are to be tested as per USP sterility testing "10% or 4 containers, whichever is the greater" should be collected for testing. After registration of the product, sample size would be increased.
	7. Give the details of originating of master seed and its source in line with the reference documents.	

	8. The storage conditions mentioned at label is 4-8 0C, while the product storage is 2-8, please clarify the difference.	7. Ottoman Pharma is using indigenous isolates which have been submitted to National Center for Biotechnology Information (NCBI) USA and granted accession by Gene Bank. This data has been published under the name of Ottoman Pharma. https://www.ncbi.nlm.nih.gov/ 8. Same as already explained against Sr. NO. 1 (Annex-II)
	Decision of 343rd meeting of the Registration Board: **The Registration Board approved the product for local manufacturing with a pack size of 300ml.**	

11.	**Name and address of product manufacturer (Applicant)**	**OTTOMAN PHARMA** 10 km Raiwind Road Lahore
	Brand Name +Dosage Form + Strength	**NEWCASTLE FLU VAC**
	Type of Form, Diary No. Date of R& I & fee	Form-5; R&I Date:18-Aug-2023; F. No.F.3-7/2024-DD-(Bio) Rs. 30,000 Date: 11-July-2023
	Composition	Each 0.3ml contains:
		Inactivated NDV LASOTA containing not < 64 HAU and EID_{50} not < 10^7/ml Inactivated AIV H9N2 containing not < 64 HAU and EID_{50} not < 10^7/ml
	Description	Inactivated vaccine against Newcastle Disease Virus and Avian Influenza Virus (AIV), H9N2
	Pharmacological Group	Biologicals (Vaccine for veterinary/poultry use)
	Finished Product Specification	Each 0.3ml finished product contains: 25 parts active ingredient A 25 parts active ingredient B 0.0005ml preservative 50 parts mineral oil excipient
	Shelf Life & Storage conditions	One year & Store at +2°C to +8°C
	Document Details	• DML No. 00502; Renewed on 05-08-2022.
		• Inactivated Viral Vaccine Section approval 03rd April, 2023.
	Pack size & Demanded Price	100ml; 300ml; 500ml MRP are De- Controlled
	Products already registered in Pakistan	*GPVAC ND+FLU*

12.	Remarks of Evaluator	• Product applied for both veterinary/ poultry products in the application form, i.e., Form-5; But dose for administration in veterinary and poultry subjects is not mentioned clearly, clarification is required. • Dose for different population/ species among poultry (Breeder, Layer, Broiler) is need to be clarified. • Long term and accelerated stability studies data to support the shelf life of applied products is not provided. • Give the preference with regard to multiple pack sizes mentioned in the application form, i.e., Form-5, as only one pack size can be granted with one application. • What are the parameters/methods adapted for the collection of allantoic fluids during the manufacturing process? (Give its compendial evidence or justification) • Give the details of originating of master seed and its source in line with the reference documents. • Label parameters are different from the application form, like. So it is advised to submit the correct version of the label and revised the application form, i.e., Form-5, alongwith applicable fee as per new S.R.O 1324(I)2024.

Decision of 340th meeting of the Registration Board:

Registration Board deliberated the case and deferred for submission/ clarification of followings: -

- Label parameters are different from the application form, like. So it is advised to submit the correct version of the label and revised the application form, i.e., Form-5, alongwith applicable fee as per new S.R.O 1324(I)2024.Long term and accelerated stability studies data to support the shelf life of applied products is not provided.
- Product applied for both veterinary/ poultry products in the application form, i.e., Form-5; But dose for administration in veterinary and poultry subjects is not mentioned clearly, clarification is required.
- Dose for different population/ species among poultry (Breeder, Layer, Broiler) is need to be clarified.
- Long term and accelerated stability studies data to support the shelf life of applied products is not provided.
- Give the preference with regard to multiple pack sizes mentioned in the application form, i.e., Form-5, as only one pack size can be granted with one application.
- What are the parameters/methods adapted for the collection of allantoic fluids during the manufacturing process? (Give its compendial evidence or justification)
- Give the details of originating of master seed and its source in line with the reference documents.

The manufacturer has responded to deficinces as under;

Deficiency	**Response of the firm**

	1. Label parameters are different from the application form, like. So, it is advised to submit the correct version of the label and revised the application form, i.e., Form-5, along with applicable fee as per new S.R.O 1324(I)2024.Long term and accelerated stability studies data to support the shelf life of applied products is not provided.	1. Label parameters and dossier will be kept as 2 – 8°C which seems to be desire of evaluator. Drugs Registration Board has the authority to amend such things. However, technically speaking there would be nothing wrong if the storage limits are kept within the WHO Guidelines for maintaining vaccine cold chain" https://cdn.who.int/media/docs/default-source/searo/india/publications/immunization-handbook-107-198-part2.pdf
	2. Product applied for both veterinary/ poultry products in the application form, i.e., Form-5; But dose for administration in veterinary and poultry subjects is not mentioned clearly, clarification is required.	2. Ottoman Pharma is a Poultry Inactivated Vaccine producing unit, therefore in Form-5, the dose of 0.3ml per bird has been indicated in accordance with the Bible on the subject i.e. "COBB Vaccination Procedure Guide" https://www.cobbgenetics.com/assets/Cobb-Files/Cobb_Vaccination_Guide.pdf and FAO "Technology Review Chapter 3 Vaccination. https://www.fao.org/4/y5162e/y5162e00.htm#Contents
	3. Dose for different population/ species among poultry (Breeder, Layer, Broiler) is need to be clarified.	3. Breeder, Broiler and Layer all fall in the category of Poultry, therefore 0.3ml dose per bird has been given in the Form-5 in accordance with "COBB Vaccination Procedure Guide" and FAO "Technology Review Chapter 3 Vaccination. https://www.cobbgenetics.com/assets/Cobb-Files/Cobb_Vaccination_Guide.pdf and https://www.fao.org/4/y5162e/y5162e00.htm#Contents
	4. Long term and accelerated stability studies data to support the shelf life of applied products is not provided.	4. According to WHO "Guidelines on stability evaluation of vaccines" accelerated or stressed stability studies are not mandatory for killed viral vaccines. However, long term stability data will be shared after the registration is allowed as per practice. https://cdn.who.int/media/docs/default-source/biologicals/vaccine-quality/guidelines-on-stability-evaluation-of-vaccinesec802a21-dc04-455b-b09c-b7ff76c4d160.pdf?sfvrsn=9a3a8dcb_1
	5. Give the preference with regard to multiple pack sizes mentioned in the application form, i.e., Form-5, as only one pack size can be granted with one application.	5. It is requested that for all applied products registration, a pack of 300ml may be approved.
	6. What are the parameters/methods adapted for the collection of allantoic fluids during the manufacturing process? (Give its compendial evidence or justification)	6. Amniotic Allantoic Fluid (AAF) is collected / harvested from embryonated

	7. Give the details of originating of master seed and its source in line with the reference documents.	eggs through a liquid aspiration assembly (vacuum aspirator) that aspirate the AAF from every single egg. 7. Ottoman Pharma is using indigenous isolates which have been submitted to National Center for Biotechnology Information (NCBI) USA and granted accession by Gene Bank. This data has been published under the name of Ottoman Pharma. https://www.ncbi.nlm.nih.gov/

Decision of 343rd meeting of the Registration Board:
The Registration Board approved the product for local manufacturing with a pack size of 300ml.

12.	**Name and address of product manufacturer (Applicant)**	**OTTOMAN PHARMA** 10 km Raiwind Road Lahore
	Brand Name +Dosage Form + Strength	**GENO-VII VAC**
	Type of Form, Diary No. Date of R& I & fee	Form-5; R&I Date:18-Aug-2023; F. No.F.3-7/2024-DD-(Bio) Rs. 30,000 Date: 11-July-2023
	Composition	Each 0.3ml contains: Inactivated NDV Genotype -VII containing not < 64 HAU and EID50 not < 10^7/ml
	Description	Inactivated vaccine against Newcastle Disease Virus
	Pharmacological Group	Biologicals (Vaccine for veterinary/poultry use)
	Finished Product Specification	Each 0.3ml finished product contains: 0.12ml active ingredient 0.0005ml preservative 0.18ml parts mineral oil excipient
	Shelf Life & Storage conditions	One year & Store at +2ºC to +8ºC
	Document Details	• DML No. 00502; Renewed on 05-08-2022. • Inactivated Viral Vaccine Section approval 03rd April, 2023.
	Pack size & Demanded Price	50ml; 100ml; 150ml; 300ml; 500ml MRP are De-Controlled
	Already registered in Pakistan	*Medivac ND Emulsion*
	Remarks of Evaluator	• Dose for different population/ species among poultry (Breeder, Layer, Broiler) is need to be clarified. • Long term and accelerated stability studies data to support the shelf life of applied products is not provided. • Give the preference with regard to multiple pack sizes mentioned in the application form, i.e., Form-5, as only one pack size can be granted with one application. • Which agents or type of antibodies are used for mixing with WSV as mentioned in manufacturing process in the document. (Give its compendial evidence or justification)

		• What are the parameters/methods adapted for the collection of allantoic fluids during the manufacturing process? (Give its compendial evidence or justification) What are the justifications for choosing the first two and last two products for quality control testing? (Give its compendial evidence or justification). • Give the details of originating of master seed and its source in line with the reference documents. • Label parameters are different from the application form, like. So it is advised to submit the correct version of the label and revised the application form, i.e., Form-5, alongwith applicable fee as per new S.R.O 1324(I)2024.

Decision: Registration Board deliberated the case and deferred for submission/ clarification of followings: -

- Label parameters are different from the application form, like. So it is advised to submit the correct version of the label and revised the application form, i.e., Form-5, alongwith applicable fee as per new S.R.O 1324(I)2024.
- Dose for different population/ species among poultry (Breeder, Layer, Broiler) is need to be clarified.
- Long term and accelerated stability studies data to support the shelf life of applied products is not provided.
- Give the preference with regard to multiple pack sizes mentioned in the application form, i.e., Form-5, as only one pack size can be granted with one application.
- Which agents or type of antibodies are used for mixing with WSV as mentioned in manufacturing process in the document. (Give its compendial evidence or justification)
- What are the parameters/methods adapted for the collection of allantoic fluids during the manufacturing process? (Give its compendial evidence or justification)
- What are the justifications for choosing the first two and last two products for quality control testing? (Give its compendial evidence or justification).
- Give the details of originating of master seed and its source in line with the reference documents.

The manufacturer has responded to deficinces as under;

Deficiency	**Response of the firm**
1. Label parameters are different from the application form, like. So, it is advised to submit the correct version of the label and revised the application form, i.e., Form-5, along with applicable fee as per new S.R.O 1324(I)2024.Long term and accelerated stability studies data to support the shelf life of applied products is not provided.	1. Label parameters and dossier will be kept as 2 – 8°C which seems to be desire of evaluator. Drugs Registration Board has the authority to amend such things. However, technically speaking there would be nothing wrong if the storage limits are kept within the WHO Guidelines for maintaining vaccine cold chain" https://cdn.who.int/media/docs/default-source/searo/india/publications/immunization-handbook-107-198-part2.pdf
2. Dose for different population/ species among poultry (Breeder, Layer, Broiler) is need to be clarified.	2. Breeder, Broiler and Layer all fall in the category of Poultry, therefore 0.3ml dose per bird has been given in the Form-5 in accordance with "COBB Vaccination Procedure Guide" and FAO "Technology Review Chapter 3 Vaccination.

	3. Long term and accelerated stability studies data to support the shelf life of applied products is not provided. 4. Give the preference with regard to multiple pack sizes mentioned in the application form, i.e., Form-5, as only one pack size can be granted with one application. 5. Which agents or type of antibodies are used for mixing with WSV as mentioned in manufacturing process in the document. (Give its compendial evidence or justification) 6. What are the parameters/methods adapted for the collection of allantoic fluids during the manufacturing process? (Give its compendial evidence or justification) 7. What are the justifications for choosing the first two and last two products for quality control testing? (Give its compendial evidence or justification). 8. Give the details of originating of master seed and its source in line with the reference documents.	https://www.cobbgenetics.com/assets/Cobb-Files/Cobb_Vaccination_Guide.pdf and https://www.fao.org/4/y5162e/y5162e00.htm#Contents 3. According to WHO "Guidelines on stability evaluation of vaccines" accelerated or stressed stability studies are not mandatory for killed viral vaccines. However, long term stability data will be shared after the registration is allowed as per practice. https://cdn.who.int/media/docs/default-source/biologicals/vaccine-quality/guidelines-on-stability-evaluation-of-vaccinesec802a21-dc04-455b-b09c-b7ff76c4d160.pdf?sfvrsn=9a3a8dcb_1 4. It is requested that for all applied products registration, a pack of 300ml may be approved. 5. Vaccines are composed of specific purified proteins derived from whole viruses. During production, no **antibodies** or biological agents are mixed with the vaccine. 6. Amniotic Allantoic Fluid (AAF) is collected / harvested from embryonated eggs through a liquid aspiration assembly (vacuum aspirator) that aspirate the AAF from every single egg. 7. We are using USP procedure, according to pilot scale project of this product, minimum 4 containers are to be tested as per USP sterility testing "10% or 4 containers, whichever is the greater" should be collected for testing. After registration of the product, sample size would be increased. 8. Ottoman Pharma is using indigenous isolates which have been submitted to National Center for Biotechnology Information (NCBI) USA and granted accession by Gene Bank. This data has been published under the name of Ottoman Pharma. https://www.ncbi.nlm.nih.gov/
	Decision of 343rd meeting of the Registration Board: **The Registration Board approved the product for local manufacturing with a pack size of 300ml.**	

Case No.2. Transfer of registration/ change in importer from M/s Marush Pvt Ltd to M/s Inouko Animal Health (Private) Limited

Sr. No.	Reg. No. and date	Brand Name and Composition	Existing manufacturer and MA Holder	Existing Registration Holder/ Importer	Demanded/ New Registration Holder/ Importer:
13.	103999 Dated 10.08.2020	**Cevac I-Bird,** Live Freeze- dried vaccine Each dose contains, Avian infectious Bronchitis virus, variant strain 1/96 at least 2.8 log $10EID_{50}$ (BP specification)	**Manufacturer Holder:** M/s CEVA PHYLAXIA Veterinary Biological Co. Ltd. 1107 Budapest Szallas u. 5. Hungary **MAH: Not mentioned**	M/s Marush Pvt Ltd **Address:** 117-A, Ahmad Block, New Garden Town, Lahore	M/s Inouko Animal Health (Private) Limited **Address:** 3rd Floor, Plaza No.3, Block D, DHA Phase 5, Cantt, Lahore Pakistan
14.	104000 Dated 10.08.2020	**Cevac Mass L,** Live Freeze- dried vaccine Each dose of vaccine contains, Infectious Bronchitis virus (IBV), Massachusetts type strain B-48……..min 2.8log $10EID_{50}$ (BP specification)			
15.	104001 Dated 10.08.2020	**Cevac Transmune,** Live Freeze- dried complex vaccine Each dose contains: Infectious Bursal Disease Virus(IBDV), Winterfield 2512 strain, G-61……min 0.1 CID_{50} (BP specification)			
16.	107877 Dated 19.01.2021	**Vectormune ND** Live recombinant frozen vaccine Each one dose of vaccine contains, Live recombinant turkey herpes virus with inserted F (Fusion) gene of NDV: at least 2500 PFU (As per Innovator's Specifications)			
17.	081818 Dated 24.06.2020	**Vectormune HVT NDV & Rispens** Each dose contains, Marek's disease-Newcastle disease virus….at least 2474 PFU's through expiration Marek's disease, Rispens CVI988 strain….at least 1206 PFU's through expiration Cryoprotectant No.1 + HVT/NDV Strains---------50-90% (75% in CLI) Cryoprotectant No.2--------10- 50% (BP specification)	**Manufacturer:** M/s Biomune Company 8906 Rosehill Road Lenexa, Kansas USA.		

18.	081817 Dated 24.06.2020	**CEVAC MD HVT & RISPENS** Each dose contains: Marek's Disease, HVT Strain…. At least 2164 PFU per dose through expiration. -Marek's Disease, Rispens CVI988 Strain…. at least 1322 PFU per dose through expiration. Cryoprotectant No.1 + HVT and Rispens CV1988 Strains--------- 50-90% (75% in CLI) Cryoprotectant No.2---------10- 50% (BP specification)			
19.	083903 Dated 24.06.2020	**Sterile Diluent for Vectormune HVT NDV** Each 1000ml contains: Sucrose……10.0 g NZ Amine AS……..4.0 g Sorbitol……45.0 g K2HPO4……1.20 g KH2PO4……..0.50 g Phenol Red……..0.02 g Deionzed Water qs to 10000ml (Innovator's Specifications)			

The case was evaluated as per approved Guidelines: Post Registration Variation Guidelines and tabulated below:

Documents required as per Guidelines	**Documents submitted by the firm**	**Remarks**
Application	Submitted	
Required fee as per relevant SRO.	Fee Challan of Rs. 75,000/- Online Slip Number: 7283593909 dated 18.05.2023 has been submitted for **Sterile Diluent for Vectormune HVT NDV** Online Slip Number: 06304484 dated 18.05.2023 has been submitted for **Cevac I-Bird,** Online Slip Number: 4740993595 dated 18.05.2023 has been submitted for **Vectormune HVT NDV & Rispens** Online Slip Number: 90422838833 dated 18.05.2023 has been submitted for **Cevac Mass-L** Online Slip Number: 18275892099 dated 18.05.2023 has been submitted for **CEVAC MD HVT & RISPENS** Online Slip Number: 15822146785 dated 18.05.2023 has been submitted for **Cevac Transmune**	

	Online Slip Number: 792400133 dated 18.05.2023 has been submitted for **Vectormune ND,**	
Copy of registration letter and last renewal status	Copy of Registration letters submitted on dated 10-08-2020 for the product at sr. No.1-3 are submitted. Copy of Registration letters submitted on dated 19.01.2021 for the product at sr. No.4 is submitted. Copy of Registration letters submitted on dated 24.06.2020 for the product at sr. No.5-7 are submitted.	
Termination letter (original) from marketing authorization holder/ manufacturer for previous importer.	Submitted	
Legalised Authority letter/sole agent letter (original) from marketing authorization holder/ manufacturer in name of new importer.	Firm has Submitted Original, Appostile Sole Agency Agreement between M/s Ceva Sante Animale S.A. 10 Avenue de la Ballastiere 33500 Libourne, France and Inouko Animal Health (Private) Limited, Lahore. Company Relationship among Ceva Sante Animale S.A (Parent company of all Ceva subsidiaries), Ceva-Phylaxia Veterinary Biologicals Co. Ltd.(Hungry Manufacturing site) Budapest Hungry and Biomune Company (USA manufacturing site) 8906 Rosehill Road, Lenexa, Kansas 66215, USA has also been attached.	
No Objection Certficate (issued within last 6 Months) from existing registration holder in name of applicant for registration of drug product.	Submitted.	Not within 6 months
Revised drafts of the package insert and labeling incorporating the proposed variation.	Not submitted	
Legalized Certficate of Pharmaceutical Product (CoPP) or other relevant documents as defined by Registration Board.	Apostille Free sale Certificates of The products at Sr.No 1-4 are submitted Legalized Certificatess of LCertificate of Licensing and Inspection of The products at Sr.No 5-7are submitted	Legalized/Apostille GMP Certificates of The products at Sr.No 1-4 are required to be submitted.

The applications were evaluated as per approved SOPs for post registration variations, following deficiencies/discrepancies were found.

i. Differential fee of Rs. 75,000/- for each product is required to be submitted.

ii. No Objection Certficate (issued within last 6 Months) from existing registration holder in name of applicant for registration of drug product is required to be submitted as per PRV Guidelines.

iii. Clarification is required that the Marketing Authorization Holder of the Products i.e **Cevac I-Bird, (Reg. No. 103999), Cevac Mass L, (Reg. No. 104000), Cevac Transmune (Reg. No. 104001) and Vectormune ND (Reg. No. 107877)** on registration letter and Free Sale Certificates **is M/s** CEVA PHYLAXIA Veterinary Biological Co. Ltd. 1107 Budapest Szallas u. 5. Hungary while the Apostille Sole agency agreement submitted is of M/s Ceva Sante Animal S.A Office address 10 Avenue de la Basllastiere 33500 Libourne, France.

iv. Clarification is required that the Marketing Authorization Holder of the Products i.e **Cevac I-Bird, (Reg. No. 103999), Cevac Mass L, (Reg. No. 104000), Cevac Transmune (Reg. No. 104001) and Vectormune ND (Reg. No. 107877)** on registration letter and Free Sale Certificates is M/s CEVA PHYLAXIA Veterinary Biological Co. Ltd. 1107 Budapest Szallas

u. 5. Hungary while the Termination of Agreement with M/s Marush Pvt Ltd submitted is of M/s Ceva Sante Animal S.A Office address 10 Avenue de la Basllastiere 33500 Libourne. France.

v. Clarification is required that the Marketing Authorization Holder of the Products **Vectormune HVT NDV & Rispens (Reg. No. 081818), CEVAC MD HVT & RISPENS (Reg. No. 081817) and Sterile Diluent for Vectormune HVT NDV (Reg. No. 083803) is not mentioned in registration Letter and Certificate of Licensing and Inspection and the manufacturer is** M/s Biomune Company 8906 Rosehill Road Lenexa, Kansas USA while the Termination of Agreement with M/s Marush Pvt Ltd submitted is of M/s Ceva Sante Animal S.A Office address 10 Avenue de la Basllastiere 33500 Libourne. France.

vi. Legalized/Apostille GMP Certificates of the products at Sr.No 1-4 are required to be submitted.

vii. Revised drafts of the package insert and labeling incorporating the proposed variation.

Registration Board in its 333rd meeting delegated its power/functions for Change of importer from Existing Registration Holder/ Importer to New Registration Holder/ Importer and manufacturer/ manufacturing site abroad remains unchanged which is already registered in the Chairman Registration Board.

In view of the above a deficiency letter No.10-3/2024-DD(BD)(PRV-D) dated 26-06-2024 was issued to the firm for which the firm has submitted following reply with following document:

i. Differential Fee of Rs. 75,000/- for all the products has been submitted.
ii. NOC from M/s Marush Private Limited dated 31-07-2024.
iii. Clarification that **M/s** CEVA PHYLAXIA Veterinary Biological Co. Ltd. is a directly, wholly-owned subsidiary of "Ceva sante animale". **M/s** CEVA PHYLAXIA Veterinary Biological Co. Ltd endorses and certifies that all the actions taken by its direct parent company Ceva sante animale.

Decision: Keeping in view the termination of sole agency agreement by the manufacturer abroad in name M/s Marush Pvt Ltd , authorization by manufacturer abroad in name of M/s Inouko Animal Health (Private) Limited and NOC issued by M/s Marush Pvt Ltd in favor of M/s Inouko Animal Health (Private) Limited for transfer of above products, Chairman Registration Board, on recommendation of committee, decided to issue show cause notice to M/s Marush Pvt Ltd Address:117-A, Ahmad Block, New Garden Town, Lahore, under Section 42 of the Drugs Act, 1976 and also provide them chance of personal Hearing in upcoming Registration Board Meeting for transfer of their above mentioned products to M/s Inouko Animal Health (Private) Limited Address: 3rd Floor, Plaza No.3, Block D, DHA Phase 5, Cantt, Lahore Pakistan.

In the light of above decision, a Show cause notice and personnel hearing letter were issued to M/s Marush Pvt Ltd Address**:** 117-A, Ahmad Block, New Garden Town, Lahore.

Proceeding of the Board in its 340th meeting:
In compliance to the personal hearing letter Mr. Usman on behalf of M/s Marush (Pvt) Ltd Lahore appeared before the Board and confirms that they have served a written no objection certificate for grant of registrations of the subject products to the applicant i.e. M/s Inouko Animal Health (Private) Limited, Lahore, but, still they have the valid written agreement with M/s CEVA PHYLAXIA Veterinary Biological Co. Ltd., France, therefore, they will definitely continue the business of subject products in the local market. Regisrtaion Board also provided the opportunity of persobal hearing to M/s Inouko Animal Health (Private) Limited, Lahore and Mr. Umer Hameed wherein, it was informed that the M/s Inouko Animal Health (Private) Limited, Lahore is the exclusive/sole agent of M/s CEVA PHYLAXIA Veterinary Biological Co. Ltd., France, for the above products.

Decision of 340th meeting of Registration Board:
Keeping in veiw the above facts, the Board decided to defer the case till the submission of the written statement of the termination/revocation of the sole agency agreement from M/s CEVA PHYLAXIA Veterinary Biological Co. Ltd., France in name of M/s Marush (Pvt) Ltd., Lahore.
Updated status of the Case:
An email has been received to CEO, DRAP & Director (BE&R) from Antonin Bonneau (Vice President of Ceva Sante Animale - APAC). Ceva Sante Animale S.A., the contents of which are

reproduced as under;

"This is Antonin Bonneau (Vice President of Ceva Sante Animale - APAC). Ceva Sante Animale S.A., is the parent company of CEVA Phylaxia having office at 1107 Budapest, Szallas u. 5 Hungary, Biomune Company having office at 8906 Rosehill Road, Lenexa, Kansas USA. Both the aforementioned are subsidiaries of Ceva Sante Animale S.A. having office at 10 Avenue, deja) Ballastiere 33500, Libourne, France.

1. Following products manufactured by CEVA Phylaxia were earlier registered in the name of Marush Pvt. Ltd. However, CEVA Phylaxia through it's parent company namely CEVA Sante Animale has now terminated the Sole Agency agreement with Marush Pvt. Ltd and we have filed application for the transfer of Registration in the favor of CEVA Sante Animale subsidiary namely Inouko Animal Health (Private) Limited.

S. No.	Name of the Drug	Packing	Drug Registration Number issued by DRAP
1.	Cevac I-Bird	2500 doses Vial	103999
2.	Cevac Transmume	2000 doses Vial	104001
3.	Cevac Mass L	2500 Doses Vial	104000
4.	Vectormune ND	2000 Doses Glass Ampoule	107877

2. Following products manufactured by Biomune Company were earlier registered in the name of Marush Pvt. Ltd. However, Biomune Company through it's parent company namely CEVA Sante Animale has now terminated the Sole Agency agreement with Marush Pvt. Ltd. And filed application for the transfer of Registration in the favor of CEVA Sante's subsidiary namely Inouko Animal Health.

S. No.	Name of the Drug	Packing	Drug Registration Number issued by DRAP
1.	Vectormune HVT NDV & Rispens	2000 doses	081818
2.	Cevac MD HVT & Rispens	2000 doses	081817
3.	Sterile Dilument for Vectromune HVT NDV	400ml Vial	083903

3. The applications remained pending for a very long period and were finally considered in the 340th Meeting of the Registration Board held on 1st to 2nd October 2024, wherein it was noted that Marush Pvt. Ltd. holds a valid Sole Agency Agreement with CEVA.

4. Our legal counsel, Mr, Umar Hameed Khan met on 29-11-2024 with Mr. Babar Khan, Director Biological Evaluation and Registration. I pursuance of the meeting we hereby confirm that there is no Sole Agency Agreement between Marush Pvt. Ltd. and CEVA Phylaxia, Biomune Company and/or CEVA Sante Animale. Scans of the letter authenticating it is attached herewith for the ease of your reference.

We are now in the process of obtaining the apostille document from Ceva Sante Animale. We will poll intend to forward the apostilled document to your esteemed office directly via postal service as soon as it is ready to ensure the document's legal recognition, and this email is to facilitate the complete transfer of List B products from Marush to Inouko Animal Health (Private) Limited.

Thank you for your understanding in this matter and will notify you promptly once the document has been dispatched. You are once again requested to promptly transfer the products in favour of Inouko."
Another email has been received to CEO, DRAP & Director (BE&R) from Tamas Szamko (Vice President of Ceva Phylaxia - Hunagary, Ceva Phylaxia the contents of which are reproduced as under;
"This is Tamas Szamko (Vice President of Ceva Phylaxia - Hunagary, Ceva Phylaxia located at 1107 Budapest u.5 Szallas Hungary and it is a subsidiary of Ceva Sante Animale S.A. having office at 10 Avenue. de la Ballastiere 33500, Liboume, France.
Following products manufactured by CEVA Phylaxia were earlier registered in the name of Marush Pvt. Ltd. However, CEVA Phylaxia through it's parent company namely CEVA Sante Animale has now

terminated the Sole Agency agreement with Marush Pvt. Ltd and we have filed application for the transfer of Registration in the favor of CEVA Sante Animale subsidiary namely Inouko Animal Health (Private) Limited.

S. No.	Name of the Drug	Packing	Drug Registration Number issued by DRAP
1.	Cevac I-Bird	2500 doses Vial	103999
2.	Cevac Transmume	2000 doses Vial	104001
3.	Cevac Mass L	2500 Doses Vial	104000
4.	Vectormune ND	2000 Doses Glass Ampoule	107877

Our applications were considered in the 340th Meeting of the Registration Board held on 1st to 2nd October 2024 wherein it was noted that Marush Pvt. Ltd. holds a valid Sole Agency Agreement with Ceva - Phylaxia France.

Our legal counsel, Mr. Umar Hameed Khan met on 29-11-2024 with Mr. Babar Khan, Director Biological Evaluation and Registration. In pursuance of the meeting we hereby confirm that there is no Sole Agency Agreement between Marush Pvt. Ltd. and CEVA Phylaxis. Scan of the letter authenticating it is attached herewith for the ease of your reference.

We have started the process of obtaining the apostille document. We will send the original apostilled document to your esteemed office directly via postal service as soon as s it is ready. This email is to facilitate the DRAP to complete the transfer of List B products from Marush to Inouko Animal Health (Private) Limited.

Thank you for your understanding in this matter and we will notify you promptly once the document has been dispatched."

Proceedings of 343rd Meeting:

The Board was apprised that show-cause notice & opportunity of personal hearing has already been given to M/s Marush (Pvt) Ltd in 340th meeting of the Board. Mr. Usman on behalf of M/s Marush (Pvt) Ltd Lahore appeared before the Board in the said meeting and confirmed that they have served a written no objection certificate for grant of registrations of the subject products to the applicant i.e. M/s Inouko Animal Health (Private) Limited, Lahore, but, still they have the valid written agreement with M/s CEVA PHYLAXIA Veterinary Biological Co. Ltd., France, therefore, they will definitely continue the business of subject products in the local market. The Board was further apprised that the opportunity of personal hearing to M/s Inouko Animal Health (Private) Limited, Lahore has also been provided in the same meeting and Mr. Umer Hameed appeared before the Board on behalf of M/s Inouko Animal Health (Private) Limited, Lahore. He informed that M/s Inouko Animal Health (Private) Limited, Lahore is the exclusive/sole agent of M/s CEVA PHYLAXIA Veterinary Biological Co. Ltd., France, for the subject products.

Decision of 343rd Meeting:

Keeping in view above proceedings and the latest email received from Vice President of Ceva Sante Animale – APAC, Ceva Sante Animale S.A, parent company of CEVA Phylaxia, Hungary & Biomune Company, USA, regarding termination of sole agency agreement with Marush Pvt. Ltd, the Board decided to approve the change / grant Marketing Authorization Holder / Registration holder of the subject products from M/s Marush Pvt. Ltd to M/s Inouko Animal Health (Private) Limited.

Registration Board 343 Meeting Minutes:

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
1	**Pacific Pharmaceuticals Ltd.** Plot No.384, Sundar Industrial Estate, Raiwind Road, Lahore (**000902**) Tracking ID: (4J9-HVB-YYNG, 2023-12-11) Fee Paid: 30000.0 Paid Date: 2023-11-22 Case Category: Routine **(Adil Saeed)**	Proposed Name: **Lidocaine HCl Injection 2% w/v** Each 1 ml Contains: Lidocaine HCl ..... 20 mg British Pharmacopeia RRA Status: Lidocaine HCl Injection 2% w/v - Hameln Pharma Ltd. UK Me Too Status: Lignox 2% Injection Pack Size(s): 2 ml Ampoule-As per SRO
	Evaluation Remarks: Drug substance taken loan from Cunningham, Firm was asked to submit Ad attested invoice or clearance certificate. Copy of clearance certificate is submitted.	
	Decision: Approved	
2	**CURATECH PHARMA PVT.LTD.** 35Km Main Multan Road Lahore, Pakistan (**000619**) Tracking ID: (2XG-R3H-YME5, 2024-06-25) Fee Paid: 30000.0 Paid Date: 2024-04-23 Case Category: New Section **(Adil Saeed)**	Proposed Name: **Brainy Syrup 500mg/5ml** Each 5ml contains...citicoline as sodium 500mg As per Innovators Specification RRA Status: Somazine 100 mg/ml oral solution - Cima Spain Me Too Status: Citolin Syrup reg# 029540 by Global Pharmaceutical (Pvt.) Ltd. Pack Size(s): 60ml-As per SRO
	Evaluation Remarks: Submit reply of following observations for further processing of your case. Section: 1.3.4: Submit GMP certificate issued by DRAP for manufacturing facility of Syrup Genera Section which should be valid till date. GMP certificate valid till 18.02.2022 is submitted. Section 3.2.P.7: Clarify that primary container mentioned as HDPE white colored bottle while in the table of Product general details the the nature of primary container has been mentioned as A light brown color clear viscous liquid filled in amber color pet bottle sealed with cap and packed in specially designed tray holder with insertion of leaflet in unit carton. Firm has stated that amber coloured PET bottle is the container closure system	
	Decision: Approved	
3	**Pacific Pharmaceuticals Ltd.** Plot No.384, Sundar Industrial Estate, Raiwind Road, Lahore (**000902**) Tracking ID: (73H-JPL-SG1S, 2023-12-11) Fee Paid: 30000.0 Paid Date: 2023-11-22 Case Category: Routine **(Adil Saeed)**	Proposed Name: **Lidocaine HCl Injection 1% w/v** Each 1 ml Contains: Lidocaine HCl ..... 10 mg British Pharmacopeia RRA Status: Lidocaine HCl Injection 1% w/v - Hameln Pharma Ltd. UK Me Too Status: Lacain 1% Injection Pack Size(s): 2 ml Ampoule-As per SRO
	Evaluation Remarks: Drug substance taken loan from Cunningham, Firm was asked to submit Ad attested invoice or clearance certificate. Clearance certificate is submitted.	
	Decision: Approved	
4	**Titlis Pharma (Private) Limited** 528-A Sundar Industrial Estate, Raiwind Road Lahore (**000799**) Tracking ID: (4X3-DEB-73XP, 2024-06-03) Fee Paid: 30000.0 Paid Date: 2022-03-28 Case Category: New Section **(Adil Saeed)**	Proposed Name: **Emlint** Each Film Coated Tablet Contains: Linagliptin.....5mg Empagliflozin.....10mg As per Innovators Specification RRA Status: USFDA APPROVED (Glyxambi 5/10mg Tablet) Me Too Status: Diampa-LT by GETZ Pharma Pack Size(s): 14s-As per SRO
	Evaluation Remarks: Deferred in 339th. The registration Board deferred the case. Firm shall again perform assay and submit chromatograms with value of resolution between the peak of interest and other peaks in the chromatogram. Firm has submitted the required data.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
5	**PHARMEVO (PVT) LTD.** A-29, NORTH WESTERN INDUSTRIAL ZONE, PORT QASSIM KARACHI. (**000504**) Tracking ID: (87T-GGM-SXN8, 2023-12-13) Fee Paid: 75000.0 Paid Date: 2023-10-02 Case Category: Routine **(Adil Saeed)**	Proposed Name: **Vergat 2.5mg Tablet** Each Film Coated Tablet Contains: Vericiguat....2.5mg (As per innovators specification) As per Innovators Specificatio RRA Status: US-FDA (Verquvo) Me Too Status: Not Applicable Pack Size(s): 7’s,10’s,14’s,20’s,2-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
6	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (JH9-3E7-1UUA, 2024-08-21) Fee Paid: 30000.0 Paid Date: 2024-02-23 Case Category: New License **(Adil Saeed)**	Proposed Name: **oridone** Each film coated tablet contains: Risperidone ……2mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: RIsperidal 2mg tablet by Aspin pharma Pack Size(s): 10's,20's,30's,50's,-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
7	**Fortune Pharma (Pvt.) LTD** Plot 20/K SITE,Super High Way Phase II Karachi (**000924**) Tracking ID: (L5S-PYQ-47WP, 2024-05-28) Fee Paid: 30000.0 Paid Date: 2022-08-15 Case Category: New License **(Adil Saeed)**	Proposed Name: **RELIEF** Each 1ml Ampoule Contains: Nalbuphine Hydrochloride.....20mg As per Innovators Specification RRA Status: NUBAIN INJECTION Me Too Status: NALBIN 20mg INJECTION Pack Size(s): 5's-As per SRO
	Evaluation Remarks: Deferred in 336th Rb fr RRA Reference. USFDA Approval is submitted.	
	Decision: Approved	
8	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (LX2-VLG-LTVY, 2024-08-22) Fee Paid: 30000.0 Paid Date: 2024-02-23 Case Category: New License **(Adil Saeed)**	Proposed Name: **oridone** Each film coated tablet contains: Risperidone ……1mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: RIsperidal 1mg tablet by Aspin pharma Pack Size(s): 10's,20's,30's,50's,-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
9	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (M1P-U5G-XAA2, 2024-09-11) Fee Paid: 30000.0 Paid Date: 2024-02-23 Case Category: New License **(Adil Saeed)**	Proposed Name: **oridone** Each film coated tablet contains: Risperidone ……3mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: RIsperidal 3mg tablet by Aspin pharma Pack Size(s): 10's,20's,30's,50's,-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
10	**World Biz Pharmaceuticals Company, Multan** 340, Phase-II, Industrial Estate, Multan (**000942**) Tracking ID: (N3A-781-NSTP, 2024-06-12) Fee Paid: 30000.0 Paid Date: 2024-03-27 Case Category: New Section **(Adil Saeed)**	Proposed Name: **EsoBiz Capsule 40mg** Each Capsule contains:- Delayed Release Pellets of Esomeprazole Magnesium Trihydrate Equivalent to Esomeprazole……40mg (USP Specification) United States Pharmacopeia RRA Status: Esomeprazole Capsule 40mg by Cipla EU Ltd (MHRA Approved) Me Too Status: Esso-40 Capsule 40mg Reg No. 032961 (Shaigan Pharmaceutical Private Limited) Pack Size(s): 1’s, 5’s, 7’s, 10’s,-As per SRO

<table>
<tr><th>Sr. No</th><th>Name of Applicant, Manufacturer & Fee Details</th><th>Product Info</th></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
<table>
<tr><th>Section</th><th>Observations</th><th>Reply of the firm</th></tr>
<tr><td rowspan="2">3.2.P.8</td><td>In the chromatograms submitted, two different components are eluting very close together (peak of interest vs unknown peak). clarify that why the analysis being carried out when parameters were out of control?</td><td>The peak appearing close to peak of interest is of blank/diluent peak.</td></tr>
<tr><td>Submit evidence that Chromatograms are in electronically stored records and must have an audit trail ensuring traceability.</td><td>Audit trail submitted</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved
Source of pellets: Vision Pharmaceuticals (Pvt.) Limited Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan</td></tr>
<tr><td>11</td><td>CURATECH PHARMA PVT.LTD.
35Km Main Multan Road
Lahore, Pakistan (000619)
Tracking ID: (9XB-8TV-74B4, 2024-05-20)
Fee Paid: 30000.0
Paid Date: 2024-04-23
Case Category: New Section
(Adil Saeed)</td><td>Proposed Name: Moody Syrup
Each 1ml syrup contains: Risperidone.....1mg

RRA Status: USFDA Approved.
Me Too Status: Risp Oral Suspension (Manufacturer by Addamjee Pharmaceutical Pvt. Ltd.)
Pack Size(s): 30ml-As per SRO</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
3.2.S.4.1
Submit data in section 3.2.S.4.1 and 3.2.S.4.2 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.” Submitted
3.2.S.4.3
Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states that “Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as noncompendial drug substance(s) shall be submitted”. Submitted
3.2.P.5.2
The standard and sample preparation in USP(200mcg/ml) is different than preparation(0.1mg/ml) provided in section 3.2.P.5.2.Clarification is required. Submitted Its a typo mistake
3.2.P.7
Clarification for container closure system is required whether HPDE or PET bottle due to variation in data provided in Module .
3.2.P.8.3 PET Bottle
a) The container closure system for applied formulation is semipermeable, but the test of water loss has not been performed. Justify. Studies submitted.
b) The Chromatograms of sample solution contains three major peaks .Identify the peak at RT 1 and 2. Peaks are of solvent

c) Submit commercial invoice for import of API. Submitted</td></tr>
<tr><td></td><td colspan="2">Decision: Approved
.</td></tr>
<tr><td>12</td><td>Bosch Pharmaceuticals (Pvt) Ltd.
Plot No. 221-223, Sector-23, Korangi Industrial Area
(000350)
Tracking ID: (QPY-8P4-UGPU, 2023-12-14)
Fee Paid: 75000.0
Paid Date: 2023-10-05
Case Category: Routine
(Adil Saeed)</td><td>Proposed Name: Ericig
Each film coated tablet contains: Vericiguat 2.5mg
Manufacturer Specification
RRA Status: European Medicines Agency (EMA)
Me Too Status: Not Applicable
Pack Size(s): 14's-As per SRO</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
The firm has applied for Manufacturer specifications instead of Innovator specifications.</td></tr>
<tr><td></td><td colspan="2">Decision: Approved
Approved with Innovator specifications. Firm shall submit fee of Rs. 9000/- for pre-registration variation before issuance of letter.</td></tr>
<tr><td>13</td><td>Orbis Pharmaceuticals
Plot # K-138 , SITE Super Highway Phase 2 , Karachi
(000979)
Tracking ID: (RQ6-MB6-YJSN, 2024-08-21)
Fee Paid: 30000.0
Paid Date: 2024-07-24
Case Category: New License
(Adil Saeed)</td><td>Proposed Name: oridone
Each ml contain: Risperidone 1mg
United States Pharmacopeia
RRA Status: USFDA Approved
Me Too Status: RIsperidal 1mg/ml oral solution by Aspin pharma
Pack Size(s): 30ml,60ml,120ml-As per SRO</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
Drug susbtance taken loan from M/s Lisko</td></tr>
<tr><td></td><td colspan="2">Decision: Approved</td></tr>
<tr><td>14</td><td>Orbis Pharmaceuticals
Plot # K-138 , SITE Super Highway Phase 2 , Karachi
(000979)
Tracking ID: (SJL-LSE-NEU2, 2024-08-20)
Fee Paid: 30000.0
Paid Date: 2024-02-23
Case Category: New License
(Adil Saeed)</td><td>Proposed Name: oridone
Each film coated tablet contains: Risperidone 4mg
United States Pharmacopeia
RRA Status: USFDA Approved
Me Too Status: RIsperidal 4mg tablet by Aspin pharma
Pack Size(s): 10's,20's,30's,50's,-As per SRO</td></tr>
<tr><td></td><td colspan="2">Details of Certificates (CoPP/cGMP, Authorization Letter etc):</td></tr>
</table>

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
15	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (TTR-6E5-944H, 2024-08-30) Fee Paid: 75000.0 Paid Date: 2024-08-07 Case Category: New License **(Adil Saeed)**	Proposed Name: **oridone** Each film coated tablet contains: Risperidone ……0.5mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: NA Pack Size(s): 10's,20's,30's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
16	**CRYSTOLITE PHARMACEUTICALS** Plot # 1 & 2, street S-2, National Industrial Zone Rawat, Islamabad (**000778**) Tracking ID: (TTU-JBR-4LS6, 2023-12-13) Fee Paid: 30000.0 Paid Date: 2023-10-20 Case Category: Routine **(Adil Saeed)**	Proposed Name: **Valtril 200mg Tablet** Each Film Coated Tablet Contains: Sacubitril……97mg Valsartan ……103mg (as sacubitril valsartan sodium salt complex) As per Innovators Specificatio RRA Status: Entresto 200mg tablet approved by FDA Me Too Status: savesto 200mg tablet by getz pharma Pack Size(s): 14's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
17	**Neophar Healthcare Pakistan (Pvt.) Limited** 66-N, Model Town Lahore-54700 (**000994**) Tracking ID: (WEY-EA3-W5JV, 2024-10-24) Fee Paid: 37000.0 Paid Date: 2024-10-14 Case Category: New License **(Adil Saeed)**	Proposed Name: **Neophazole** Each dealyed release capsule contains: Esomeprazole…..40 mg as 22.5% Enteric Coated Esomeprazole Magnesium Pellets United States Pharmacopeia RRA Status: FDA Me Too Status: Yes Pack Size(s): 14-As per SRO
	Evaluation Remarks: Source of Pellets: Pharmazone Chemicals (Pvt.) Limited Lahore	
	Decision: Approved	
18	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (EYD-ANX-TTTR, 2024-10-09) Fee Paid: 75000.0 Paid Date: 2024-09-11 Case Category: New License **(Adil Saeed)**	Proposed Name: **Lepinza** Each film coated tablet contains: Olanzapine……2.5mg United States Pharmacopeia RRA Status: Medicines and Healthcare Regulatory Agency (MHRA Me Too Status: NA Pack Size(s): 10's,20's,30's,50's,-As per SRO
	Details of Certificates (CoPP/cGMP, Authorization Letter etc): As per USP monograph system suitability has 2 parameters, resolution and RSD, For resolution: NLT2.0 between olanzapine ad olanzapine related compound A, firm has performed only RSD part and resolution part is not performed.	
	Evaluation Remarks: The firm was asked: (3.2.P.5), The system suitability mentioned in assay method is different from the one mentioned in USP monograph of the product (use of Olanzapine Related compound A). Please clarify. Firm has replied: System suitability RSD is not more than 2%, already mentioned in all specs and for USP monograph of olanzapine is also attached.	
	Decision: Approved	
19	**CURATECH PHARMA PVT.LTD.** 35Km Main Multan Road Lahore, Pakistan (**000619**) Tracking ID: (G83-PG1-75D5, 2024-05-16) Fee Paid: 30000.0 Paid Date: 2024-04-23 Case Category: New Section **(Adil Saeed)**	Proposed Name: **Swish Oral Drops (Suspension)** Each 1ml contains Nystatin 100,000 IU. United States Pharmacopeia RRA Status: Nilstat Oral Drops approved in TGA link: https://www.tga.gov.au/resources/lab-test-reports/nilstat-oral-drops-nystatin-100000-iuml-suspension-bottle-aspen-pharma-pty-ltd-0 Me Too Status: Nilstat Drops Reg # 001554, Manufactured by ICI Pakistan Ltd. Pack Size(s): 50ml-As per SRO

<table>
<tr><th>Sr. No</th><th>Name of Applicant, Manufacturer & Fee Details</th><th>Product Info</th></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
(2.3.R.1.1)Submit executed production documents. Submitted
(3.2.S.4.1)Submit data in section 3.2.S.4.1 and 3.2.S.4.2 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.” Submitted
(3.2.S.4.3)Submit data in section 3.2.S.4.3 as per the decision of 293rd meeting of Registration Board, which states that “Analytical Method Verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer for both compendial as well as noncompendial drug substance(s) shall be submitted”. Submitted
(3.2.S.4.4)Submit discussion and justification for any incomplete analyses of the drug substance / API by Drug Product manufacturer. Submitted
(3.2.P.2)Submit compatibility studies of the Drug Substance(s) with excipients if the formulation is not similar to innovator / reference product. Submitted
(3.2.P.7)Clarification for container closure system is required whether HPDE or PET bottle due to variation in data provided in section 3.2.P.7 and 3.2.P.8.3 . PET Bottle (3.2.P.8.3) Submitted
Ø Submit approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. Submitted
Ø Submit commercial invoice for import of API. Submitted</td></tr>
<tr><td></td><td colspan="2">Decision: Approved
.</td></tr>
<tr><td>20</td><td>Orbis Pharmaceuticals
Plot # K-138 , SITE Super Highway Phase 2 , Karachi (000979)
Tracking ID: (HD8-49V-A5JD, 2024-09-18)
Fee Paid: 37000.0
Paid Date: 2024-09-11
Case Category: New License
(Adil Saeed)</td><td>Proposed Name: Lepinza
Each film coated tablet contains: Olanzapine……10mg
United States Pharmacopeia
RRA Status: Medicines and Healthcare Regulatory Agency (MHRA
Me Too Status: Zapin by Glitz Pharma
Pack Size(s): 10's,20's,30's,50's,-As per SRO</td></tr>
<tr><td></td><td colspan="2">Details of Certificates (CoPP/cGMP, Authorization Letter etc):
As per USP monograph system suitability has 2 parameters, resolution and RSD, For resolution: NLT2.0 between olanzapine ad olanzapine related compound A, firm has performed only RSD part and resolution part is not performed.</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
The firm was asked: (3.2.P.5), The system suitability mentioned in assay method is different from the one mentioned in USP monograph of the product (use of Olanzapine Related compound A). Please clarify.
Firm has replied: System suitability RSD is not more than 2%, already mentioned in all specs and for USP monograph of olanzapine is also attached.</td></tr>
<tr><td></td><td colspan="2">Decision: Approved</td></tr>
<tr><td>21</td><td>World Biz Pharmaceuticals Company, Multan
340, Phase-II, Industrial Estate, Multan (000942)
Tracking ID: (L8H-R1M-7HEH, 2024-06-11)
Fee Paid: 30000.0
Paid Date: 2024-03-27
Case Category: New Section
(Adil Saeed)</td><td>Proposed Name: EsoBiz Capsule 20mg
Each Capsule contains:- Enteric Coated Pellets of Esomeprazole Magnesium Trihydrate Equivalent to Esomeprazole……20mg (USP Specification)
United States Pharmacopeia
RRA Status: MHRA approved Esomeprazole Capsule 20mg by Cipla EU Ltd
Me Too Status: Esso-20 Capsule 20mg REG No. 032960 (SHAIGAN Pharmaceuticals)
Pack Size(s): 1’s, 5’s, 7’s, 10’s,-As per SRO</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
<table>
<tr><th>Section</th><th>Observations</th><th>Reply of the firm</th></tr>
<tr><td>3.2.P.8</td><td>In the chromatograms submitted, two different components are eluting very close together (peak of interest vs unknown peak). clarify that why the analysis being carried out when parameters were out of control?</td><td>The peak appearing close to peak of interest is of blank/diluent peak.</td></tr>
<tr><td></td><td>Submit evidence that Chromatograms are in electronically stored records and must have an audit trail ensuring traceability.</td><td>Copy of Audit trail submitted</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved
Source of pellets: Vision Pharmaceuticals (Pvt.) Limited Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan</td></tr>
<tr><td>22</td><td>Orbis Pharmaceuticals
Plot # K-138 , SITE Super Highway Phase 2 , Karachi (000979)
Tracking ID: (PEL-74E-QMVW, 2024-10-29)
Fee Paid: 37000.0
Paid Date: 2024-10-23
Case Category: New License
(Adil Saeed)</td><td>Proposed Name: Orgab
Each capsule contains: Pregabalin ……75mg
Manufacturer Specification
RRA Status: Lyrica by USFDA Approved
Me Too Status: Gabia 75mg by Getz pharma
Pack Size(s): 12's,14's-As per SRO</td></tr>
<tr><td></td><td colspan="2">Details of Certificates (CoPP/cGMP, Authorization Letter etc):
The parameters of HPLC system in assay like Column temperature, detection wavelength and injection volume are different in submitted testing method then the one prescribed in BP monograph.</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
API is taken loan from M/s Lisko.

The firm had applied for Manufacturer specifications, monograph of product is available in BP. Firm was asked for clarification, and firm has submitted that it was a typographic mistake, and they have used BP method of analysis.But the parameters like Column temperature, detection wavelength and injection volume are different in submitted testing method then the one prescribed in BP monograph.</td></tr>
<tr><td></td><td colspan="2">Decision: Approved
Approved with BP specifications. Before issuance of letter, firm shall submit fee of Rs. 9000/- for revision of specifications and shall also submit testing report of trial batches as per BP method on next time point.</td></tr>
</table>

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
23	**CURATECH PHARMA PVT.LTD.** 35Km Main Multan Road Lahore, Pakistan (**000619**) Tracking ID: (WGH-R5S-3JWY, 2024-05-22) Fee Paid: 30000.0 Paid Date: 2024-04-23 Case Category: New Section **(Adil Saeed)**	Proposed Name: **Curaon Syrup** Each 5ml contains:Ondansetron (as) HCL Dihydrate....4mg RRA Status: MHRA Approved. Me Too Status: Dysit syrup 4mg/5ml (Manufactured by Wimits Reg:) Pack Size(s): 50ml-As per SRO
	Evaluation Remarks: The case was deferred in 339th RB for submission of reply. Firm has submitted documents against each observation. As per submitted response, firm has used drug substance that has potency of 81.53%. As per USP monograph and specs submitted by the firm it should be between 98% and 102%	
	Decision: Deferred Deferred for clarification regarding potency of drug substance used in manufacturing of trial batches.	
24	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (YQ4-QJE-V3UX, 2024-09-18) Fee Paid: 37000.0 Paid Date: 2024-09-11 Case Category: New License **(Adil Saeed)**	Proposed Name: **Lepinza** Each film coated tablet contains: Olanzapine.....5mg United States Pharmacopeia RRA Status: Medicines and Healthcare Regulatory Agency (MHRA Me Too Status: Zapin by Glitz Pharma Pack Size(s): 10's,20's,30's,50's,-As per SRO
	Details of Certificates (CoPP/cGMP, Authorization Letter etc): As per USP monograph system suitability has 2 parameters, resolution and RSD, For resolution: NLT2.0 between olanzapine ad olanzapine related compound A, firm has performed only RSD part and resolution part is not performed.	
	Evaluation Remarks: The firm was asked: (3.2.P.5), The system suitability mentioned in assay method is different from the one mentioned in USP monograph of the product (use of Olanzapine Related compound A). Please clarify. Firm has replied: System suitability RSD is not more than 2%, already mentioned in all specs and for USP monograph of olanzapine is also attached.	
	Decision: Approved	
25	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (Z8B-Q24-EUST, 2024-10-29) Fee Paid: 37000.0 Paid Date: 2024-10-23 Case Category: New License **(Adil Saeed)**	Proposed Name: **Orgab** Each capsule contains: Pregabalin .....50mg Manufacturer Specification RRA Status: Lyrica by USFDA Approved Me Too Status: Gabia 50mg by Getz pharma Pack Size(s): 12's,14's-As per SRO
	Details of Certificates (CoPP/cGMP, Authorization Letter etc): Mfg. specifications are applied. The parameters like Column temperature, detection wavelength and injection volume are different in submitted testing method then the one prescribed in BP monograph.	
	Evaluation Remarks: The firm had applied for Manufacturer specifications, monograph of product is available in BP. Firm was asked for clarification, and firm has submitted that it was a typographic mistake, and they have used BP method of analysis. But the parameters like Column temperature, detection wavelength and injection volume are different in submitted testing method then the one prescribed in BP monograph.	
	Decision: Approved Approved with BP specifications. Before issuance of letter, firm shall submit fee of Rs. 9000/- for revision of specifications and shall also submit testing report of trial batches as per BP method on next time point.	
26	**CURATECH PHARMA PVT.LTD.** 35Km Main Multan Road Lahore, Pakistan (**000619**) Tracking ID: (ZDZ-RY4-PXMH, 2024-05-13) Fee Paid: 30000.0 Paid Date: 2024-02-12 Case Category: New Section **(Adil Saeed)**	Proposed Name: **Zinc-OD Syrup** Each 5ml syrup contains: Zinc sulphate monohydrate equivalent to Elemental zinc.....20mg United States Pharmacopeia RRA Status: Applied formulation has been verified from International Pharmacopoeia of WHO (Available strengths: Me Too Status: OSIRIS 20mg/5ml Syrup Reg# 066902 by Sami Pharmacueticals Pack Size(s): 60ml-As per SRO
	Evaluation Remarks: The case was deferred in 339th Meeting. The firm has addressed all the deficiencies, one observation needs consideration. The firm was asked to submit RRA reference. In response the firm has submitted that the monograph of international pharmacopeia under the heading of Additional information specifies that “Available strengths: 10 mg or 20 mg of zinc per 5 ml.Moreover, Zinc sulfate 20mg/5ml is also approved in 327th meeting of DRB held on 13-April,2024.	
	Decision: Approved	
27	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (**000978**) Tracking ID: (13X-LBL-JXLL, 2024-11-14) Fee Paid: 30000.0 Paid Date: 2024-09-05 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Xynazole 150mg capsule** Each Hard gelatin capsule contain Fluconazole .....150mg(BP Spes,s) British Pharmacopeia RRA Status: USFDA Approved Me Too Status: Duflucan 150mg capsule Pack Size(s): 1x1s-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Your instant application has been evaluated and found deficient for following observations: Drug substance specification, analytical procedure and analytical method verification studies shall be submitted from M/s PHARMAQIO Details of the reference product against which Pharmaceutical and CDP studies has been performed shall be submitted. Valid GMP certificate/DML of the drug substance manufacturer, issued by the relevant regulatory authority o country of origin shall be submitted. Documents confirming procurement/import of drug substance, with approval of DRAP I&E Office shall be submitted. Firm's response: Firm has submitted following: Drug substance specification, analytical procedure and analytical method verification studies shall from M/s PHARMAQIO Details of the reference product as of Fungone capsule of M/s Sami GMP certificate/DML of the drug substance manufacturer Loan lettter of Drug substance form M.s Lawari International along with clearance certificate.	
	Decision: Approved	
28	**Global Pharmaceuticals Pakistan** Plot # 8, Street # S-8, RCCI, Industrial Estate Rawat, Islamabad-Pakistan (**000724**) Tracking ID: (1EM-17G-8TJ8, 2023-12-05) Fee Paid: 75000.0 Paid Date: 2023-11-22 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Nuben 10mg Injection** Each Ampoule (1ml) contains: Nalbuphine Hydrochloride .....10mg (Innovator's Specifications) As per Innovators Specificatio RRA Status: USFDA Me Too Status: Nalfoline 10mg/ml Injection by Mediate Pharmaceuticals, Karachi Pack Size(s): 1's-As per SRO,10's-As per SRO
	Manufacturer(s): Formulation-Global Pharmaceuticals (Pvt) Ltd.-Plot # 204-205 Industrial Triangle, Kahuta Road, Islamabad- Pakistan.-	
	Evaluation Remarks:	
	Decision: Approved	
29	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (**000978**) Tracking ID: (1V9-4V4-MW9X, 2024-11-19) Fee Paid: 30000.0 Paid Date: 2024-09-05 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Qioflox 500 mg Tablet** Each film coated tablets contains Levofloxacin as hemihydrate.....500mg (USP-Spec,s) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: LEFLOX TABLETS 500mg Pack Size(s): 1x10s-Controlled
	Evaluation Remarks: Your instant application has been evaluated and found deficient for following observations: Drug substance specification, analytical procedure and analytical method verification studies shall be submitted from M/s PHARMAQIO Pharmaceutical and CDP studies has been submitted for 250mg strength while applied formulation is of 500mg strength. COA of reference/working standard used for analysis of drug product shall be submitted. Revised section 3.2.P.1 shall be submitted with correct salt form of drug substance. Firm has submitted relevant documents against above observations	
	Decision: Approved Firm shall submit fee of pre-registration variation i.e., Rs. 9,000/- for each strength as per SRO1324 (I)/2024 dated 30-08-2024.	
30	**TABROS PHARMA (PVT). LTD.** Plot No. L-20/B, Sector 22, F.B. Industrial Area (**000106**) Tracking ID: (5PU-MTH-J12A, 2023-11-07) Fee Paid: 30000.0 Paid Date: 2023-11-06 Case Category: Routine **(Ammar Ashraf Awan)**	Proposed Name: **Pertz-S Tablet 5mg/100mg** Each film coated tablet contains: Ertugliflozin L-Pyroglutamic Acid eq to Ertugliflozin.....5mg+ Sitagliptin phosphate monohydrate equivalent to Sitagliptin...100mg As per Innovators Specification RRA Status: STEGLUJAN TABLET Merck Sharp & Dohme Corp. USFDA Approved Me Too Status: Trevia R2 Tablet 5/100mg Getz Pharma, Eglaro-S Tablet 5/100mg Pharm Evo Pack Size(s):
	Evaluation Remarks:	
	Decision: Approved	
31	**Scilife Pharma Private Limited** FD-57/58-A2, Korangi Creek Industrial Park (KCIP) (**000837**) Tracking ID: (3X4-1DB-38NB, 2023-11-17) Fee Paid: 30000.0 Paid Date: 2023-10-30 Case Category: Routine **(Ammar Ashraf Awan)**	Proposed Name: **SCILINA 10MG/5MG TAB** Each film coated tablet contains: Empagliflozin 10mg Linagliptin 5mg As per Innovators Specification RRA Status: Product is U.S FDA approved. GLYXAMBI 10MG/5MG TABLET Manufactured by Boehringer Ingelheim. Me Too Status: Following is already rea. Manufacturer: M/s Getz Pharma Pakistan (Pvt.) Ltd. b. Brand Name: Diampa L Pack Size(s):

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Instant application has been evaluated and found deficient for following observations: Justification shall be submitted for the solubility of Empagliflozin in water declared as "practically insoluble" with reference to the innovator drug product literature. Justification shall be submitted for not including test of Enantiomeric purity for Linagliptin, by both drug substance manufacturer and M//s Scilife, as recommended by innovator drug product literature Firm's response: On behalf of Scilife Pharma, we would like to address the discrepancy in the solubility specification of Empagliflozin in water. The solubility information in the innovator drug product literature from the US FDA and EMA states that Empagliflozin is “very slightly soluble in water (pH 1-7.4).” However, the initial specification provided by the API manufacturer incorrectly stated the solubility as “practically insoluble in water,” which was a typographical error. The original manufacturer specification described Empagliflozin as: • Sparingly soluble in methanol, practically insoluble in water, toluene, and 0.1 mol/L HCl, and very slightly soluble in acetonitrile and ethanol. The revised manufacturer specification described Empagliflozin as : • Very slightly soluble in water (pH 1-7.4), slightly soluble in acetonitrile and ethanol, sparingly soluble in methanol, and practically insoluble in toluene On behalf of Scilife Pharma, , we acknowledge that the “Enantiomeric Purity” test was not initially included in the initial specifications of Linagliptin by both the API manufacturer and Scilife Pharma (Pvt.) Limited. However, both the API manufacturer and the FPP manufacturer have now revised their respective specifications to include this test, aligning with the recommendations in the innovator drug product literature. We are submitting the updated documents to reflect the inclusion of the “Enantiomeric Purity” tes	
	Decision: Approved Firm shall submit fee of pre-registration variation i.e., Rs. 9,000/- as per SRO1324 (I)/2024 dated 30-08-2024.	
32	**AMB HK ENTERPRISES (PVT) LTD, LAHORE** 2nd floor plaza 60, Commercial Block K, Phase-1 DHA, Lahore. (**05-352-0058**) Tracking ID: (4P9-8ED-5PX4, 2023-12-29) Fee Paid: 150000.0 Paid Date: 2023-10-23 Case Category: Import **(Ammar Ashraf Awan)**	Proposed Name: **Vorizol** Each vial contains: Voriconazole ..... 200mg Manufacturer Specification RRA Status: FDA Me Too Status: Generic Pack Size(s): 1's; As per SRO-As per SRO
	Marketing Authorization Holder (Abroad): M/s ABM HK ENTERPRISES (PVT) LTD , 2nd Floor, Plaza 60, Commercial Block-K, Phase-1,DHA, Lahore, Pakistan **Manufacturer(s):** FPP manufacturer-Livzon (Group) Pharmaceutical Factory-No. 38 Chuangye Rode North, Jinwan District, Zhuhai, Guangdong-China	
	Details of Certificates (CoPP/cGMP, Authorization Letter etc): Firm has submitted COPP no. 20230044 issued by Gunagdong Medical product Administration dated 13-12-2023 declaring free sale status of the applied product along with GMP status of the product manufacturer.	
	Evaluation Remarks: JP monograph is available for applied formulation	
	Decision: Approved As per Innovator specifications. Firm shall submit fee of pre-registration variation i.e., Rs. 9,000/- for each strength as per SRO1324 (I)/2024 dated 30-08-2024 along with analytical record for the submitted drug product stability data including chromatograms/spectrums etc., before issuance of registration letter.	
33	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (**000978**) Tracking ID: (887-ME8-JUQT, 2024-11-12) Fee Paid: 30000.0 Paid Date: 2024-09-05 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Qiocephen 250mg IV** Each vial contains: Ceftriaxone as Sodium..... 250 mg (USP Spec,s) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Oxidil250 mg Injection I.V Pack Size(s): 1s-Controlled
	Evaluation Remarks:	
	Decision: Approved	
34	**Horizon HealthCare (Pvt) Ltd** plot no 33 sunder industrial estate lahore (**000782**) Tracking ID: (5S6-8RV-LYVT, 2023-12-15) Fee Paid: 75000.0 Paid Date: 2023-11-24 Case Category: Routine **(Ammar Ashraf Awan)**	Proposed Name: **Pytol Orodispersible 250mg Tablet** Each Orodispersible tablet contains: Paracetamol .....250mg (As per Innovator’s Specs.) As per Innovators Specificatio RRA Status: Registered drug by HPRA Health Products Regulatory Authority (HPRA) of Ireland Calpol Six Plus FASTM Me Too Status: N/A Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: Instant application has been evaluated and found deficient for following observations: • Justification shall be submitted for using USP reference standard for the analysis of BP grade drug substance. • Justification shall be submitted for the use of Benzyl alcohol as preservative agent in the formulation, with reference to the innovator drug product literature. • Justification shall be submitted for the limits of disintegration test with reference to the general standards for the oro-dispersible tablet. • Clarification shall be submitted for the performance of antimicrobial preservative test. • The analysis method for paracetamol in the British Pharmacopoeia (BP) relies on a titration method. This approach does not require a reference standard because titration directly determines the amount of the active ingredient based on a chemical reaction, such as acid-base or redox reactions. Unlike chromatographic methods, which require a standard to quantify the analyte through comparison, titration measures the analyte stoichiometrically without external calibration. Moreover, the other testing parameters for the analysis of drug substance in B.P are almost similar to USP like identification by IR, loss on drying, and sulfated ash. • The innovator drug product has used Benzyl alcohol in their formulation. So, we followed the innovator formulation to prepare equivalent drug product. • As per the USP general guidelines for uncoated tablet under the section the oral drug products quality tests “Uncoated tablets include single-layer tablets that result from a single compression of particles and multilayer tablets that consist of concentric or parallel layers obtained by successive compression of particles of different composition. The excipients used generally are not specifically intended to modify the release of the active substance in the digestive fluids. Uncoated tablets include but are not limited to: effervescent tablets, buccal tablets, sublingual tablets, chewable tablets, orally disintegrating tablets, tablets for oral solution, and tablets for oral suspension”. Additionally, as per FDA guidelines “ODTs be considered solid oral preparations that disintegrate rapidly in the oral cavity, with an in-vitro disintegration time of approximately 30 seconds or less, when based on the United States Pharmacopeia (USP) disintegration test method or alternative”. Moreover, our product disintegration time results are observed less than 30 seconds which indicated out product disintegration time results are concordant to FDA guidelines. • We have performed the microbials limit tests as our results falls within limits as provided by USP guideline.	
	Decision: Deferred For further deliberation upon the pharmacokinetic and pharmacodynamic features of applied formulation.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
35	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (**000978**) Tracking ID: (9VJ-2ZU-VMW2, 2024-11-11) Fee Paid: 30000.0 Paid Date: 2024-09-05 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Qioxime 200mg/5ml dry suspension** Each 5ml reconstituted suspension contains Cefixime as Trihydrate.....200mg(USP-Spec,s) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Cefspan 200mg/5mlDry Suspension Pack Size(s): 1x1s-Controlled
	Evaluation Remarks: Firm has submitted differential fee of Rs. 7000 vide deposit slip no. 77798588718. The fee details have to be added in the e-app dashboard.	
	Decision: Approved	
36	**CRYSTOLITE PHARMACEUTICALS** Plot # 1 & 2, street S-2, National Industrial Zone Rawat, Islamabad (**000778**) Tracking ID: (66N-HR1-46XL, 2023-12-13) Fee Paid: 75000.0 Paid Date: 2023-09-26 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Ozenox 1% Cream** Each gram contains: Ozenoxacin .....10mg As per Innovators Specificatio RRA Status: ozenoxacin 1% cream approved by USFDA Me Too Status: Not available new product Pack Size(s): 5g-As per SRO
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks: Instant application has been evaluated and found deficient for following observations: 1. Justification shall be submitted for not including tests of "Viscosoty", " Benzoic acid Assay" and " Microbial limits" in drug product specifications, as recommended by the innovator drug product literature. Firm's response: The microbial tests and viscosity measurements are added in Certificate of analysis which were missed in previous Certificate of analysis due to personnel error. Revised Certificates of analysis is attached. 2. Benzoic acid assay, we did not test in product as it was tested and approved at raw stage, which is used by the production for the cream preparation. So that raw material tests of benzoic acid is now provided in documents Because we used it as a excipient. Certificate of analysis of Benzoic acid is submitted along with Antimicrobial preservative efficacy test reports	
	Decision: Approved Firm shall submit fee of pre-registration variation i.e., Rs. 9,000/- for each strength as per SRO1324 (I)/2024 dated 30-08-2024.	
37	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (**000978**) Tracking ID: (6VP-GWV-724W, 2024-11-12) Fee Paid: 30000.0 Paid Date: 2024-09-05 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Qiocephen 500mg IM** Each vial contains: Ceftriaxone as Sodium..... 500 mg (USP Spec,s) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Oxidil500 mg Injection I.M Pack Size(s): 1s-Controlled
	Evaluation Remarks: Your instant application has been evaluated and found deficient for following observations: Drug substance specification, analytical procedure and analytical method verification studies shall be submitted from M/s PHARMAQIO Details of the re-constitution diluent used for the reconstitution of drug product shall be submitted. Firm has submitted following: Drug substance specifications, analytical method and verification studies. Details of Re constitution diluent as Lignocaine injection from M/s Jaens Pharmaceuticals	
	Decision: Approved	
38	**Pharmatec Pakistan (Pvt.) Limited** D-86/A, S.I.T.E., Karachi - 75700, Pakistan (**000024**) Tracking ID: (712-45G-NTBV, 2024-03-12) Fee Paid: 30000.0 Paid Date: 2023-12-20 Case Category: Routine **(Ammar Ashraf Awan)**	Proposed Name: **Empazin-L Tablet 25mg/5mg** Each film coated Tablet contains: Empagliflozin.....25mg Linagliptin.....5mg As per Innovators Specification RRA Status: Glyxambi 25mg/5mg film-coated Tablets by Boehringer Ingelheim International GmbH, MHRA Approved. Me Too Status: Diampa LT Tablet 25mg/5mg by Getz Pharma (Private) Limited. Pack Size(s): 1 x 7's, 1 x 10's, 1-As per SRO
	Evaluation Remarks:	
	Decision: Approved Firm shall submit fee of pre-registration variation i.e., Rs. 9,000/- for each strength as per SRO1324 (I)/2024 dated 30-08-2024.	
39	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (**000978**) Tracking ID: (GB9-A8E-S2U2, 2024-11-11) Fee Paid: 30000.0 Paid Date: 2024-09-05 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Qioprole 30mg Capsule** Each hard gelatin capsule contain:Lansoprazole(as enteric coated pellets).....30mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: caralans 30mg capsule(caraway pharmaceuticalc Pack Size(s): 2x7s-Controlled
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
40	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (**000978**) Tracking ID: (8R8-DE9-XUU2, 2024-11-12) Fee Paid: 30000.0 Paid Date: 2024-09-05 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Qiocephen 500mg IV** Each vial contains: Ceftriaxone as Sodium..... 500 mg (USP Spec,s) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Oxidil500 mg Injection I.V Pack Size(s): 1s-Controlled
	Evaluation Remarks: instant application has been evaluated and found deficient for following observations: Drug substance specification, analytical procedure and analytical method verification studies shall be submitted from M/s PHARMAQIO Details of the re-constitution diluent used for the reconstitution of drug product shall be submitted. Firm has submitted following: Drug substance specifications, analytical method and verification studies. Details of Re constitution diluent as Lignocaine injection from M/s Jaens Pharmaceuticals	
	Decision: Approved	
41	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (**000978**) Tracking ID: (9U6-1RY-AJB2, 2024-11-12) Fee Paid: 30000.0 Paid Date: 2024-09-05 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Qiocephen 250mg IM** Each vial contains: Ceftriaxone as Sodium..... 250 mg (USP Spec,s) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Oxidil250 mg Injection I.M Pack Size(s): 1s-Controlled
	Evaluation Remarks: Instant application has been evaluated and found deficient for following observations: Drug substance specification, analytical procedure and analytical method verification studies shall be submitted from M/s PHARMAQIO Details of the re-constitution diluent used for the reconstitution of drug product shall be submitted.	
	Decision: Approved	
42	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (**000978**) Tracking ID: (N28-9GM-VEYL, 2024-11-12) Fee Paid: 30000.0 Paid Date: 2024-09-05 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Qiocephen 1 gm IV** Each vial contain: Ceftriaxone as sodium.....1 g (USP Spec,s) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Oxidil 1gm Injection I.V Pack Size(s): 1s-Controlled
	Evaluation Remarks:	
	Decision: Approved	
43	**World Biz Pharmaceuticals Company, Multan** 340, Phase-II, Industrial Estate, Multan (**000942**) Tracking ID: (QGY-PV1-H61E, 2024-04-18) Fee Paid: 30000.0 Paid Date: 2024-02-15 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Deslo Biz Tablet 5mg** Each film coated Tablet Contain:- Desloratadine 5mg (USP Specifications) United States Pharmacopeia RRA Status: Desloratadine Tablet 5mg by Accord Healthcare Limited, United Kingdom (Approved in MHRA) Me Too Status: Neo-Antial Tablet 5mg Reg No. 061440 (SAMI Pharmaceuticals) Pack Size(s): 1’s, 5’s, 10’s,20’s,-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: The case was deferred in 339th meeting for following observation sot which firm has replied as detailed hereafter: Valid DML/GMP certificate of the drug substance manufacturer of drug substance shall be submitted. 3.2.S.4 Reference of drug substance specifications adopted by drug substance manufacturer shall be submitted. Drug substance analytical procedure for Assay test submitted by M/s World Biz, does not include details of performance of System suitability. Justification shall be submitted in this regard. Details of standard and sample concentrations in term of mg/ml, used for performance of accuracy parameter shall be submitted. Submitted COA from drug substance manufacturer claims “In-House” specifications, while Pharmacopoeial monograph is available for Desloaratadine. Justification shall be submitted on this regard. 3.2.S.5 Clarification shall be submitted for use of “In-House” grade working standard for the analysis of USP grade drug substance. 3.2.S.7 Justification shall be submitted for not performing test of related substances in stability studies. 3.2.P.5 Justification shall be submitted for not including test of “Uniformity of Dosage units” by way of content uniformity, in drug product specifications. 3.2.P.8.3 Complete raw data sheets for the Dissolution test performed during stability studies shall be submitted declaring the details of sample and standard solution preparation. As evident from the submitted HPLC chromatograms, the run time for the performance of Assay test by HPLC is not as per the recommendations of USP monograph. Justification shall be submitted in this regard Firm’s response: • DML of drug substance manufacturer submitted. • Desloratadine is manufactured at Amsal Chem Private Limited is as per In-house specification and has to comply with established InHouse specifications. • As material was loaned from DeMont Laboratories and Desloratadine Related Compound B was not available so system suitability testing as per USP was skipped. • Once the product gets registered, we will perform system suitability as per USP specifications on API. • Details of standard and sample concentrations in term of mg/ml, used for performance of accuracy parameter is mentioned and revised method verification is attached • Desloratadine is manufactured at Amsal Chem Private Limited is as per In-house specification and has to comply with established InHouse specifications. We World Biz perform the API testing as per USP monograph which complies with the USP Specifications. • We have emailed to Amsal Chem Pvt. Ltd. India about the provision of justification/revised stability document, once the document received, we will provide the record. • “Uniformity of Dosage units” by way of content uniformity, in drug product specifications is included. Drug product specification is attached • Raw data sheets for dissolution test for Desloratadine tablets are attached • We have given more than two times from the retention time of the Desloratadine peak in assay performance test and found no excipient/impurity peak. Once the product gets registered, we will adopt the same run time as per the recommendations of USP monograph	
	Decision: Approved	
44	**Scilife Pharma Private Limited** FD-57/58-A2, Korangi Creek Industrial Park (KCIP) (**000837**) Tracking ID: (AXT-UMV-R7EN, 2023-11-20) Fee Paid: 30000.0 Paid Date: 2023-10-30 Case Category: Routine **(Ammar Ashraf Awan)**	Proposed Name: **SCILINA 25MG/5MG TAB** Each film coated tablet contains: Empagliflozin 25mg Linagliptin 5mg As per Innovators Specification RRA Status: Product is U.S FDA approved. GLYXAMBI 25MG/5MG TABLET Manufactured by Boehringer Ingelheim. Me Too Status: a. Manufacturer: M/s Getz Pharma Pakistan (Pvt.) Ltd. b. Brand Name: Diampa LT c. Strength: 25MG/5 Pack Size(s):
	Evaluation Remarks: Instant application has been evaluated and found deficient for following observations: Justification shall be submitted for the solubility of Empagliflozin in water declared as "practically insoluble" with reference to the innovator drug product literature. Justification shall be submitted for not including test of Enantiomeric purity for Linagliptin, by both drug substance manufacturer and M//s Scilife, as recommended by innovator drug product literature Firm's response: On behalf of Scilife Pharma, we would like to address the discrepancy in the solubility specification of Empagliflozin in water. The solubility information in the innovator drug product literature from the US FDA and EMA states that Empagliflozin is “very slightly soluble in water (pH 1-7.4).” However, the initial specification provided by the API manufacturer incorrectly stated the solubility as “practically insoluble in water,” which was a typographical error. The original manufacturer specification described Empagliflozin as: • Sparingly soluble in methanol, practically insoluble in water, toluene, and 0.1 mol/L HCl, and very slightly soluble in acetonitrile and ethanol. The revised manufacturer specification described Empagliflozin as : • Very slightly soluble in water (pH 1-7.4), slightly soluble in acetonitrile and ethanol, sparingly soluble in methanol, and practically insoluble in toluene On behalf of Scilife Pharma, , we acknowledge that the “Enantiomeric Purity” test was not initially included in the initial specifications of Linagliptin by both the API manufacturer and Scilife Pharma (Pvt.) Limited. However, both the API manufacturer and the FPP manufacturer have now revised their respective specifications to include this test, aligning with the recommendations in the innovator drug product literature. We are submitting the updated documents to reflect the inclusion of the “Enantiomeric Purity” test	
	Decision: Approved Firm shall submit fee of pre-registration variation i.e., Rs. 9,000/- as per SRO1324 (I)/2024 dated 30-08-2024.	
45	**TABROS PHARMA (PVT). LTD.** Plot No. L-20/B, Sector 22, F.B. Industrial Area (**000106**) Tracking ID: (T5N-5VZ-JY6T, 2023-11-23) Fee Paid: 30000.0 Paid Date: 2023-11-06 Case Category: Routine **(Ammar Ashraf Awan)**	Proposed Name: **Pertz-S Tablet 15mg/100mg** Each film coated tablet contains: Ertugliflozin-LPGA eq. to Ertugliflozin 15mg Sitagliptin as Phosphate monohydrate .....100mg As per Innovators Specification RRA Status: STEGLUJAN TABLET Merck Sharp & Dohme Corp. USFDA Approved Me Too Status: Trevia R2 Tablet 15/100mg Getz Pharma and Eglaro-S Tablet 15/100mg Pharm Evo Pack Size(s):
	Evaluation Remarks:	
	Decision: Approved	

<table>
<tr><th>Sr. No</th><th>Name of Applicant, Manufacturer & Fee Details</th><th>Product Info</th></tr>
<tr><td>46</td><td>World Biz Pharmaceuticals Company, Multan
340, Phase-II, Industrial Estate, Multan (000942)
Tracking ID: (TSL-31N-DPE1, 2024-04-17)
Fee Paid: 30000.0
Paid Date: 2024-02-15
Case Category: New License
(Ammar Ashraf Awan)</td><td>Proposed Name: Linzo Biz Tablet 600mg
Each Film Coated Tablet Contains:- Linezolid 600mg (USP Specifications)
United States Pharmacopeia
RRA Status: Zyvox 600mg Tablet (Pfizer Limited) Approved in USFDA
Me Too Status: Ecasil Tablet 600mg (SAMI Pharmaceuticals) Reg. No. 067162
Pack Size(s): 1's, 6's,10’s, 12’s-As per SRO</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
<table>
<tr><th>Section#</th><th>Observations</th><th>Firm's response</th></tr>
<tr><td>1.6.5</td><td>· Valid DML/GMP certificate of the drug substance manufacturer of drug substance shall be submitted.</td><td>Submitted</td></tr>
<tr><td>3.2.S.4</td><td>· Reference of drug substance specifications adopted by drug substance manufacturer shall be submitted.
· Drug substance analytical procedure for Assay test submitted by drug substance manufacturer, is not as per USP monograph of “Linezolid”. Justification shall be submitted din this regard.
· Justification shall be submitted for the declared limit of Water content by the drug substance manufacturer.
· Details of standard and sample concentrations in term of mg/ml, used for performance of accuracy parameter shall be submitted.
· System suitability has not been performed as per USP monograph, in the analytical method verification studies.
· Justification shall be submitted for varied limits of water content test between the COAs form drug substance manufacturer and drug product manufacture.
· Submitted COA from drug substance manufacturer claims “In-House” specifications, while Pharmacopoeial monograph is available for Linezolid. Justification shall be submitted on this regard.</td><td>Revised Drug substance specifications by drug substance manufacturer is submitted as per Indian Pharmacopoeia.

Drug substance manufacturer follow the Indian Pharmacopoeia and inhouse specification for performance of assay test.

As Drug substance manufacturer follow the Indian Pharmacopeia so they perform Loss on drying test and adopted limit mentioned in the IP

Details of standard and sample concentrations in term of mg/ml, used for performance of accuracy parameter is mentioned and revised method verification is submitted

As material was loaned from DeMont Laboratories and Linezolid Related Compound D was not available so system suitability testing as per USP was skipped. Once the product gets registered, we will perform system suitability as per USP specifications

Drug substance manufacturer follow IP procedure and perform LOD test while drug product manufacturer follow USP and

When Linezolid API production was started, USP monograph was not available so company adopted inhouse procedure as per the pharmacopeial tests requirement for API. We drug product manufacturer perform the analysis of API as per USP monograpgh.</td></tr>
<tr><td>3.2.P.1</td><td>Justification shall be submitted for using SLS as dissolution enhancer in the applied formulation against the innovator drug product literature.</td><td>SLS was used as dissolution enhancer in the applied formulation and compatibility study was also performed. The purpose was to achieve effective release of API from the Tablet.</td></tr>
<tr><td>3.2.P.8.3</td><td>· Complete raw data sheets for the Dissolution test performed during stability studies shall be submitted declaring the details of sample and standard solution preparation.
· Documents confirming procurement of drug substance in name of M.s De Mont Research Laboratories, issued by DRAP I&E Office shall be submitted.</td><td>Submitted

Not submitted.</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved
Registration letter will be issued after submission of following documents:
Drug substance specifications and analytical method as per the USP monograph, from drug substance manufacturer and drug product manufacturer.
• Drug substance analytical method verification studies as per the USP monograph, from drug product manufacturer
• Documents confirming import of drug substance approved by DRAP I&E Office in name of M.s Demont research Laboratories, from which firm has claimed to borrow API.</td></tr>
<tr><td>47</td><td>Horizon HealthCare (Pvt) Ltd
plot no 33 sunder industrial estate lahore (000782)
Tracking ID: (VWA-YYA-Q4D8, 2023-11-27)
Fee Paid: 75000.0
Paid Date: 2023-11-21
Case Category: Routine
(Ammar Ashraf Awan)</td><td>Proposed Name: Mirgab 15mg Tablet
Each Film Coated Tablet Contains: Mirogabalin as Besylate.... 15mg (As per Innovator’s specifications)
As per Innovators Specificatio
RRA Status: Approved Drug by PMDA OF Japan Tarlige 15mg Tablets (Mirogabalin Besylate)
Me Too Status: N/A
Pack Size(s): As per SRO-As per SRO</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:</td></tr>
<tr><td></td><td colspan="2">Decision: Deferred
For clarification of storage conditions of drug substance declared by drug substance manufacturer against that recommended by the innovator.</td></tr>
<tr><td>48</td><td>PHARMAQIO RAWALPINDI
10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (000978)
Tracking ID: (W5J-P2M-UJHM, 2024-11-12)
Fee Paid: 30000.0
Paid Date: 2024-09-05
Case Category: New License
(Ammar Ashraf Awan)</td><td>Proposed Name: Qiocephen 1 gm IM
Each vial contain: Ceftriaxone as sodium.....1 g (USP Spec,s)
United States Pharmacopeia
RRA Status: USFDA Approved
Me Too Status: Oxidil 1gm Injection I.M
Pack Size(s): 1s-Controlled</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:</td></tr>
<tr><td></td><td colspan="2">Decision: Approved</td></tr>
</table>

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
49	**Polyfine Chempharma** 51 Industrial Estate Hayatabad Peshawar, Pakistan (**000216**) Tracking ID: (X53-RLR-45JT, 2024-03-18) Fee Paid: 30000.0 Paid Date: 2024-03-05 Case Category: New Section **(Ammar Ashraf Awan)**	Proposed Name: **Optibram 0.3% w/w ointment** Each gram of ointment contains: Tobramycin USP. .....3mg (0.3%w/w) RRA Status: Tobrex by Novartis Pakistan Ltd. Me Too Status: Tobrex by Novartis Pakistan Ltd. Pack Size(s): 1's-As per SRO

Evaluation Remarks:

The case was deferred in 339th meeting for following observations to which firm has replied detailed as detailed against each:

Observations	Firm's response
1.6.5 Valid DML/GMP certificate of the drug substance manufacturer shall be submitted, issued by the relevant regulatory authority of country of origin.	Submitted
2.3.R Complete batch manufacturing record of stability batches shall be submitted.	Submitted
3.2.S.4 Drug substance specifications and analytical procedure shall be submitted from the drug substance manufacturer	Submitted
3.2.S.4.3 Clarification shall be submitted regarding the composition of placebo solution, applied for the performance of specificity parameter in analytical method verification studies.	In the method verification of tobramycin raw material the specificity test was performed by injecting sample solution, standard solution and diluent. The placebo was written mistakenly as there is no placebo in the raw material
3.2.S.7.3 Long term stability studies data of drug substance shall be submitted till clamed shelf life.	Submitted
3.2.P.5.1 Justification shall be submitted for not including test of Antimicrobial/preservative effectiveness studies in drug product specifications as required by the USP general chapter <51>, since applied formulation contains preservative.	As per Table 1 of USP general chapter 51 the antimicrobial effectiveness is mandatory for the preparations that are made with aqueous base or aqueous vehicle. Since the applied product is ointment i.e. aqueous free formulation so the test of Antimicrobial/preservative effectiveness was not added in the specification. However while testing the microbial attributes of product; the Antimicrobial/preservative effectiveness was tested
3.2.P.5.3 Sample preparation method applied for the performance of precision and recovery parameter in analytical method verification studies are not as recommended by the USP monograph.	The sample prepared for the performance of precision and recovery are in accordance with USP. After preparation the sample were derivatized as per USP method as tobramycin cannot be tested on HPLC without derivatization. However, in validation report derivatization was not mentioned, instead mentioned in standard analytical procedure, Detailed results shall be submitted along with details of blank and placebo solution preparation for the performance of specificity parameter. System suitability parameter performance is not as recommended by the USP monograph.
3.2.P.6 COA of reference/working standard used for the analysis of the drug product stability batches shall be submitted since submitted COA declares expiry date prior to the manufacturing dates of the stability batches.	Submitted
3.2.P.8.3 Sample and standard preparation as evident form the submitted raw data sheets as per USP monograph of Tobramycin Ointment, since it recommends use of Derivatized standard solution, Derivatized sample solution, and Blank solution while firm has used simple standad and sample solution. Peak heights reported in the submitted chromatograms does not co-relate with the scale of the graph. Systems suitability has not been performed as required by the USP monograph of Tobramycin Ointment. Justification shall be submitted for not performing Antimicrobial/preservative effectiveness studies during stability studies, as required by the USP general chapter <51>, since applied formulation contains preservative.	Sample and standard solution were prepared and derivatized as per USP monograph as tobramycin can't be analyzed on HPLC without derivatization. The sample, standard preparation and derivatization method is given in standard analytical procedure The mentioned information on the peak is the retention time of the peak. The area is mentioned in the table below in chromatogram. The chromatograms are auto integrated by the Empower 2 software. We have fulfilled the relative standard deviation as per requirement with the repeated injection of derivitized standard solution. As per "Table 1" entitled "Compendial Product Categories " of USP General Chapter <51>, the antimicrobial effectiveness is mandatory for the preparations that are made with aqueous base or aqueous vehicle. Since the applied product is ointment i.e. aqueous free formulation so the test of Antimicrobial/preservative effectiveness was not added in the specification. However while testing the microbial attributes of product; the antimicrobial preservative effectiveness testing was performed.

Decision: Approved

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
50	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (**000978**) Tracking ID: (DJW-TBV-48ZR, 2024-11-11) Fee Paid: 30000.0 Paid Date: 2024-09-05 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Qioxime 200 mg capsule** Each Hard gelatin Capsule contain:Cefixime as trihydrate .....200 mg(JP Spec,s) Any Other RRA Status: USFDA Approved Me Too Status: Cepspan 200 mg capsule Pack Size(s): 1x5s-Controlled

Evaluation Remarks:

instant application has been evaluated and found deficient for following observations:
Documents confirming procurement of drug substance shall be submitted.
Justification shall be submitted for adopting JP specifications for applied product instead of monograph approved by Registration Board in its 313rd meeting.
Firm has submitted following:
Commercial invoice from M/s Pharmagen
Revised specifications along with long term stability data at 9th month time point

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved Firm shall submit fee of pre-registration variation i.e., Rs. 9,000/- for each strength as per SRO1324 (I)/2024 dated 30-08-2024.	
51	**Horizon HealthCare (Pvt) Ltd** plot no 33 sunder industrial estate lahore (**000782**) Tracking ID: (HJP-MJJ-9QQ4, 2023-12-14) Fee Paid: 75000.0 Paid Date: 2023-11-21 Case Category: Routine **(Ammar Ashraf Awan)**	Proposed Name: **Mirgab 10mg Tablet** Each Film coated tablet contains: Mirogabalin as Besylate ...10mg (As per Innovator's specifications) As per Innovators Specificatio RRA Status: Approved Drug by PMDA of Japan Tarlige 10mg Tablets (Mirogabalin Besylate) Me Too Status: N/A Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: instant application has been evaluated and found deficient for following observations: Clarification shall be submitted regarding the storage condition of freezer for drug substance declared on the COA from M/s Horizon. The characterization of unidentified peak in the Assay chromatogram shall be submitted. Drug product stability study data for the 6th month time point shall be submitted. Firm's response Manufacturer storage condition is -20°C. COA, WS COA and API stability has been attached The unidentified peak in the Assay chromatogram is Benzene sulfonic acid. We have performed the characterization of unidentified peak in the method validation. The unidentified peak observed is benzene sulfonic acid. Chromatograms have been attached. Drug product stability study data for the 6th month time point has been submitted.	
	Decision: Deferred For clarification of storage conditions of drug substance declared by drug substance manufacturer against that recommended by the innovator.	
52	**Global Pharmaceuticals Pakistan** Plot # 8, Street # S-8, RCCI, Industrial Estate Rawat, Islamabad-Pakistan (**000724**) Tracking ID: (JSB-YRY-Y77N, 2023-11-30) Fee Paid: 75000.0 Paid Date: 2023-11-22 Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Lidofenac Injection** Each ampoule (2ml) contains: Diclofenac Sodium..... 75mg Lidocaine hydrochloride.....20mg As per Innovators Specificatio RRA Status: Swissmedic Switzerland Me Too Status: Aaram Plus Injection by Bosch Pharmaceuticals Pack Size(s): 10's -As per SRO,20's-As per SRO
	Manufacturer(s): Formulation-Global Pharmaceuticals (Pvt.) Ltd-Plot # 204-205 Industrial Triangle, Kahuta Road, Islamabad- Pakistan-	
	Evaluation Remarks:	
	Decision: Approved	
53	**Horizon HealthCare (Pvt) Ltd** plot no 33 sunder industrial estate lahore (**000782**) Tracking ID: (LQH-Q19-83ZU, 2023-11-27) Fee Paid: 75000.0 Paid Date: 2023-11-21 Case Category: Routine **(Ammar Ashraf Awan)**	Proposed Name: **Mirgab 5mg Tablet** Each Film Coated Tablet Contains: Mirogabalin as Besylate.... 5mg (As per Innovator's specifications) As per Innovators Specificatio RRA Status: Approved Drug by PMDA OF Japan Tarlige 5mg Tablets (Mirogabalin Besylate) Me Too Status: N/A Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: instant application has been evaluated and found deficient for following observations: Clarification shall be submitted regarding the storage condition of freezer for drug substance declared on the COA from M/s Horizon. The characterization of unidentified peak in the Assay chromatogram shall be submitted. Drug product stability study data for the 6th month time point shall be submitted. Firm's response Manufacturer storage condition is -20°C. COA, WS COA and API stability has been attached The unidentified peak in the Assay chromatogram is Benzene sulfonic acid. We have performed the characterization of unidentified peak in the method validation. The unidentified peak observed is benzene sulfonic acid. Chromatograms have been attached. Drug product stability study data for the 6th month time point has been submitted.	
	Decision: Deferred For clarification of storage conditions of drug substance declared by drug substance manufacturer against that recommended by the innovator.	
54	**Horizon HealthCare (Pvt) Ltd** plot no 33 sunder industrial estate lahore (**000782**) Tracking ID: (MNH-84X-741P, 2023-12-18) Fee Paid: 75000.0 Paid Date: 2023-11-24 Case Category: Routine **(Ammar Ashraf Awan)**	Proposed Name: **Pytol Actifast 500mg Tablet** Each film-coated tablet contains: Paracetamol .....500mg (As per Innovator's Specs.) As per Innovators Specificatio RRA Status: Registered drug by UK-MEHRA as Panadol Advance 500 mg Tablets Me Too Status: N/A Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Instant application has been evaluated and found deficient for following observations: • Justification shall be submitted for using USP reference standard for the analysis of BP grade drug substance. • Clarification shall be submitted regarding the difference between two formulation applied by firm i.e., "Paracetamol Advance" and "Paracetamol Actifast" in terms of Pharmacokinetic and Pharmacodynamic features. • Justification shall be submitted for not adopting USP monograph of "Acetaminophen tablets" for the applied formulation. • The analysis method for paracetamol in the British Pharmacopoeia (BP) relies on a titration method. This approach does not require a reference standard because titration directly determines the amount of the active ingredient based on a chemical reaction, such as acid-base or redox reactions. Unlike chromatographic methods, which require a standard to quantify the analyte through comparison, titration measures the analyte stoichiometrically without external calibration. Moreover, the other testing parameters for the analysis of drug substance in B.P are almost similar to USP like identification by IR, loss on drying, and sulfated ash. • Paracetamol Advance: The concentration in plasma reaches a peak in 30 to 60 minutes and the plasma half-life is 1 - 4 hours after therapeutic doses. Paracetamol Actifast: The mean elimination half-life of paracetamol following administration of Panadol ActiFast is 2 to 3 hours. Following administration of Panadol ActiFast, paracetamol has a median time to peak plasma concentrations (tmax) of 25 minutes in fasted subjects and 45 minutes in the fed subjects Detailed Difference is given in attachment herewith • We adhered to the innovator's specifications for the analysis and quality assessment of our drug product, as the innovator does not strictly follow the methods outlined in the reference pharmacopoeia (such as the BP, USP, or others). Instead, the innovator employs a proprietary method specific to their product formulation and manufacturing process. To ensure the quality of our drug product, we implemented in house developed method and performed it as a validated analytical procedure in compliance with international regulatory requirements.	
	Decision: Deferred For further deliberation regarding the drug product specifications applied by firm with reference to the pharmacokinetic & Pharmacodynamic features of applied formulation.	
55	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (**000978**) Tracking ID: (N8X-39H-DDM4, 2024-11-12) Fee Paid: 30000.0 Paid Date: 2024-09-05 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Qiocephen 2 gm IV** Each vial contain: Ceftriaxone as sodium.....2gm (USP Spec,s) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Oxidil 2 gm Injection I.V Pack Size(s): 1s-Controlled
	Evaluation Remarks: instant application has been evaluated and found deficient for following observations: Drug substance specification, analytical procedure and analytical method verification studies shall be submitted from M/s PHARMAQIO Details of the re-constitution diluent used for the reconstitution of drug product shall be submitted. Firm has submitted relevant documents against the above observations	
	Decision: Approved	
56	**Pharmatec Pakistan (Pvt.) Limited** D-86/A, S.I.T.E., Karachi - 75700, Pakistan (**000024**) Tracking ID: (P4G-1XH-GZZ2, 2024-03-13) Fee Paid: 30000.0 Paid Date: 2023-12-07 Case Category: Routine **(Ammar Ashraf Awan)**	Proposed Name: **Empazin-L Tablet 10mg/5mg** Each film coated Tablet contains: Empagliflozin.....10mg Linagliptin.....5mg As per Innovators Specification RRA Status: Glyxambi 10mg/5mg film-coated Tablets by Boehringer Ingelheim International GmbH, MHRA Approved. Me Too Status: Diampa LT Tablet 10mg/5mg by Getz Pharma (Private) Limited. Pack Size(s): 1 x 7's, 1 x 10's, 1-As per SRO
	Evaluation Remarks: Case was deferred in 340th meeting to which firm has responded as under: Observations Firm's response Declaration of solubility of Empagliflozin in water as "insoluble" in the general properties section, shall be justified with reference to the innovator drug product literature. We M/s Pahrmatech would like to clarify that there is a typographical error in section 3.2.S.1.3 regarding solubility of Empagliflozin. m/s Anhui Hhuijkang Pharmaceutical Co. ltd has updated this section and our solubility testing confirms that Empagliflozin is very slightly soluble in water. This finding is consistent with the literature of the innovator drug product a reference by the US FDA and EMA Reference shall be submitted for the limits of optical rotation test applied in the drug substance specifications of Empagliflozin by M/s Pharmatec. We M/s Pahrmatech would like to clarify that we have adopted the limit for the optical rotation test based on the manufacturer's specifications. COA of reference/working standard used for the analysis of drug substances by M.s Pharmatec shall be submitted. Submitted Documents confirming import of drug substance i.e., Clearance certificate issued by DRAP I&E office for Empagliflozin & Linagliptin shall be submitted Firm has submitted License to import for both Empagliflozin and Linagliptin issued by AD I&E Karachi along with copy of Good Declaration	
	Decision: Approved	
57	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (**000978**) Tracking ID: (Y3Y-9P9-G43Z, 2024-11-19) Fee Paid: 30000.0 Paid Date: 2024-09-05 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Qioxime 100mg/5ml dry suspension** Each 5ml Reconstituted Suspension contain: Cefixime as Trihydrate.....100 mg (USP Spec,s) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Cefspan 100mg/5mlDry Suspension Pack Size(s): 1x1s-Controlled
	Evaluation Remarks: In-Use stability data for the reconstituted suspension shall be submitted. Firm has submitted In-Use stability data for the reconstituted suspension	
	Decision: Approved	
58	**Horizon HealthCare (Pvt) Ltd** plot no 33 sunder industrial estate lahore (**000782**) Tracking ID: (Z6X-XM3-Q8YM, 2023-12-07) Fee Paid: 75000.0 Paid Date: 2023-11-24 Case Category: Routine **(Ammar Ashraf Awan)**	Proposed Name: **Pytol Adavance 500mg Tablet** Each film-coated tablet contains: Paracetamol .....500mg (As per Innovator's Specs.) As per Innovators Specificatio RRA Status: Registration status of applied drug: Registered drug by UK-MEHRA as Panadol Advance 500 mg Tablets Me Too Status: N/A Pack Size(s): As per SRO-As per SRO

<table>
<tr><th>Sr. No</th><th>Name of Applicant, Manufacturer & Fee Details</th><th>Product Info</th></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
• Firm has submitted drug product stability data of two batches of 5000 units each.
• Following observations have been shared
Justification shall be submitted for using USP reference standard for the analysis of BP grade drug substance.
Justification shall be submitted for the use of Sodium ethylparahydroxy benzoate, Sodium methylparahydroxy benzoate and Sodium propyparahydroxy benzoate as antimicrobial preservative agent in the formulation, with reference to the innovator drug product literature.
Justification shall be submitted for not adopting USP monograph of "Acetaminophen tablets" for the applied formulation.
Clarification shall be submitted for not performing anti-microbial preservative efficacy test.</td></tr>
<tr><td></td><td colspan="2">Decision: Deferred
For further deliberation regarding the drug product specifications applied by firm with reference to the pharmacokinetic & Pharmacodynamic features of applied formulation.</td></tr>
<tr><td>59</td><td>Horizon Healthcare (pvt.) ltd.
35-A Small Industrial Estate - Taxila (000856)
Tracking ID: (ZL4-T6H-BEYA, 2023-11-22)
Fee Paid: 75000.0
Paid Date: 2023-11-14
Case Category: Routine
(Ammar Ashraf Awan)</td><td>Proposed Name: Ozee Cream 1% w/w
Each gram of Cream contains: Ozenoxacin.....10mg
As per Innovators Specification
RRA Status: Registered drug by US FDA XEPI (Ozenoxacin Cream), for topical use.
Me Too Status: N/A
Pack Size(s): As per SRO-As per SRO</td></tr>
<tr><td></td><td colspan="2">Manufacturer(s):
---</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
Instant application has been evaluated and found deficient for following observations:
<table><tr><td>Justification shall be submitted for not including tests of ""Benzoic acid Assay" in drug product specifications, as recommended by the innovator drug product literature.</td><td>We performed benzoic acid test by microbial test. Moreover, the microbial limit tests as our results falls within limits. We have updated our drug product specifications in standard analytical procedure. The updated SAP and Specs are attached</td></tr><tr><td>Stability studies data for the 6th month time point shall be submitted.</td><td>Submitted</td></tr></table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved</td></tr>
<tr><td>60</td><td>Lab Diagnostic Systems (SMC) Pvt. Ltd.
36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan (01-374-0006)
Tracking ID: (ZV2-4D8-82V6, 2023-12-18)
Fee Paid: 150000.0
Paid Date: 2023-11-17
Case Category: Import
(Ammar Ashraf Awan)</td><td>Proposed Name: Tiroplat Injection 12.5 mg / 50 ml.
Each vial contains: Tirofiban as Hydrochloride Injection 12.5 mg/50 ml
As per Innovators Specification
RRA Status: Product name – AGGRASTAT® Dosage form – Parenteral preparation Manufacturer/Registration holder: Mer
Me Too Status: Manufacturer: ATCO Laboratories Limited Brand Name: Aggrastat Composition: Tirofiban Hydrochloride I
Pack Size(s): 1 x 50 ml vial-As per SRO</td></tr>
<tr><td></td><td colspan="2">Marketing Authorization Holder (Abroad): Lab Diagnostic Systems (SMC) Pvt. Ltd. , 36-A,PSIC,SIE, Taxila, Rawalpind, Pakistan, Pakistan
Manufacturer(s):
manufacturer-LUNAN BETTER PHARMACEUTICAL CO., LTD.-No.243, Yinqueshan Road, Linyi City, Shandong, China-China</td></tr>
<tr><td></td><td colspan="2">Details of Certificates (CoPP/cGMP, Authorization Letter etc):
Firm has submitted legalized COPP no. 20235069 issued by Shandong Provincial Medical product Administration declaring the free sale status of the product and GMP status of the drug product manufacturer</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:</td></tr>
<tr><td></td><td colspan="2">Decision: Approved
As per policy of inspection of manufacturer abroad. Registration letter will be issued upon submission of analytical record for the submitted drug product stability data including chromatograms/spectrums etc.</td></tr>
<tr><td>61</td><td>PHARMAQIO RAWALPINDI
10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (000978)
Tracking ID: (ZYY-3NZ-GEGQ, 2024-11-19)
Fee Paid: 30000.0
Paid Date: 2024-09-05
Case Category: New License
(Ammar Ashraf Awan)</td><td>Proposed Name: Qioflox 250 mg Tablet
Each film coated Tablet contain Levofloxacin as hemihydrate.....250mg (USP-Spec,s)
United States Pharmacopeia
RRA Status: USFDA Approved
Me Too Status: LEFLOX TABLETS 250mg
Pack Size(s): 1x10s-Controlled</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
Your instant application has been evaluated and found deficient for following observations:
Drug substance specification, analytical procedure and analytical method verification studies shall be submitted from M/s PHARMAQIO
COA of reference/working standard used for analysis of drug product shall be submitted.
Revised section 3.2.P.1 shall be submitted with correct salt form of drug substance.

Firm has submitted relevant documents against above observations</td></tr>
<tr><td></td><td colspan="2">Decision: Approved</td></tr>
</table>

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
62	**Nahal Pharmaceuticals (Pvt) Ltd.** Plot No. 2, Street No. SS-4, RCCI, Industrial Estate Rawat (**000989**) Tracking ID: (24G-R9B-2S8L, 2024-08-28) Fee Paid: 30000.0 Paid Date: 2024-07-30 Case Category: New License **(Dr. Farhad Ullah)**	Proposed Name: **Halpime** Each vial contain cefepime as HCl 500mg with L-Arginie United States Pharmacopeia RRA Status: MAXIPIME (500mg, 1g, 2g) for injection USFDA Approved Me Too Status: Maxipime 500mg Injection by M/s GSK Pakistan Limited (Reg#25548) Pack Size(s): 1x1 s-As per SRO
	Evaluation Remarks: Observations 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's Response • Batch Manufacturing Record (BMR) for all the batches of drug product is submitted Observations 3.2.S.4 • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance 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 shall be submitted. • Certificate of Analysis (COA) of relevant batch of drug substance used during product development and stability study by drug substance manufacturer shall be submitted Firm's Response • Copies of the Drug substance specifications by Drug Product manufacturer is submited. However, analytical procedures used for routine testing of the Drug substance by drug product manufacturer is not submitted • Analytical Method Verification studies of drug product is submitted instead of drug substance • Reply not submitted Observations 3.2.S.7 • Stability study data of 3 batches of drug substance at real time conditions at zone IV-A till claimed shelf life shall be submitted Firm's Response • Reply is not submitted Observations 3.2.P.2 • Submit details of comparator product including marketing authorization holder and strength of reference product against which Pharmaceutical equivalence studies has been performed Firm's Response • Firm has submitted details of comparator product. Brand Name; CefStar 500mg Inj, Batch No; D5289, Mfg date; 02-23 Exp date; 02-26, Manufacturer; Barrett Hodgson Pakistan Observations 3.2.P.8 • Stability study data supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. for applied strength shall be submitted • Stability study data of drug product at 6th month time point shall be submitted Firm's Response • Stability study data supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. for applied strength is submitted • Stability study data of drug product at 6th month time point is submitted	
	Decision: Approved **• Registration Board further decided that Registration letter will be issued after submission of following:** **• i. Analytical procedures used for routine testing of the Drug substance by drug product manufacturer.** **• ii. Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance.** **• iii. Certificate of Analysis (COA) of relevant batch of drug substance used during product development and stability study by drug substance manufacturer** **• iv. Stability study data of 3 batches of drug substance at real time conditions at zone IV-A till claimed shelf life**	
63	**Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (**000755**) Tracking ID: (5ZM-7W6-4LY5, 2023-11-24) Fee Paid: 75000.0 Paid Date: 2023-11-10 Case Category: Routine **(Dr. Farhad Ullah)**	Proposed Name: **Sertagyn 500mg Vaginal Tablet** Each tablet contains: Sertaconazole Nitrate.....500mg As per Innovators Specification RRA Status: Spanish Agency for Medicines and Health Products (Spain) Me Too Status: None Pack Size(s): 1's-As per SRO
	Manufacturer(s): ---	
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Observations 1.6.5 • Valid copy of cGMP certificate / Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required • The submitted copy of cGMP certificate is of different manufacturing site than that given in section 1.6.5 Firm' s Response Firm has submitted copy of cGMP certificate of API manufacturer issued by Food & Drugs Administration (Maharashtra State) India valid upto 15-01-2025. Firm has submitted cGMP certificate of same manufacturing site Observations 3.2.S.4 • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug product manufacturer is required. • Justification shall be submitted for submitting different limit of assay test in drug substance specifications by drug substance manufacturer and drug product manufacturer (98.5%-101%) than BP monograph (99%-101%) Firm' s Response • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug product manufacturer is submitted. • The firm submitted that as per the BP monograph the specification limit of assay is (98.5%-101%), BP 2022. Observations 3.2.P.8 • Justify the batch size of trial batches against the number of units required for complete testing of drug product during stability study including real time stability study till claimed shelf life • Submit copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP. • Chromatograms of stability study of applied product at 6th month time point is not submitted Firm' s Response • The firm submitted that a trial batch weighing 0.945kg was produced, each batch containing 500 tablets, which were more than sufficient for complete stability testing. Total 11 tablets are used for one time stability studies, Therefore, the number of tablets meets the required testing specifications study including real time stability study till claimed shelf life. • Firm has again submitted copy of form 6 issued dated 25-03-2022 specifying 01kg Sertaconazole Nitrate. Form 6 is issued by AD (I&E) DRAP. • Chromatograms of stability study of applied product at 6th month time point is submitted	
	Decision: Deferred Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
64	**Nahal Pharmaceuticals (Pvt) Ltd.** Plot No. 2, Street No. SS-4, RCCI, Industrial Estate Rawat (**000989**) Tracking ID: (GH9-B5H-D8Q3, 2024-10-21) Fee Paid: 37000.0 Paid Date: 2024-10-16 Case Category: New License **(Dr. Farhad Ullah)**	Proposed Name: **Nefixime 400mg Capsule** each hard gelatin capsule contains;cefixime as trihydrate-----400mg Any Other RRA Status: Suprax 400mg capsule USFDA Approved Me Too Status: Cefspan 400mg Capsule by M/s Barett Hodgson Pakistan (Reg# 13860) Pack Size(s): 1x5 s-As per SRO
	Evaluation Remarks: Observations 1.6.5 • Valid copy of cGMP certificate / Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required Firm's Response • Firm has submitted copy of Drug Manufacturing License of API manufacturer issued by DRAP valid upto 02-03-2026. Observations 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's Response • Batch Manufacturing Record (BMR) for all the batches of drug product is submitted Observations 3.2.S.4 • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance 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 shall be submitted. • Certificate of Analysis (COA) of relevant batch of drug substance used during product development and stability study by both drug substance manufacturer and drug product manufacturer shall be submitted Firm's Response • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer is submitted. • Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance is submitted. • Certificate of Analysis (COA) of relevant batch of drug substance by drug substance manufacturer is submitted. Certificate of Analysis (COA) of relevant batch of drug substance by drug product manufacturer is not submitted. Observations 3.2.P.2 • Submit results of drug excipient compatibility study as the qualitative composition of applied product is not similar to reference product Firm's Response • Results of drug excipient compatibility study is not submitted Observations 3.2.P.5 • You have claimed for JP specifications but the monograph for applied product is not available in JP • Justification shall be submitted for not including the test for water content and dissolution test in finished product specifications • Justification shall be submitted for selecting analytical method for assay and dissolution test as per DRAP testing method for cefixime capsule while claimed JP method • The copies of complete analysis of at least two batches shall be provided. Firm's Response • The firm submitted that they follow DRAP's specifications for cefixim Capsule. • The firm has submitted revised batch analysis report in Water Content and Dissolution Test has been performed. • The firm submitted that we adopted DRAP testing method for assay and dissolution test.. Observations 3.2.P.8 • Documents for procurement of API for local purchase shall be submitted Firm's Response • Firm has submitted copy of loan letter from M/s Heal Pharmaceuticals Peshawar for 03kg Cefixime (compacted) and 03Kg Cefixime (micronized). Firm has also submitted sale tax invoice for procurement of cefixime from M/s Citi Pharma in name of M/s heal pharma	
	Decision: Approved Approved with manufacturer specifications as per DRAP's notification. Registration Board further decided that Registration letter will be issued after submission of following: i. Certificate of Analysis (COA) of relevant batch of drug substance by drug product manufacturer. ii. Results of drug excipient compatibility study iii. The copies of complete analysis of at least two batches of drug product iv. Fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(l)2024 dated 30-08-2024	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
65	**Nahal Pharmaceuticals (Pvt) Ltd.** Plot No. 2, Street No. SS-4, RCCI, Industrial Estate Rawat (**000989**) Tracking ID: (Q8Q-ZJJ-EQAS, 2024-08-29) Fee Paid: 30000.0 Paid Date: 2024-08-28 Case Category: New License **(Dr. Farhad Ullah)**	Proposed Name: **Cefobact** Each vial containsCefoperazone as Sodium ---500mgSulbactam as Sodium -------500mg Any Other RRA Status: SULPERAZON injection 1g PMDA Japan Approved Me Too Status: 2Sum Injection 1gm by M/s Sami Pharmaceuticals (Reg#047002) Pack Size(s): 1x1 s-As per SRO
	Evaluation Remarks: Observations 1.6.5 • Valid copy of cGMP certificate / Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required Firm's Response • Reply not submitted Observations 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's Response • Batch Manufacturing Record (BMR) for all the batches of drug product is submitted Observations 3.2.S.4 • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance 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 shall be submitted. • Certificate of Analysis (COA) of relevant batch of drug substance used during product development and stability study by both drug substance manufacturer and drug product manufacturer shall be submitted Firm's Response • Reply not submitted • Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance is submitted • Certificate of Analysis (COA) of relevant batch of drug substance by drug product manufacturer is submitted. Certificate of Analysis (COA) of relevant batch of drug substance by drug substance manufacturer is not submitted. Observations 3.2.S.7 • Stability study data of 3 batches of drug substance at real time conditions at zone IV-A till claimed shelf life shall be submitted Firm's Response • Stability study data of 3 batches of drug substance at real time conditions is submitted till 09 months Observations 3.2.P.2 • Submit details of comparator product including name of manufacturer against which Pharmaceutical equivalence studies has been performed Firm's Response • Firm has submitted details of comparator product. Brand Name; 2Sum 1g/Vial Inj Batch No; AOM011 Mfg date; 03-24 Exp date; 02-26 Manufacturer; Sami Pharamceuticals Observations 3.2.P.5 • Limits for Assay content of both active substances should be separately calculated and mentioned as per pharmacopeial reference in finished product specifications. • Justification shall be submitted for not including the test for water content and uniformity of dosage units in finished product specifications as per JP monograph • The copies of complete analysis of at least two batches shall be provided. Firm's Response • Reply is not submitted • Reply is not submitted • Reply is not submitted Observations 3.2.P.8 • Stability study data at 6th month time point for applied product shall be submitted • Documents for procurement of API (commercial invoice or clearance certificate) with approval from DRAP shall be submitted Firm's Response • Stability study data at 6th month time point for applied product is submitted • Firm has submitted copy of loan letter from M/s Nicholas Pharmaceuticals (Pvt) Ltd for 10kg Cefoperazone sodium+sulbactam sodium. • Firm has submitted copy of clearance certificate dated 12-01-2022 from M/s Nicholas Pharmaceuticals specifying 100kg Cefoperazone sodium+sulbactam sodium. The clearance certificate is issued by AD (I&E) DRAP.	
	Decision: Deferred Registration Board decided to defer the case for submission of following: i. Valid copy of cGMP certificate / Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin. ii. Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer. iii. Certificate of Analysis (COA) of relevant batch of drug substance by drug substance manufacturer. iv. Limits for Assay content of both active substances should be separately calculated and mentioned as per pharmacopeial reference in finished product specifications v. Justification shall be submitted for not including the test for water content and uniformity of dosage units in finished product specifications as per JP monograph vi. The copies of complete analysis of at least two batches of drug product.	
66	**Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (**000755**) Tracking ID: (BMB-AM8-ZXPX, 2023-11-24) Fee Paid: 75000.0 Paid Date: 2023-11-10 Case Category: Routine **(Dr. Farhad Ullah)**	Proposed Name: **Sertagyn 2% Vaginal Cream** Each gram contains: Sertaconazole Nitrate.....20mg As per Innovators Specification RRA Status: Ginedermofix 2% vaginal cream CIMA Spain Approved Me Too Status: None Pack Size(s): 40g tube-As per SRO
	Manufacturer(s): ---	
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: 1.3.5 • Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority. Firm's Response • Firm has submitted copy of renewal of DML dated 03-03-2023 specifying Oral Hygiene (Mouth Wash)/Semi solid and Tooth Paste section. Observations 1.6.5 • Valid copy of cGMP certificate / Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required • The submitted copy of cGMP certificate is of different manufacturing site than that given in section 1.6.5 Firm's Response • Firm has submitted copy of cGMP certificate of API manufacturer issued by Food & Drugs Administration (Maharashtra State) India valid upto 15-01-2025. • Firm has submitted cGMP certificate of same manufacturing site as given in section 1.6.5. Observations 3.2.S.4 • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug product manufacturer is required. • Justification shall be submitted for submitting different limit of assay test in drug substance specifications by drug substance manufacturer and drug product manufacturer (98.5%-101%) than BP monograph (99%-101%) Firm's Response • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug product manufacturer is submitted. • The firm submitted that as per the BP monograph the specification limit of assay is (98.5%-101%), BP 2022. Observations 3.2.P.8 • Clarify the batch size of trial batches manufactured in terms of number of units of product manufactured • Submit copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP. Firm's Response • The firm submitted that a trial batch weighing 600g was produced, each tube containing 20g with cream distributed into 30 tubes which were more than sufficient for complete stability testing as per ICH guidelines. For long term stability 06 tubes and for accelerated stability 02 tubes are required for 1 time testing. Therefore, the number of tubes meets the required testing specifications. • Firm has again submitted copy of form 6 issued dated 25-03-2022 specifying 01kg Sertaconazole Nitrate. Form 6 is issued by AD (I&E) DRAP.	
	Decision: Deferred Registration Board decided to defer the case for submission of following: Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
67	**Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (**000755**) Tracking ID: (DHE-AQ8-H9H8, 2023-12-19) Fee Paid: 30000.0 Paid Date: 2023-11-10 Case Category: Routine **(Dr. Farhad Ullah)**	Proposed Name: **Sertaderm 2% Topical Cream** Each gram contains:Sertaconazole Nitrate.....20mg As per Innovators Specification RRA Status: ERTACZO (sertaconazole nitrate) 2% cream, for topical use USFDA Approved Me Too Status: Sertazol Cream 2% by M/s Hudson Pharma (Reg# 92642) Pack Size(s): 30gm Tube-As per SRO,60gm Tube-As per SRO
	Evaluation Remarks: Observations 1.3.5 • Submit Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority. Firm's Response • Firm has submitted copy of renewal of DML dated 03-03-2023 specifying Oral Hygiene (Mouth Wash)/Semi solid and Tooth Paste section. Observations 1.6.5 • Valid copy of cGMP certificate / Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required • The submitted copy of cGMP certificate is of different manufacturing site than that given in section 1.6.5 Firm's Response • Firm has submitted copy of cGMP certificate of API manufacturer issued by Food & Drugs Administration (Maharashtra State) India valid upto 15-01-2025. • Firm has submitted cGMP certificate of same manufacturing site as given in section 1.6.5. Observations 3.2.S.4 • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug product manufacturer is required. • Justification shall be submitted for submitting different limit of assay test in drug substance specifications by drug substance manufacturer and drug product manufacturer (98.5%-101%) than BP monograph (99%-101%) Firm's Response • Copies of the Drug substance analytical procedures used for routine testing of the Drug substance by Drug product manufacturer is submitted. • The firm submitted that as per the BP monograph the specification limit of assay is (98.5%-101%), BP 2022. Observations 3.2.P.8 • Clarify the batch size of trial batches manufactured in terms of number of units of product manufactured • Submit copy of commercial invoice or clearance certificate for the procurement of API with approval from DRAP. Firm's Response • The firm submitted that a trial batch weighing 600g was produced, each tube containing 20g with cream distributed into 30 tubes which were more than sufficient for complete stability testing as per ICH guidelines. For long term stability 06 tubes and for accelerated stability 02 tubes are required for 1 time testing. Therefore, the number of tubes meets the required testing specifications. • Firm has again submitted copy of form 6 issued dated 25-03-2022 specifying 01kg Sertaconazole Nitrate. Form 6 is issued by AD (I&E) DRAP.	
	Decision: Deferred Registration Board decided to defer the case for submission of following: Evidence of approval of required manufacturing facility / Approved Section from Licensing Authority.	
68	**Nahal Pharmaceuticals (Pvt) Ltd.** Plot No. 2, Street No. SS-4, RCCI, Industrial Estate Rawat (**000989**) Tracking ID: (L3L-UXP-2YBB, 2024-09-11) Fee Paid: 30000.0 Paid Date: 2024-08-06 Case Category: New License **(Dr. Farhad Ullah)**	Proposed Name: **Nefixime 100 mg /5ml Dry Suspension** Each 5ml of reconstituted Suspension contains: Cefixime (as trihydrate)..... 100 mg United States Pharmacopeia RRA Status: SUPRAX { Lupin Pharma ,Maryland 21202 USA Me Too Status: Cefiget Dry Suspension 100 mg/5ml by M/s Getz Pharma Pack Size(s): 30 ml Suspension in -As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Observations 1.1 • Update the details of submitted differential fee in relevant field of e-app interphase (online portal) Firm's Response • Details of submitted differential fee in relevant field of e-app interphase (online portal) is updated Observations 1.6.5 • Valid copy of cGMP certificate / Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required Firm's Response • Firm has submitted copy of cGMP certificate of API manufacturer issued by DRAP valid upto 02-03-2026. Observations 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's Response • Batch Manufacturing Record (BMR) for all the batches of drug product is submitted Observations 3.2.S.4 • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance 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 shall be submitted. • Certificate of Analysis (COA) of relevant batch of drug substance used during product development and stability study by drug product manufacturer shall be submitted Firm's Response • Copies of the Drug substance specifications by Drug Product manufacturer is submited. However, analytical procedures used for routine testing of the Drug substance by drug product manufacturer is not submitted • Analytical Method Verification studies of drug product is submitted instead of drug substance • Certificate of Analysis (COA) of relevant batch of drug substance by drug substance manufacturer is submitted instead of drug product manufacturer Observations 3.2.P.2 • Submit results of drug excipient compatibility study as the qualitative composition of applied product is not similar to reference product • Submit numerical results of test including pH test, assay test in pharmaceutical equivalence studies instead of only mentioning complies • Submit details of comparator product including batch No, manufacturing date, expiry date and name of manufacturer against which Pharmaceutical equivalence studies has been performed Firm's Response • Reply not submitted • Firm has submitted revised pharmaceutical equivalence report in which numerical results of pH and assay test has been reported. • Firm has submitted details of comparator product. • Brand Name; Cefiget 100mg powder for oral suspension Batch No; 3662 Mfg date; 08-23 Exp date; 07-25 Manufacturer; Getz Pharma Observations 3.2.P.5 • Justification shall be submitted for not including the test for uniformity of dosage units and deliverable volume in finished product specifications as per USP monograph • Detailed analytical procedures used for testing the drug product shall be provided • The copies of complete analysis of at least two batches shall be provided. Firm's Response • Firm has submitted revised finished product specifications in which test for uniformity of dosage units and deliverable volume is incorporated. • Analytical procedure for drug product is submitted • Copies of complete analysis of at least two batches is submitted Observations 3.2.P.8 • Submit numerical results of tests at initial time point in stability summary sheets instead of writing do in each test. • Documents for procurement of API shall be submitted Firm's Response • Firm has submitted numerical results of tests at initial time point in stability summary sheets • Firm has submitted copy of loan letter from M/s Heal Pharmaceuticals Peshawar for 03kg Cefixime (compacted) and 03Kg Cefixime (micronized). Firm has also submitted sale tax invoice for procurement of cefixime from M/s Citi Pharma in name of M/s heal pharma	
	Decision: Approved Decision: Registration Board further decided that Registration letter will be issued after submission of following: i. Analytical procedures used for routine testing of the Drug substance by drug product manufacturer. ii. Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance. iii. Certificate of Analysis (COA) of relevant batch of drug substance used during product development and stability study by drug product manufacturer iv. Results of drug excipient compatibility study v. Fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(l)2024 dated 30-08-2024	
69	**Nahal Pharmaceuticals (Pvt) Ltd.** Plot No. 2, Street No. SS-4, RCCI, Industrial Estate Rawat (**000989**) Tracking ID: (LEV-HRY-N192, 2024-10-03) Fee Paid: 30000.0 Paid Date: 2024-08-28 Case Category: New License **(Dr. Farhad Ullah)**	Proposed Name: **Cefobact** Each Vial Contains:Cefoperazone as Sodium --- 1gSulbactam as Sodium --------1g Any Other RRA Status: SULPERAZON injection 2g PMDA Japan Approved Me Too Status: 2Sum Injection 2gm by M/s Sami Pharmaceuticals (Reg#47003) Pack Size(s): 1x1 s-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Observations 1.5.2 • You have applied for cefobact 2gm injection but submitted label claim for cefobact 1gm injection, clarify and correct your label claim along with submission of applicable fee? Firm's Response • The firm has revised the label claim without submission of fee as: Each Vial Contains: Cefoperazone as Sodium-----1gm Sulbactam as Sodium-------1gm Observations 1.6.5 • Valid copy of cGMP certificate / Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required Firm's Response • Reply not submitted Observations 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's Response • Batch Manufacturing Record (BMR) for all the batches of drug product is submitted Observations 3.2.S.4 • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance 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 shall be submitted. • Certificate of Analysis (COA) of relevant batch of drug substance used during product development and stability study by drug substance manufacturer shall be submitted Firm's Response • Reply not submitted • Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance is submitted • Certificate of Analysis (COA) of relevant batch of drug substance by drug product manufacturer is submitted instead of drug substance manufacturer Observations 3.2.S.7 • Stability study data of 3 batches of drug substance at real time conditions at zone IV-A till claimed shelf life shall be submitted Firm's Response • Stability study data of 3 batches of drug substance at real time conditions is submitted till 09 months Observations 3.2.P.2 • Submit details of comparator product including name of manufacturer and strength of reference product against which Pharmaceutical equivalence studies has been performed Firm's Response • Firm has submitted details of comparator product. Brand Name; 2Sum 2g/Vial Inj Batch No; APMO11 Mfg date; 02-24 Exp date; 01-26 Manufacturer; Sami Pharamceuticals Observations 3.2.P.5 • Limits for Assay content of both active substances should be separately calculated and mentioned as per pharmacopeial reference in finished product specifications. • Justification shall be submitted for not including the test for water content and uniformity of dosage units in finished product specifications as per JP monograph • The copies of complete analysis of at least two batches shall be provided. Firm's Response • Reply is not submitted • Reply is not submitted • Reply is not submitted Observations 3.2.P.8 • Stability summary sheets for applied product shall be submitted • Stability study data at 6th month time point for applied product shall be submitted Firm's Response • Reply is not submitted • Reply is not submitted	
	Decision: Deferred Registration Board decided to defer the case for submission of following: i. Full fee of registration for correction of label claim ii. Valid copy of cGMP certificate / Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin. iii. Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance by Drug Product manufacturer. iv. Limits for Assay content of both active substances should be separately calculated and mentioned as per pharmacopeial reference in finished product specifications v. Justification shall be submitted for not including the test for water content and uniformity of dosage units in finished product specifications as per JP monograph vi. The copies of complete analysis of at least two batches of drug product. vii. Stability summary sheets for applied drug product viii. Stability study data at 6th month time point for applied drug product	
70	**Nahal Pharmaceuticals (Pvt) Ltd.** Plot No. 2, Street No. SS-4, RCCI, Industrial Estate Rawat (**000989**) Tracking ID: (M89-VHR-V7GX, 2024-09-03) Fee Paid: 30000.0 Paid Date: 2024-08-06 Case Category: New License **(Dr. Farhad Ullah)**	Proposed Name: **Nefixime 200 mg /5ml Dry Suspension** Each 5ml Reconstituted Suspension Contains: Cefixime (as Trihydrate) ...200 mg United States Pharmacopeia RRA Status: SUPRAX (cefixime) for oral suspension, 200mg/5ml USFDA Approved Me Too Status: Cefiget DS Powder for Oral Suspension by M/s Getz Pharma Pack Size(s): 30 ml Suspension in -As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Observations 1.1 • Submit differential fee of registration application as per SRO 1324 (I)/2024 dated 30th August 2024 for applied product and update the details of submitted differential fee in relevant field of e-app interphase (online portal). Firm's Response • Firm has submitted differential fee and updated the details of submitted differential fee in relevant field of e-app interphase (online portal). However, copy of fee challan is not submitted Observations 1.6.5 • Source of drug substance in module I section 1.6.5 and module III are different from each other. Please rectify. • Valid copy of cGMP certificate / Drug Manufacturing License of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required Firm's Response • Revised details of API manufacturer in this section is not submitted • Firm has submitted copy of cGMP certificate of API manufacturer issued by DRAP valid upto 02-03-2026. Observations 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's Response • Batch Manufacturing Record (BMR) for all the batches of drug product is submitted Observations 3.2.S.4 • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance 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 shall be submitted. • Certificate of Analysis (COA) of relevant batch of drug substance used during product development and stability study by drug product manufacturer shall be submitted Firm's Response • Copies of the Drug substance specifications by Drug Product manufacturer is submited. However, analytical procedures used for routine testing of the Drug substance by drug product manufacturer is not submitted • Analytical Method Verification studies of drug product is submitted instead of drug substance • Certificate of Analysis (COA) of relevant batch of drug substance by drug substance manufacturer is submitted instead of drug product manufacturer Observations 3.2.P.2 • Submit results of drug excipient compatibility study as the qualitative composition of applied product is not similar to reference product • Submit numerical results of test including pH test, assay test in pharmaceutical equivalence studies instead of only mentioning complies • Submit details of comparator product including batch No, manufacturing date, expiry date and name of manufacturer against which Pharmaceutical equivalence studies has been performed Firm's Response • Reply not submitted • Firm has submitted revised pharmaceutical equivalence report in which numerical results of pH and assay test has been reported. • Firm has submitted details of comparator product. • Brand Name; Cefiget 200mg powder for oral suspension Batch No; 1364 Mfg date; 08-23 Exp date; 07-25 • Manufacturer; Getz Pharma Observations 3.2.P.5 • Justification shall be submitted for not including the test for uniformity of dosage units and deliverable volume in finished product specifications as per USP monograph • Detailed analytical procedures used for testing the drug product shall be provided • The copies of complete analysis of at least two batches shall be provided. Firm's Response • Firm has submitted revised finished product specifications in which test for uniformity of dosage units and deliverable volume is incorporated. • Analytical procedure for drug product is submitted • Copies of complete analysis of at least two batches is submitted Observations 3.2.P.8 • Documents for procurement of API shall be submitted Firm's Response • Firm has submitted copy of loan letter from M/s Heal Pharmaceuticals Peshawar for 03kg Cefixime (compacted) and 03Kg Cefixime (micronized). Firm has also submitted sale tax invoice for procurement of cefixime from M/s Citi Pharma in name of M/s heal pharma	
	Decision: Approved Registration Board further decided that Registration letter will be issued after submission of following: i. Copy of submitted differential fee challan ii. Revision of address of API manufacturer in section 1.6.5 and module III as per submitted cGMP certificate iii. Analytical procedures used for routine testing of the Drug substance by drug product manufacturer. iv. Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance. v. Certificate of Analysis (COA) of relevant batch of drug substance used during product development and stability study by drug product manufacturer vi. Results of drug excipient compatibility study vii. Fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(l)2024 dated 30-08-2024	
71	**Nahal Pharmaceuticals (Pvt) Ltd.** Plot No. 2, Street No. SS-4, RCCI, Industrial Estate Rawat (**000989**) Tracking ID: (TN9-EPS-54BY, 2024-08-21) Fee Paid: 30000.0 Paid Date: 2024-08-19 Case Category: New License **(Dr. Farhad Ullah)**	Proposed Name: **Halpime 1 g Injection** Each vial Contains: Cefepime hydrochloride eq. to Cefepime 1 g with L-Arginine. United States Pharmacopeia RRA Status: Maxipime 1 g Injection (US-FDA approved) Me Too Status: Cefstar Injection 1 g Reg.No.30954 M/s. Barret and Hudgsont Pack Size(s): 1's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Observations 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's Response • Batch Manufacturing Record (BMR) for all the batches of drug product is submitted Observations 3.2.S.4 • Copies of the Drug substance specifications and analytical procedures used for routine testing of the Drug substance 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 shall be submitted. • Certificate of Analysis (COA) of relevant batch of drug substance used during product development and stability study by drug product manufacturer shall be submitted Firm's Response • Copies of the Drug substance specifications by Drug Product manufacturer is submited. However, analytical procedures used for routine testing of the Drug substance by drug product manufacturer is not submitted • Analytical Method Verification studies of drug product is submitted instead of drug substance • Reply not submitted Observations 3.2.S.7 • Stability study data of 3 batches of drug substance at real time conditions at zone IV-A till claimed shelf life shall be submitted Firm's Response • Reply is not submitted Observations 3.2.P.2 • Submit details of comparator product including marketing authorization holder against which Pharmaceutical equivalence studies has been performed Firm's Response • Reply is not submitted Observations 3.2.P.8 • Stability study data of drug product at 6th month time point shall be submitted Firm's Response • Stability study data of drug product at 6th month time point is not submitted	
	Decision: Deferred Registration Board decided to defer the case for submission of following: i. Analytical procedures used for routine testing of the Drug substance by drug product manufacturer ii. Analytical Method Verification studies performed by the Drug Product manufacturer for drug substance. iii. Certificate of Analysis (COA) of relevant batch of drug substance used during product development and stability study by drug product manufacturer iv. Stability study data of 3 batches of drug substance at real time conditions at zone IV-A till claimed shelf life v. Details of comparator product including marketing authorization holder against which Pharmaceutical equivalence studies has been performed vi. Stability study data of drug product at 6th month time point.	
72	**Aspin Pharma** Plot # 10 & 25 Sector 20 Korangi Industrial Area Karachi 74900 Pakistan (**000045**) Tracking ID: (VT4-YHP-3DGE, 2023-12-15) Fee Paid: 30000.0 Paid Date: 2023-11-15 Case Category: Routine **(Dr. Farhad Ullah)**	Proposed Name: **Stugerin Plus** Each tablet contains: Cinnarizine.....20mg Dimenhydrinate.....40mg Manufacturer Specification RRA Status: Arlevert 20 mg/40 mg tablets Germany Me Too Status: Novert Tablet (Approved in Minutes for 261st Registration Board Meeting) Pack Size(s): 1x10's-As per SRO,2x10's-As per SRO,3x10's-As per SRO
	Manufacturer(s): ---	
	Evaluation Remarks: Observations 1.1 • Update the details of submitted differential fee in relevant field of e-app interphase (online portal) 1.6.5 • Valid copy of cGMP certificate / Drug Manufacturing License of the Drug Substance manufacturer for cinnarizine and Dimenhydrinate issued by relevant regulatory authority of country of origin is required 3.2.S.4 • Clarification shall be submitted for testing the drug substance in batch analysis as per USP monograph by drug product manufacturer instead of BP monograph as by drug substance manufacturer • Justification shall be submitted for not performing the test for pH and sulphated ash in batch analysis of drug substance by drug product manufacturer as per drug substance manufactuer 3.2.S.5 • COA of primary / secondary reference standard Dimenhydrinate including source and lot number shall be provided. 3.2.P.2 • Justification shall be submitted for not submitting results of dissolution studies of Dimenhydrinate in pharmaceutical equivalence studies of applied product • Justification shall be submitted for not submitting results of CDP studies of Dimenhydrinate in applied product 3.2.P.5 • Justification shall be submitted for not including the dissolution test for dimenhydrate in finished product specifications 3.2.P.8 • Submit copy of commercial invoice or clearance certificate for the procurement of API (dimenhydrinate) with approval from DRAP.	
	Decision: Deferred Registration Board deferred the case for submission of reply to the above cited shortcomings.	
73	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (1DE-SXP-J3JX, 2024-11-12) Fee Paid: 37000.0 Paid Date: 2024-10-29 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Peroxa CR Tablet 12.5mg** Each enteric film coated controlled release Tablet contains: Paroxetine as HCL .....12.5mg United States Pharmacopeia RRA Status: Product Name: Paxil CR Tablet Extended Release Tablet 50mg Manufacturer: APOT Reference Regulatory Authority: US FDA Approved drug. Me Too Status: Brand Name: Paraxyl CR Tablet Strength: 12.5mg Dosage Form: Oral Tablets Pack Size: 30's Regn No. 055335 Manufacturer: CCL Pharmaceuticals (Pvt.) Limited. Pack Size(s): 30's-As per SRO
	Evaluation Remarks:	
	Decision: Approved .	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
74	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (42Z-WYE-PTUR, 2024-10-22) Fee Paid: 37000.0 Paid Date: 2024-10-01 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Quto XR Tablet 150mg** Each Extended Release Tablet contains: Quetiapine Fumarate Equivalent to Quetiapine USP.....150mg United States Pharmacopeia RRA Status: Product Name: Seroquel Extended Release Tablet 150mg Reference Regulatory Authority: MHRA Approved drug. Me Too Status: Brand Name: Quto XR Tablets Strength: 150mg Dosage Form: Oral Tablets Pack Size: 10's Regn No. 084696 Manufacturer: Semos Pharmaceuticals (Pvt) Limited. Pack Size(s): 10's, 100's-As per SRO
	Evaluation Remarks:	
	Decision: Approved .	
75	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (6A2-JU3-ZQ5R, 2024-10-25) Fee Paid: 37000.0 Paid Date: 2024-10-09 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Azisoft Capsule 250mg** Each capsule contains: Azithromycin dihydrate eq: to Azithromycin.....250mg United States Pharmacopeia RRA Status: Product Name: Zithromax Capsule 250mg Market Authorization Holder; Pfizer Limited UK Reference Regulatory Authority: MHRA Approved. Me Too Status: Brand Name: Azisoft Capsule Strength: 250mg Dosage Form: Oral Capsules Pack Size: 6's Regn No. 079978 Manufacturer: Safe Pharmaceuticals Pvt. Ltd. Pack Size(s): 6's-As per SRO
	Evaluation Remarks: Submit loan documents including agreemnet and letter for loan. (Submitted by the firm). Firm has applied USP specifications which requires amperometric electrochemical detector (ECD) for assay testing of the product.	
	Decision: Deferred for evidence of amperometric electrochemical detector (ECD) required for assay testing of the drug product.	
76	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (E15-YBT-T74R, 2024-09-30) Fee Paid: 37000.0 Paid Date: 2024-09-19 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Quto** Each film coated tablet contains: Quetiapine Fumarate eq. to Quetiapine.....100mg United States Pharmacopeia RRA Status: Medicines and Healthcare Regulatory Agency (MHRA Me Too Status: Evo Kalm 100mg by Pharmevo Pack Size(s): 12's,24's,60's,120's-As per SRO
	Evaluation Remarks:	
	Decision: Approved .	
77	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (E64-SSR-7EMQ, 2024-09-30) Fee Paid: 37000.0 Paid Date: 2024-09-19 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Quto** Each film coated tablet contains: Quetiapine Fumarate eq. to Quetiapine.....25mg United States Pharmacopeia RRA Status: Medicines and Healthcare Regulatory Agency (MHRA Me Too Status: Evo Kalm 25mg by Pharmevo Pack Size(s): 12's,24's,60's,120's-As per SRO
	Evaluation Remarks:	
	Decision: Approved .	
78	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (EMH-YV5-7PED, 2024-10-22) Fee Paid: 37000.0 Paid Date: 2024-10-01 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Quto XR Tablet 200mg** Each Extended Release Tablet contains: Quetiapine Fumarate Equivalent to Quetiapine USP.....200mg United States Pharmacopeia RRA Status: Product Name: Seroquel Extended Release Tablet 200mg Manufacturer: PF PRISM Reference Regulatory Authority: US FDA Approved drug. Me Too Status: Brand Name: Quto XR Tablets Strength: 200mg Dosage Form: Oral Tablets Pack Size: 10's Regn No. 084697 Manufacturer: Semos Pharmaceuticals (Pvt) Limited. Pack Size(s): 10's, 100's-As per SRO
	Evaluation Remarks:	
	Decision: Approved .	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
79	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (EZH-QR9-WT39, 2024-11-14) Fee Paid: 37000.0 Paid Date: 2024-10-29 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Peroxa CR Tablet 37.5mg** Each enteric film coated controlled release Tablet contains: Paroxetine as HCL .....37.5mg United States Pharmacopeia RRA Status: Product Name: Paxil CR Tablet Extended Release Tablet 37.5mgManufacturer: APOT Reference Regulatory Authority: US FDA Approved drug. Me Too Status: Brand Name: Paraxyl CR Tablet Strength: 37.5mg Dosage Form: Oral Tablets Pack Size: 10's Regn No. 060323 Manufacturer: CCL Pharmaceuticals (Pvt.) Limited. Pack Size(s): 10's-As per SRO
	Evaluation Remarks:	
	Decision: Approved .	
80	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (N74-VMD-3V81, 2024-11-12) Fee Paid: 37000.0 Paid Date: 2024-10-29 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Peroxa CR Tablet 25mg** Each enteric film coated controlled release Tablet contains: Paroxetine as HCL .....25mg United States Pharmacopeia RRA Status: Product Name: Paxil CR Tablet Extended Release Tablet 25mg Manufacturer: APOT Reference Regulatory Authority: US FDA Approved drug. Me Too Status: Brand Name: Paraxyl CR Tablet Strength: 25mg Dosage Form: Oral Tablets Pack Size: 30's Regn No. 055336 Manufacturer: CCL Pharmaceuticals (Pvt.) Limited. Pack Size(s): 30's-As per SRO
	Evaluation Remarks:	
	Decision: Approved .	
81	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (QTR-QUE-2MAX, 2024-09-18) Fee Paid: 37000.0 Paid Date: 2024-09-09 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Peroxa** Each film coated tablet contains: Peroxetine HCl eq. to Peroxetine.....20mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Zapin by Glitz Pharma Pack Size(s): 10's,20's,30's,50's,-As per SRO
	Evaluation Remarks: Submit loan documents including agreemnet and letter for loan. (submitted by the firm)	
	Decision: Approved .	
82	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (RQ7-ZZ6-PTMZ, 2024-10-22) Fee Paid: 37000.0 Paid Date: 2024-10-01 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Quto XR Tablet 300mg** Each Extended Release Tablet contains: Quetiapine Fumarate Equivalent to Quetiapine USP.....300mg United States Pharmacopeia RRA Status: Product Name: Seroquel Extended Release Tablet300mg Manufacturer: PF PRISM Reference Regulatory Authority: US FDA Approved drug. Me Too Status: Brand Name: Quto XR Tablets Strength: 300mg Dosage Form: Oral Tablets Pack Size: 10's Regn No. 084698 Manufacturer: Semos Pharmaceuticals (Pvt) Limited. Pack Size(s): 10's, 100's-As per SRO
	Evaluation Remarks:	
	Decision: Approved .	
83	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (VW4-BW8-5JTZ, 2024-10-22) Fee Paid: 37000.0 Paid Date: 2024-10-01 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Quto XR Tablet 50mg** Each Extended Release Tablet contains: Quetiapine Fumarate Equivalent to Quetiapine USP.....50mg United States Pharmacopeia RRA Status: Product Name: Seroquel Extended Release Tablet 50mg Manufacturer: PF PRISM Reference Regulatory Authority: US FDA Approved drug. Me Too Status: Brand Name: Zoph XR Tablets Strength: 50mg Dosage Form: Oral Tablets Pack Size: 10's Regn No. 098772 Manufacturer: AGP Private Limited. Pack Size(s): 10's, 100's-As per SRO
	Evaluation Remarks:	
	Decision: Approved .	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
84	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (NN4-S9G-UWVD, 2024-10-25) Fee Paid: 37000.0 Paid Date: 2024-10-09 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Azisoft Tablet 500mg** Each Film coated Tablet contains: Azithromycin dihydrate eq: to Azithromycin USP.....500mg United States Pharmacopeia RRA Status: Product Name: Azithromycin Tablet 500mg Reference Regulatory Authority: US FDA Approved drug & MHRA Approved. Me Too Status: Brand Name: Azisoft Tablet Strength: 500mg Dosage Form: Oral Tablets Pack Size: 6's Regn No. 083044 Manufacturer: Safe Pharmaceuticals Pvt. Ltd. Pack Size(s): 6's-As per SRO
	Evaluation Remarks: Submit loan documents including agreemnet and letter for loan. Response by the firm: Firm has submitted loan documents from Newton Healthcare Pvt Ltd, Baluchistan for 9Kg Azithromycin dated 14-12-2023	
	Decision: Approved .	
85	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (U2J-G49-N96T, 2024-10-29) Fee Paid: 37000.0 Paid Date: 2024-10-09 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Azisoft Dry Powder for Oral Suspension 200mg/5ml** Each 5ml reconstituted Suspension contains: Azithromycin dihydrate eq: to Azithromycin USP.....200mg United States Pharmacopeia RRA Status: Product Name: Zithromax Dry Powder Suspension Strength: 200mg/5ml Dosage Form: Oral Dry Powder Suspension Market Authorization Holder: Pfizer Limited UK Reference Regulatory Authority: MHRA Approved. Me Too Status: Brand Name: Azisoft Dry Powder Suspension Strength: 200mg/5ml Dosage Form: Oral Dry Powder Suspension Pack Size: 15ml Regn No. 076633 Manufacturer: Safe Pharmaceuticals Pvt. Ltd. Pack Size(s): 15ml-As per SRO
	Evaluation Remarks: Kindly clarify, since you have submitted two different applications for similar formulation i.e. Azithromycin 200mg/5ml suspension Submit loan documents including agreemnet and letter for loan. Response by the firm: It is clarfy that Azisoft Dry Suspension 200mg /5ml two different applications with same formulation due to pack size different one 15ml pack size while the other 30ml pack size.	
	Decision: Approved .	
86	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (V9U-QWY-LNY1, 2024-11-13) Fee Paid: 37000.0 Paid Date: 2024-10-29 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Azisoft Dry Powder for Oral Suspension 200mg/5ml** Each 5ml reconstituted Suspension contains: Azithromycin dihydrate eq: to Azithromycin USP.....200mg United States Pharmacopeia RRA Status: Product Name: Zithromax Dry Powder Suspension Strength: 200mg/5ml Dosage Form: Oral Dry Powder Suspension Market Authorization Holder: Pfizer Limited UK Reference Regulatory Authority: MHRA Approved. Me Too Status: Brand Name: Azisoft Dry Powder Suspension Strength: 200mg/5ml Dosage Form: Oral Dry Powder Suspension Pack Size: 30ml Regn No. 076633 Manufacturer: Safe Pharmaceuticals Pvt. Ltd. Pack Size(s): 30ml-As per SRO
	Evaluation Remarks: Firm has submitted two applications with fee for same formulation i.e. azithromycin 200mg/5ml suspension Submit loan documents including agreemnet and letter for loan. Response by the firm: It is clarfy that Azisoft Dry Suspension 200mg /5ml two different applications with same formulation due to pack size different one 15ml pack size while the other 30ml pack size.	
	Decision: Rejected since the same formulation of the firm applied vide application Tracking ID: U2J-G49-N96T is already approved in the instant meeting.	
87	**Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (**000755**) Tracking ID: (WNV-6DL-HSQ9, 2023-11-28) Fee Paid: 75000.0 Paid Date: 2023-11-03 Case Category: Routine **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Ibat** Each film coated tablet contain: Elobixibat hydrate eq to Elobixibat.....5mg As per Innovators Specification RRA Status: Goofice Tablets 5 mg PMDA Japan Me Too Status: NA Pack Size(s): 10's-As per SRO
	Manufacturer(s): ---	
	Evaluation Remarks: 1. Submit BMR for executed stability batches Submitted 2. Submit copy of Valid GMP certificate of API manufacturer Submitted 3. Justify the use of SLS in your dissolution medium Elobaxibat is a water-insoluble substance, categorized as a BCS Class II material. For such water-insoluble compounds, the FDA recommends incorporating a surfactant, like sodium lauryl sulfate (SLS), into the dissolution medium. As a result, we included 0.5% SLS in the medium. The FDA's guidelines for dissolution method development are provided as a reference, with key points highlighted on page 12 (A-1) 4. Specify the polymorphic form of API used in stability studies. Crystalline Form IV. (https://www.pmda.go.jp/files/000232054.pdf)	
	Decision: Approved .	

<table>
<tr><th>Sr. No</th><th>Name of Applicant, Manufacturer & Fee Details</th><th>Product Info</th></tr>
<tr><td>88</td><td>Vision Pharmaceuticals Pvt Ltd
Plot#22-23, Industrial Triangle, Kahuta Road, Islamabad. (000517)
Tracking ID: (WVQ-TGN-JPZ7, 2023-11-28)
Fee Paid: 75000.0
Paid Date: 2023-11-16
Case Category: Routine
(Dr. Muhmmad Haseeb Tariq)</td><td>Proposed Name: Co-Acetamol 1000mg/300mg IV Infusion
Each 100ml vial contains: Paracetamol.....1000mg, Ibuprofen (as sodium dihydrate).....300mg
As per Innovators Specification
RRA Status: MAXIGESIC IV Infusion (TGA Australia)
Me Too Status: Not Available
Pack Size(s): 1 vial-As per SRO</td></tr>
<tr><td></td><td colspan="2">Manufacturer(s):
---</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
1 You have performed testing for TAMC and TYMC for Paracetamol API while the same test is not the part of your API specifications nor this test has been performed by API manufacturer as evident from its COA. Moreover, API manufacturer has performed BET test, which is not performed by Vision Pharma. Clarification is required in this regard.
TAMC and TYMC for Paracetamol API is performed as the material is used in Injections, and this is for patient safety purpose. Furthermore, our micro department conducts the BET test; however, the report is inadvertently missing from the file.
An annex containing a copy of the BET report is attached.

2. Submit COA of reference standard / working standard actually used in the analysis of API.
COA of working standard attached here as

3 Clarify why your analytical method for assay testing of Ibuprofen sodium is different from that of its API manufacturer. API manufacturer has used valerophenone as internal standard while you have not used any internal standard. Clarify how you can have a different analytical method from that specified by API manufacturer.
As Ibuprofen sodium Raw material testing method is not available in USP or BP monograph, Development of Analytical method for assay testing of Ibuprofen sodium was performed in RND department, After development of this testing method, Validation was performed. (Test method Validation protocol and report attached here with).

4 Submit pictorial evidence of the reference product i.e. Maxigesic Infusion against which PE studies are conducted.
Pictorial evidence attached</td></tr>
<tr><td></td><td colspan="2">Decision: Approved
. Firm shall follow the analytical method of Ibuprofen sodium of the drug substance manufacturer until the monograph is included in any official pharmacopoeia.</td></tr>
<tr><td>89</td><td>Aptcure (PVT.) Ltd
8th Pharma city , 30-km, multan road lahore (000648)
Tracking ID: (88Y-R1U-SUPG, 2023-12-18)
Fee Paid: 30000.0
Paid Date: 2023-10-20
Case Category: Routine
(Maham Misbah)</td><td>Proposed Name: VONAPT

As per Innovators Specificatio
RRA Status: TAKECAB 10MG TABLET BY TAKEDA PHARMA. PMDA APPROVED
Me Too Status: VOCINTI 10MG TABLAT BY SEARLE
Pack Size(s): 10's & 14's-As per SRO</td></tr>
<tr><td></td><td colspan="2">Manufacturer(s):
---</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
The Board was apprised of the following shortcomings:

<table><tr><th>Shortcomings</th></tr><tr><td>Label claim shall be changed in online submission as per reference product label claim given in 1.5.2 i.e “Vonoprazan (as fumarate)....10mg”.</td></tr><tr><td>Valid GMP certificate/report of the applicant shall be submitted</td></tr><tr><td>Specify the polymorphic form of the drug substance used in the development of stability batches. Also clarify how the polymorphic form was identified by drug substance manufacturer and drug product manufacturer.</td></tr><tr><td>Justification shall be submitted for not including test of Fumaric acid content in drug substance specifications.</td></tr><tr><td>Submit verification studies of the analytical method of API performed by drug product manufacturer in section 3.2.S.4.3.</td></tr><tr><td>Raw data of analytical method validation of drug product shall be submitted.</td></tr><tr><td>Submit COA of reference / working standard actually used in analysis of drug substance and drug product.</td></tr><tr><td>The innovator’s product has recommended 15 minutes for dissolution test with 4.5pH acetate buffer as dissolution medium, while you have submitted dissolution test method and limits as follows:
“0.1N HCl 900ml at 75rpm for 30 min
NLT 80% should be released in 45 min.”
Revise your specification and submit results as per the innovator’s recommendation, along with submission of requisite fee.</td></tr><tr><td>Executed BMRs of stability batches shall be submitted.</td></tr><tr><td>Submit inference of results of CDP studies by calculating f1 and f2 factor.</td></tr></table></td></tr>
<tr><td></td><td colspan="2">Decision: Deferred
Deferred for submission of satisfactory response to afore-mentioned shortcomings.</td></tr>
<tr><td>90</td><td>Hilton Pharma (Pvt) Limited.
Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area (000136)
Tracking ID: (AZL-RQA-6PY1, 2023-12-13)
Fee Paid: 75000.0
Paid Date: 2023-11-30
Case Category: Routine
(Maham Misbah)</td><td>Proposed Name: Hilbur Injection 400mg /3ml
Each 3ml Contains: Ibuprofen Lysine.....400mg
As per Innovators Specificatio
RRA Status: Country Name : Italy, Product Name: Arfen Injection 400mg/3ml, Manufactured by: Laboratorio Italia
Me Too Status: N/A
Pack Size(s): 10s-As per SRO,1s-As per SRO,5s-As per SRO</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
The Board was apprised of the following shortcomings:
Submission of label claim in 1.5.2,
Documents for procurement of API.</td></tr>
</table>

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Deferred Applicant shall submit the following: Submission of label claim in 1.5.2; Documents for procurement of API.	
91	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (2N5-GP4-Y25W, 2024-08-12) Fee Paid: 30000.0 Paid Date: 2024-07-12 Case Category: New License **(Najia Saleem)**	Proposed Name: **SUPER ZOLE BOLUS 600** Each Bolus Contains (USP Spec.) Levamisole Hcl .....600mg United States Pharmacopeia RRA Status: N/A Me Too Status: ZEUS 600 FORTE BOLUS (094413) INTERNATIONAL PHARMA Pack Size(s): 1X5 Boli Blister Pac-De-Controlled
	Evaluation Remarks: Target species: Cattle, sheep, goats	
	Decision: Approved	
92	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (196-ZNY-DD5X, 2024-09-16) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Diclocena-8 Injection** Each ml contains: Meloxicam ... 8mg British Pharmacopeia RRA Status: Local me-too Available Me Too Status: MEXIBAK 8% INJECTION 049779 Attabak Pharmaceutical Industries Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: Target species: Cattle, horse, dogs, cats Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
93	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (1E4-RVZ-H29A, 2024-09-16) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Gentacen Injection 20%** Each ml Contains: Gentamicin Sulphate Eq to Gentamicin 200mg United States Pharmacopeia RRA Status: Local me-too Available Me Too Status: Gelox-20 Injection Reg. No. 099436 Wimits Pharma Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Target species: Dogs, cats Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
94	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (1ED-U32-VGV8, 2024-09-18) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Oxytena Injection 30%** Each ml contains: Oxytetracycline hydrochloride ... 300mg As per Innovators Specification RRA Status: Local me-too Available Me Too Status: Oxy Rold Inj Reg. No. 109253 Haarold's Pharma Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Target section: cattle Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
95	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (1GD-5PN-D1S5, 2024-09-20) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Clorver-120 Injection** Each ml contains: Ivermectin…20mg Clorsulon…100mg United States Pharmacopeia RRA Status: Local me-too Available Me Too Status: Actimec DS Injection of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 101524) Pack Size(s): 10ml-De-Controlled
	Evaluation Remarks: Target Animals: Calves, Camels, Cattle, Cows, Goats, Sheep Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 10ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
96	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (1HA-HXT-J9Z5, 2024-09-18) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Trigent 50/100 Injection** Each ml Contains: Gentamicin Sulphate Eq to Gentamicin 50mg & Tylosin as Tartrate 100mg As per Innovators Specification RRA Status: Local me-too Available Me Too Status: Tylogent Injection of M/s Nawal Pharmaceuticals, Taxila-Rawalpindi. (Reg. No. 113609) Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: Target Animals: Cats, Dogs, Cattle, Goats, Sheep Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
97	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (2QB-3H8-1W4B, 2024-08-12) Fee Paid: 30000.0 Paid Date: 2024-07-12 Case Category: New License **(Najia Saleem)**	Proposed Name: **CLOMI BOLUS 2400** Each Bolus Contains (As Per Innovator Spec.) Levamisole HCl……1000mg Oxyclozanide ……1400mg As per Innovators Specification RRA Status: N/A Me Too Status: LEVOX BOLUS (043279) PRIX PHARMA LAHORE Pack Size(s): 1X5 Boli Blister Pac-De-Controlled
	Evaluation Remarks: Target species: Cattle, sheep	
	Decision: Approved	
98	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (1WE-RXA-EP6E, 2024-09-18) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Oxytena Injection 5%** Each ml contains: Oxytetracycline hydrochloride … 50mg As per Innovators Specification RRA Status: Local me-too Available Me Too Status: Terrarok M 50 Parenteral solution of M/s. Manhattan Pharma (Reg. No. 074043) Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Target species: Cattle Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
99	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (2PW-7A5-1MWZ, 2024-09-18) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Trigent 50/100 Injection** Each ml Contains: Gentamicin Sulphate Eq to Gentamicin 50mg Tylosin as Tartrate 100mg As per Innovators Specification RRA Status: Local me-too Available Me Too Status: Tylogent Injection of M/s Nawal Pharmaceuticals, Taxila-Rawalpindi. (Reg. No. 113609) Pack Size(s): 100ml-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Target Animals: Cats, Dogs, Cattle, Goats, Sheep Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
100	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (5DY-HGB-6ZVZ, 2024-08-10) Fee Paid: 30000.0 Paid Date: 2024-07-12 Case Category: New License **(Najia Saleem)**	Proposed Name: **ZOLOBEN 300 BOLUS** Each Bolus Contains (USP Spec.) Albendazole .....300mg United States Pharmacopeia RRA Status: N/A Me Too Status: ALBENDAZOLE BOLUS (075645) PRIX PHARMA Pack Size(s): 1X5 Boli Blister Pac-De-Controlled
	Evaluation Remarks: Target species: calves, cattle, sheep and goats	
	Decision: Approved	
101	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (5P8-4BA-7LJU, 2024-08-12) Fee Paid: 30000.0 Paid Date: 2024-07-12 Case Category: New License **(Najia Saleem)**	Proposed Name: **SUPER ZOLE BOLUS 400** Each Bolus Contains (USP Spec.) Levamisole Hcl .....400mg United States Pharmacopeia RRA Status: N/A Me Too Status: LEVA PAR BOLUS (102063) GRAND PHARMA Pack Size(s): 1X5 Boli Blister Pac-De-Controlled
	Evaluation Remarks: Target species: Cattle, sheep, goats	
	Decision: Approved	
102	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (2X9-MYU-GEDS, 2024-09-20) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Avienro Injection 10%** Each ml contains: Enrofloxacin.....100mg British Pharmacopeia RRA Status: Local me-too Available Me Too Status: Enflox-10% Injection of M/s. Univet Pharmaceuticals, Rawalpindi. (Reg. No. 112212) Pack Size(s): 10ml-De-Controlled
	Evaluation Remarks: Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 10ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
103	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (2ZN-4RG-Y74J, 2024-09-20) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Clorver-110 Injection** Each ml contains: Ivermectin...10mg Clorsulon...100mg United States Pharmacopeia RRA Status: Local me-too Available Me Too Status: Actimec Plus Injection Reg. NO. 033251 Selmore Pharma Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: Target Animals: Calves, Camels, Cattle, Cows, Goats, Sheep Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
104	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (61G-YA7-ZRWH, 2024-08-10) Fee Paid: 30000.0 Paid Date: 2024-07-12 Case Category: New License **(Najia Saleem)**	Proposed Name: **ZOLOBEN 150 BOLUS** Each Bolus Contains (USP Spec.) Albendazole .....150mg United States Pharmacopeia RRA Status: N/A Me Too Status: ABENVET BOLUS 150mg (043150) GUYTON PHARMA LAHORE Pack Size(s): 1X5 Boli Blister Pac-De-Controlled
	Evaluation Remarks: Target species: calves, sheep and goats	
	Decision: Approved	
105	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (3AJ-WR1-AMQD, 2024-09-18) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Nitroxena Injection 20%** Each ml contains: Nitroxinil ... 200mg As per Innovators Specification RRA Status: Local me-too Available Me Too Status: Troxy-20% Injection M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. Reg. No. 034596 Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
106	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (3AU-GT9-NRT9, 2024-09-16) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Avienro Injection 5%** Each ml contains: Enrofloxacin.....50mg British Pharmacopeia RRA Status: Local me-too Available Me Too Status: Ceriflox Injection (50ml) of M/s Star Laboratories Lahore (Reg. No. 025703) Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
107	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (4B7-VTN-J417, 2024-09-16) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Avienro Injection 5%** Each ml contains: Enrofloxacin.....50mg British Pharmacopeia RRA Status: Local me-too Available Me Too Status: Ceriflox Injection of M/s Star Laboratories Lahore (Reg. No. 025703) Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
108	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (4R8-194-RZ8W, 2024-09-19) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Multicena Injection** Each ml Contains: VITAMIN A 100,000 IU VITAMIN D3 40,000 IU VITAMIN E 40mg As per Innovators Specification RRA Status: Local me-too Available Me Too Status: Product Name:: ADE-Max Injection Registration No: 058990 Company Name: Nawan Laboratories Pvt Ltd Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Target Animals: Calves, Camels, Cats, Cattle, Cows, Equine, Goats, Horses, Sheep Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
109	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (53R-X1J-H8G6, 2024-09-16) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Diclocena-7.5 Injection** Each ml contains: Meloxicam ... 7.5mg British Pharmacopeia RRA Status: Local me-too Available Me Too Status: Camilox Injection of M/S. Selmore Pharma (Reg. No. 071089) Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: Target species: Cattle, horses, dogs, cats Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
110	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (7SA-SQ8-SMG1, 2024-08-10) Fee Paid: 30000.0 Paid Date: 2024-07-12 Case Category: New License **(Najia Saleem)**	Proposed Name: **ZOLOBEN 1500 BOLUS** Each Bolus Contains (USP Spec.) Albendazole .....1500mg United States Pharmacopeia RRA Status: N/A Me Too Status: VETY ALBEN BOLUS 1500 (058856) LEADS PHARMA Pack Size(s): 1X5 Boli Blister Pac-De-Controlled
	Evaluation Remarks: Target species: calves, cattle, sheep and goats	
	Decision: Approved	
111	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (7ZR-5VV-QZ95, 2024-08-10) Fee Paid: 30000.0 Paid Date: 2024-07-12 Case Category: New License **(Najia Saleem)**	Proposed Name: **ZOLOBEN 200 BOLUS** Each Bolus Contains (USP Spec.) Albendazole .....200mg United States Pharmacopeia RRA Status: N/A Me Too Status: ALBEN PAR 200 BOLUS (102255) GRAND PHARMA Pack Size(s): 1X5 Boli Blister Pac-De-Controlled
	Evaluation Remarks: Target species: calves, sheep and goats	
	Decision: Approved	
112	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (855-HJ4-NUA3, 2024-08-12) Fee Paid: 30000.0 Paid Date: 2024-07-12 Case Category: New License **(Najia Saleem)**	Proposed Name: **SUPER ZOLE BOLUS 300** Each Bolus Contains (USP Spec.) Levamisole Hcl .....300mg United States Pharmacopeia RRA Status: N/A Me Too Status: LEVA 300 BOLUS (073987) INTERVAC (PVT) Ltd. Pack Size(s): 1X5 Boli Blister Pac-De-Controlled
	Evaluation Remarks: Target species: Cattle, sheep, goats	
	Decision: Approved	
113	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (58N-J8A-2X6H, 2024-09-16) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Diclocena-5 Injection** Each ml contains: Meloxicam ... 5mg British Pharmacopeia RRA Status: Local me-too Available Me Too Status: Diclostar Super injection of M/s. Star Labs (Reg. No. 053957) Pack Size(s): 50ml-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Target species: Cattle, horse, dogs, cats Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
114	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (5L9-YY2-BH9X, 2024-09-20) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Clorver-120 Injection** Each ml contains: Ivermectin...20mg Clorsulon...100mg United States Pharmacopeia RRA Status: Local me-too Available Me Too Status: Actimec DS Injection of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 101524) Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: Target Animals: Calves, Camels, Cattle, Cows, Goats, Sheep Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
115	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (5R5-JTJ-4812, 2024-09-14) Fee Paid: 37000.0 Paid Date: 2024-09-12 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Avimec Injection 2%** Each ml Contains: Ivermectin..... 20mg British Pharmacopeia RRA Status: Local me-too Available Me Too Status: Selmec Injection of M/s. Selmore Pharma (Reg. No. 071087) Pack Size(s): 50ml-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc): Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Evaluation Remarks: Target species: Cattle	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
116	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (87U-7SJ-Z8JR, 2024-08-12) Fee Paid: 30000.0 Paid Date: 2024-07-12 Case Category: New License **(Najia Saleem)**	Proposed Name: **T SOLE BOLUS 600** Each Bolus Contains (As Per Innovator Spec.) Tetramisole Hcl .....600mg As per Innovators Specification RRA Status: N/A Me Too Status: Tramiz 600 BOLUS (094409) INTERNATIONAL PHARMA Pack Size(s): 1X5 Boli Blister Pac-De-Controlled
	Evaluation Remarks: Target species: cattle, sheep, dogs, cats, and poultry	
	Decision: Approved	
117	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (69L-HAD-R5YR, 2024-09-19) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Flumeg-83 Injection** Each ml Contains: Flunixin as Meglumine....83mg United States Pharmacopeia RRA Status: Local me-too Available Me Too Status: Nixsym Injection of M/s Symans Pharmaceuticals (Pvt) Ltd, Lahore (Reg. No. 063852) Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Target species: Horse, cattle Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility. Moreover, reattach complete form-5 for 100ml pack size since you have attached the dossier for 50ml pack	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
118	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (AA6-P5A-L8TR, 2024-08-12) Fee Paid: 30000.0 Paid Date: 2024-07-12 Case Category: New License **(Najia Saleem)**	Proposed Name: **T SOLE BOLUS 1000** Each Bolus Contains (As Per Innovator Spec.) Tetramisole HCl.....1000mg As per Innovators Specification RRA Status: N/A Me Too Status: Tramiz DS BOLUS (094410) INTERNATIONAL PHARMA Pack Size(s): 1X5 Boli Blister Pac-De-Controlled
	Evaluation Remarks: Target species: cattle, sheep, dogs, cats, and poultry	
	Decision: Approved	
119	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (B2E-UN4-B18M, 2024-09-18) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Oxytena Injection 20%** Each ml contains: Oxytetracycline hydrochloride ... 200mg As per Innovators Specification RRA Status: Local me-too Available Me Too Status: Terrasym LA-200 Injection Reg. No. 022750 Symans Pharma Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Target species: cattle	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
120	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (BMU-RZP-HLYR, 2024-08-10) Fee Paid: 30000.0 Paid Date: 2024-07-12 Case Category: New License **(Najia Saleem)**	Proposed Name: **ZOLOBEN 250 BOLUS** Each Bolus Contains (USP Spec.) Albendazole .....250mg United States Pharmacopeia RRA Status: N/A Me Too Status: ALBAMIT-250 BOLUS (081323) WIMITS PHARMA Pack Size(s): 1X5 Boli Blister Pac-De-Controlled
	Evaluation Remarks: Target species: calves, cattle, sheep and goats	
	Decision: Approved	
121	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (7NY-P6R-68Q6, 2024-09-16) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Diclocena-8 Injection** Each ml contains: Meloxicam ... 8mg British Pharmacopeia RRA Status: Local me-too Available Me Too Status: MEXIBAK 8% INJECTION 049779 Attabak Pharmaceutical Industries Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Target species: cattle, horse, dogs, cats Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
122	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (7XV-3DV-REAR, 2024-09-19) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Flumeg-50 Injection** Each ml Contains: Flunixin as Meglumine....50mg United States Pharmacopeia RRA Status: Local me-too Available Me Too Status: Phoenix Injection (073914) M/s. Mylab (Pvt) Ltd. Bahawalpur Pack Size(s): 100ml-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Target species: Horses, cattle Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
123	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (8H1-DNY-BUJZ, 2024-09-18) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Oxytena Injection 30%** Each ml contains: Oxytetracycline hydrochloride ... 300mg As per Innovators Specification RRA Status: Local me-too Available Me Too Status: Oxy Rold Inj Reg. No. 109253 Haarold's Pharma Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: Target species: Cattle Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
124	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (BYP-5NN-PBV2, 2024-08-12) Fee Paid: 30000.0 Paid Date: 2024-07-12 Case Category: New License **(Najia Saleem)**	Proposed Name: **CLOMI BOLUS 3375** Each Bolus Contains (As Per Innovator Spec.) Oxyclozanide BP .....2250mg Levamisole HCl BP.....1125mg As per Innovators Specification RRA Status: N/A Me Too Status: LEVAFOS BOLUS (074752) ZAKFAS PHARMA Pack Size(s): 1X5 Boli Blister Pac-De-Controlled
	Evaluation Remarks: Target species: Cattle, sheep	
	Decision: Approved	
125	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (DJS-NAU-N8S5, 2024-08-12) Fee Paid: 30000.0 Paid Date: 2024-07-12 Case Category: New License **(Najia Saleem)**	Proposed Name: **T SOLE BOLUS 2000** Each Bolus Contains (As Per Innovator Spec.) Tetramisole HCL .....2000mg As per Innovators Specification RRA Status: N/A Me Too Status: TRAMIZ 2.0 BOLUS (094407) INTERNATIONAL PHARMA Pack Size(s): 1X5 Boli Blister Pac-De-Controlled
	Evaluation Remarks: Target species: cattle, sheep, dogs, cats, and poultry	
	Decision: Approved	
126	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (DUM-LA6-DE1B, 2024-08-10) Fee Paid: 30000.0 Paid Date: 2024-07-12 Case Category: New License **(Najia Saleem)**	Proposed Name: **ZOLOBEN 600 BOLUS** Each Bolus Contains (USP Spec.) Albendazole .....600mg United States Pharmacopeia RRA Status: N/A Me Too Status: I-ZOLE 600 BOLUS (094446) INTERNATIONAL PHARMA Pack Size(s): 1X5 Boli Blister Pac-De-Controlled
	Evaluation Remarks: Target species: calves, cattle, sheep and goats	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
127	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (8JZ-DT1-A5Q8, 2024-09-16) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Avienro Injection 20%** Each ml contains: Enrofloxacin.....200mg British Pharmacopeia RRA Status: Local me-too Available Me Too Status: Enras-20 Injection of (Reg. No. 057071) M/s Zakfas Pharmaceutical Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
128	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (EP3-84S-T2HD, 2024-08-10) Fee Paid: 30000.0 Paid Date: 2024-07-12 Case Category: New License **(Najia Saleem)**	Proposed Name: **ZOLOBEN 152 BOLUS** Each Bolus Contains (USP Spec.) Albendazole .....152mg United States Pharmacopeia RRA Status: N/A Me Too Status: I-BENZAL 152 BOLUS (073926) INTERNATIONAL PHARMA Pack Size(s): 1X5 Boli Blister Pac-De-Controlled
	Evaluation Remarks: Target species: calves, sheep and goats	
	Decision: Approved	
129	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (GT2-N43-ST51, 2024-08-12) Fee Paid: 30000.0 Paid Date: 2024-07-12 Case Category: New License **(Najia Saleem)**	Proposed Name: **SUPER ZOLE BOLUS 184** Each Bolus Contains (USP Spec.) Levamisole Hcl .....184mg United States Pharmacopeia RRA Status: N/A Me Too Status: ZEUS 184 BOLUS (094414) INTERNATIONAL PHARMA Pack Size(s): 1X5 Boli Blister Pac-De-Controlled
	Evaluation Remarks: Target species: Cattle, sheep, goats	
	Decision: Approved	
130	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (8M9-V2Z-23TZ, 2024-09-16) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Diclocena-10 Injection** Each ml contains: Meloxicam ... 10mg British Pharmacopeia RRA Status: Local me-too Available Me Too Status: Meloxi-10 Injection of M/s. Selmore Pharma (Reg. No. 049643) Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: Target species: Horse, cattle, dogs, cats Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
131	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (8ZX-4JV-M78N, 2024-09-14) Fee Paid: 37000.0 Paid Date: 2024-09-12 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Avimec Injection 1.2%** Each ml Contains: Ivermectin..... 12mg British Pharmacopeia RRA Status: Local me-too Available Me Too Status: Animectin 1.2% Injection 088827 Biolab Islamabad Pack Size(s): 100ml-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc): Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Target species: cattle	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
132	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (HM7-T6J-HMT1, 2024-08-12) Fee Paid: 30000.0 Paid Date: 2024-07-12 Case Category: New License **(Najia Saleem)**	Proposed Name: **ZOLODINE BOLUS** Each Bolus Contains (As Per Innovator Spec.) Closantel .....350mg Mebendazole.....525mg As per Innovators Specification RRA Status: N/A Me Too Status: CLOMEB BOLUS (057066) PRIX PHARMA Pack Size(s): 1X5 Boli Blister Pac-De-Controlled
	Evaluation Remarks: Target species: Sheep and goats	
	Decision: Approved	
133	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (JD2-2MX-NUQG, 2024-08-10) Fee Paid: 30000.0 Paid Date: 2024-07-12 Case Category: New License **(Najia Saleem)**	Proposed Name: **ZOLOBEN 360 BOLUS** Each Bolus Contains (USP Spec.) Albendazole .....360mg United States Pharmacopeia RRA Status: N/A Me Too Status: ALVENAX-360 BOLUS (049552) STAR LABORATORIES Pack Size(s): 1X5 Boli Blister Pac-De-Controlled
	Evaluation Remarks: Target species: calves, cattle, sheep and goats	
	Decision: Approved	
134	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (999-984-Y5NW, 2024-09-16) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Diclocena-10 Injection** Each ml contains:Meloxicam ... 10mg British Pharmacopeia RRA Status: Local me-too Available Me Too Status: Meloxi-10 Injection of M/s. Selmore Pharma (Reg. No. 049643) Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Target species: Horse, cattle, dogs, cats Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
135	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (9JG-JDD-T559, 2024-09-20) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Clorver-110 Injection** Each ml contains: Ivermectin...10mg Clorsulon...100mg United States Pharmacopeia RRA Status: Local me-too Available Me Too Status: Actimec Plus Injection Reg. NO. 033251 Selmore Pharma Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Target Animals: Calves, Camels, Cattle, Cows, Goats, Sheep Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
136	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (JL7-RUJ-Y775, 2024-08-12) Fee Paid: 30000.0 Paid Date: 2024-07-12 Case Category: New License **(Najia Saleem)**	Proposed Name: **CLOMI BOLUS 1000** Each Bolus Contains (As Per Innovator Spec.) Levamisole Hcl .....0.5g Oxyclozanide .....1.0g As per Innovators Specification RRA Status: N/A Me Too Status: LEAMASOLE BOLUS (034591) LEADS PHARMA Pack Size(s): 1X5 Boli Blister Pac-De-Controlled
	Evaluation Remarks: Target species: Cattle, sheep	
	Decision: Approved	
137	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (LB6-JP1-EG3S, 2024-08-12) Fee Paid: 30000.0 Paid Date: 2024-07-12 Case Category: New License **(Najia Saleem)**	Proposed Name: **SUPER ZOLE BOLUS 1125** Each Bolus Contains (USP Spec.) Levamisole Hcl .....1125mg United States Pharmacopeia RRA Status: N/A Me Too Status: ZEUS 1125 BOLUS (094415) INTERNATIONAL PHARMA Pack Size(s): 1X5 Boli Blister Pac-De-Controlled
	Evaluation Remarks: Target species: Cattle, sheep, goats	
	Decision: Approved	
138	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (LMN-3GT-ML9R, 2024-08-10) Fee Paid: 30000.0 Paid Date: 2024-07-12 Case Category: New License **(Najia Saleem)**	Proposed Name: **TRIZINE BOLUS** Each Bolus Contains (BP Vet Spec.) Trimethoprim.....200mg Sulphadiazine.....1000mg British Pharmacopeia RRA Status: N/A Me Too Status: TREMOSULF (074037) INTERNATIONAL PHARMA Pack Size(s): 1X5 Boli Blister Pac-De-Controlled
	Evaluation Remarks: Target species: cattle, horse, sheep, goat, poultry, fish, dogs, cats	
	Decision: Approved	
139	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (9MT-TYP-YVP6, 2024-09-16) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Gentacen Injection 11%** Each ml Contains: Gentamicin Sulphate Eq to Gentamicin 110mg United States Pharmacopeia RRA Status: Local me-too Available Me Too Status: Gent ROLD 11 Liquid Injection Reg. No 108985 Haarold;s Pharma Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: Target species: Dogs, cats Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
140	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (9N1-VLW-TJ93, 2024-09-16) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Avienro Injection 10%** Each ml contains: Enrofloxacin.....100mg British Pharmacopeia RRA Status: Local me-too Available Me Too Status: Enflox-10% Injection of M/s. Univet Pharmaceuticals, Rawalpindi. (Reg. No. 112213) Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
141	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (9WB-BH4-76VD, 2024-09-18) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Nitroxena Injection 34%** Each ml contains: Nitroxinil ... 340mg As per Innovators Specification RRA Status: Local me-too Available Me Too Status: Nitroxl Forte Injection of M/s Mediexcel Pharmaceuticals, Islamabad. (Reg. No. 106697) Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
142	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (QDZ-VLT-VHM5, 2024-09-20) Fee Paid: 37000.0 Paid Date: 2024-09-12 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Avimec Injection 1%** Each ml Contains: Ivermectin..... 10mg British Pharmacopeia RRA Status: Local me-too Available Me Too Status: Intermectin Injection 1% Reg. No. 073986 Pack Size(s): 10ml-De-Controlled
	Evaluation Remarks: Target species: Cattle	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
143	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (ADR-87Q-L76L, 2024-09-14) Fee Paid: 37000.0 Paid Date: 2024-09-12 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Avimec Injection 3.15%** Each ml Contains: Ivermectin..... 31.50mg British Pharmacopeia RRA Status: Local me-too Available Me Too Status: Vectin Injection Aamster Lab Rawalpindi 112158 Pack Size(s): 100ml-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc): Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Evaluation Remarks: Target species: Cattle	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
144	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (ADS-6MT-9UYG, 2024-09-14) Fee Paid: 37000.0 Paid Date: 2024-09-12 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Gentacen Injection 5%** Each ml Contains: Gentamicin Sulphate Eq to Gentamicin 50mg United States Pharmacopeia RRA Status: Local me-too Available Me Too Status: Gentasym 5% Injection 022739 Symans Pharma Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: Target species: Dogs, cats Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
145	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (AJ5-2Q3-1XUW, 2024-09-19) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Flumeg-50 Injection** Each ml Contains: Flunixin as Meglumine....50mg United States Pharmacopeia RRA Status: Local me-too Available Me Too Status: Phoenix Injection (073914) M/s. Mylab (Pvt) Ltd. Bahawalpur Pack Size(s): 50ml-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Target species: Horses, cattle Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
146	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (AQS-JNQ-1VA2, 2024-09-19) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Avi-EAD3 Injection** Each ml Contains: Vitamin A…80,000 IU Vitamin D3…40,000 IU Vitamin E…20mg As per Innovators Specification RRA Status: Local me-too Available Me Too Status: VAD3 Injection (100ml) of M/s Breeze Pharma Islamabad (Reg. No. 059179) Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Target Animals: Calves, Camels, Cats, Cattle, Cows, Equine, Goats, Horses, Sheep Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
147	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (B67-UJZ-W9QU, 2024-09-18) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Nitroxena Injection 34%** Each ml contains: Nitroxinil … 340mg As per Innovators Specification RRA Status: Local me-too Available Me Too Status: Nitroxl Forte Injection of M/s Mediexcel Pharmaceuticals, Islamabad. (Reg. No. 106697) Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
148	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (S7X-8QM-JRW7, 2024-09-18) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Oxytena Injection 10%** Each ml contains: Oxytetracycline hydrochloride … 100mg As per Innovators Specification RRA Status: Local me-too Available Me Too Status: Terrasym PVP-100 Injection 022749 Symans Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: Target species: cattle	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
149	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (BMR-5RQ-8NBZ, 2024-09-16) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Diclocena-50 Injection** Each ml contains: Meloxicam … 50mg British Pharmacopeia RRA Status: Local me-too Available Me Too Status: Meloxin Injection Reg. No. 043583 Leads Pharma Pvt Ltd. Islamabad Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: Target species: Cattle, horse, dogs, cats Shortcomings: Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility. Moreover, attach relevant Form 5 along with its annexures for 50ml pack size.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
150	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (UBP-731-2M6R, 2024-08-12) Fee Paid: 30000.0 Paid Date: 2024-07-12 Case Category: New License **(Najia Saleem)**	Proposed Name: **T SOLE BOLUS 150** Each Bolus Contains (As Per Innovator Spec.) Tetramisole Hcl .....150mg As per Innovators Specification RRA Status: N/A Me Too Status: Tramiz Forte BOLUS (094408) INTERNATIONAL PHARMA Pack Size(s): 1X5 Boli Blister Pac-De-Controlled
	Evaluation Remarks: Target species: cattle, sheep, dogs and poultry	
	Decision: Approved	
151	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (D24-DMT-HXGU, 2024-09-13) Fee Paid: 37000.0 Paid Date: 2024-09-12 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Avimec Injection 1%** Each ml Contains: Ivermectin..... 10mg British Pharmacopeia RRA Status: Local me-too Available Me Too Status: Intermectin Injection 1% Reg. No. 073986 Pack Size(s): 50ml-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc): Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Evaluation Remarks: Target species: Cattle	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
152	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (UL5-YPS-P89J, 2024-08-10) Fee Paid: 30000.0 Paid Date: 2024-07-12 Case Category: New License **(Najia Saleem)**	Proposed Name: **PHARDINE BOLUS** Each Bolus Contains (As Per Innovator Spec.) Sulphadimidine Sodium .....2.5gm As per Innovators Specification RRA Status: N/A Me Too Status: SULF-C BOLUS (094444) INTERNATIONAL PHARMA Pack Size(s): 1X5 Boli Blister Pac-De-Controlled
	Evaluation Remarks: Target species: Camel, cow, goat, sheep	
	Decision: Approved	
153	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (DGM-EN2-23RN, 2024-09-14) Fee Paid: 37000.0 Paid Date: 2024-09-12 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Avimec Injection 2%** Each ml Contains: Ivermectin..... 20mg British Pharmacopeia RRA Status: Local me-too Available Me Too Status: Selmec Injection of M/s. Selmore Pharma (Reg. No. 071087) Pack Size(s): 100ml-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc): Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Evaluation Remarks: Target species: Cattle	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
154	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (DHZ-347-8YBB, 2024-09-16) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Gentacen Injection 11%** Each ml Contains: Gentamicin Sulphate Eq to Gentamicin 110mg United States Pharmacopeia RRA Status: Local me-too Available Me Too Status: Gent ROLD 11 Liquid Injection Reg. No 108986 Haarold;s Pharma Pack Size(s): 100ml-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Target species: Dogs, cats Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
155	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (XA9-YBW-ZD3P, 2024-08-12) Fee Paid: 30000.0 Paid Date: 2024-07-26 Case Category: New License **(Najia Saleem)**	Proposed Name: **QUINMEN BOLUS** Each Bolus Contains (As Per Innovator Spec.) Flumequin .....350mg As per Innovators Specification RRA Status: N/A Me Too Status: QULENN BOLUS (094411) INTERNATIONAL PHARMA Pack Size(s): 1X5 Boli Blister Pac-De-Controlled
	Evaluation Remarks: Target species: Calves, cattle, cows, equine, goats, horses, sheep	
	Decision: Approved	
156	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (XYR-MPD-SDH2, 2024-08-10) Fee Paid: 30000.0 Paid Date: 2024-07-12 Case Category: New License **(Najia Saleem)**	Proposed Name: **ARC CLOSA BOLUS** Each Bolus Contains (As Per Innovator Spec.) Niclosamide .....1250mg As per Innovators Specification RRA Status: N/A Me Too Status: I-CLOSAMIDE (074038) INTERNATIONAL PHARMA Pack Size(s): 1X5 Boli Blister Pac-De-Controlled
	Evaluation Remarks: Target species: cattle, sheep, goat, dogs, cats	
	Decision: Approved	
157	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (YJH-BS6-G4T6, 2024-08-10) Fee Paid: 30000.0 Paid Date: 2024-07-12 Case Category: New License **(Najia Saleem)**	Proposed Name: **ZOLOBEN 2500 BOLUS** Each Bolus Contains (USP Spec.) Albendazole .....2500mg United States Pharmacopeia RRA Status: N/A Me Too Status: I-ZOLBIN 2500 BOLUS (073927) INTERNATIONAL PHARMA Pack Size(s): 1X5 Boli Blister Pac-De-Controlled
	Evaluation Remarks: Target species: calves, cattle, sheep and goats	
	Decision: Approved	
158	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (EEQ-ERB-T6L9, 2024-09-16) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Diclocena-7.5 Injection** Each ml contains: Meloxicam ... 7.5mg British Pharmacopeia RRA Status: Local me-too Available Me Too Status: Camilox Injection of M/S. Selmore Pharma (Reg. No. 071089) Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Target species: Cattle, horse, dogs, cats Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
159	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (EQ5-7EJ-XGWN, 2024-09-20) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Clorver-110 Injection** Each ml contains: Ivermectin…10mg Clorsulon…100mg United States Pharmacopeia RRA Status: Local me-too Available Me Too Status: Actimec Plus Injection Reg. NO. 033251 Selmore Pharma Pack Size(s): 10ml-De-Controlled
	Evaluation Remarks: Target Animals: Calves, Camels, Cattle, Cows, Goats, Sheep Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 10ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
160	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (YTS-W9W-4L21, 2024-09-18) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Oxytena Injection 10%** Each ml contains: Oxytetracycline hydrochloride … 100mg As per Innovators Specification RRA Status: Local me-too Available Me Too Status: Terrasym PVP-100 Injection 022749 Symans Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Target species: cattle	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
161	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (ZTS-ADZ-Q89Z, 2024-08-10) Fee Paid: 30000.0 Paid Date: 2024-07-12 Case Category: New License **(Najia Saleem)**	Proposed Name: **ZENIX BOLUS** Each Bolus Contains (As Per Innovator Spec.) Closantel .....500mg As per Innovators Specification RRA Status: N/A Me Too Status: I-ZENTEL BOLUS (073928) INTERNATIONAL PHARMA Pack Size(s): 1X5 Boli Blister Pac-De-Controlled
	Evaluation Remarks: Target species: Cattle, Sheep and Goats	
	Decision: Approved	
162	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (HBD-YH1-TMAG, 2024-09-19) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Flumeg-83 Injection** Each ml Contains: Flunixin as Meglumine….83 mg United States Pharmacopeia RRA Status: Local me-too Available Me Too Status: Nixsym Injection of M/s Symans Pharmaceuticals (Pvt) Ltd, Lahore (Reg. No. 063852) Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Target species: Cattle, horse Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
163	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (JS9-TPB-BULB, 2024-09-19) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Avi-AD3E Injection** Each ml Contains: VITAMIN A 50,000 IU VITAMIN D3 75,000 IU VITAMIN E 50mg As per Innovators Specification RRA Status: Local me-too Available Me Too Status: Duravit AD3E Injection of M/s Mylab (Pvt) Ltd. Bahawalpur (Reg. No. 074018) Pack Size(s): 50ml-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Target Animals: Calves, Camels, Cats, Cattle, Cows, Equine, Goats, Horses, Sheep Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
164	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (LGH-JLD-5JVX, 2024-09-16) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Diclocena-20 Injection** Each ml contains: Meloxicam ... 20mg British Pharmacopeia RRA Status: Local me-too Available Me Too Status: Melo Grand 20 Injection of M/s. Grand Pharma (Pvt) Ltd., Islamabad (Reg. No. 111556) Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Target species: Horse, cattle, dogs, cats Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
165	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (LS2-DA7-4LG6, 2024-09-16) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Gentacen Injection 15%** Each ml Contains: Gentamicin Sulphate Eq to Gentamicin 150mg United States Pharmacopeia RRA Status: Local me-too Available Me Too Status: Gentapak 15% Injection 043162 Leads Pharma (Pvt) Ltd. Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Target species: Dogs, cats Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
166	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (LVT-M79-RLE6, 2024-09-19) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Avi-EAD3 Injection** Each ml Contains: Vitamin A...80,000 IU Vitamin D3...40,000 IU Vitamin E...20mg As per Innovators Specification RRA Status: Local me-too Available Me Too Status: VAD3 Injection (100ml) of M/s Breeze Pharma Islamabad (Reg. No. 059179) Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: Target Animals: Calves, Camels, Cats, Cattle, Cows, Equine, Goats, Horses, Sheep Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
167	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (MB2-THZ-12HG, 2024-09-20) Fee Paid: 37000.0 Paid Date: 2024-09-12 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Avimec Injection 2%** Each ml Contains: Ivermectin..... 20mg British Pharmacopeia RRA Status: Local me-too Available Me Too Status: Selmec Injection of M/s. Selmore Pharma (Reg. No. 071087) Pack Size(s): 10ml-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc): Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 10ml pack size, submit the approval letter for relevant manufacturing facility.	
	Evaluation Remarks: Target species: cattle	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
168	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (MRU-EEG-RHUV, 2024-09-20) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Flumeg-83 Injection** Each ml Contains: Flunixin as Meglumine....83 mg United States Pharmacopeia RRA Status: Local me-too Available Me Too Status: Nixsym Injection of M/s Symans Pharmaceuticals (Pvt) Ltd, Lahore (Reg. No. 063852) Pack Size(s): 10ml-De-Controlled
	Evaluation Remarks: Target species: cattle, horse Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 10ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
169	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (MY6-6J6-6A2A, 2024-09-18) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Gentacen Injection 20%** Each ml Contains: Gentamicin Sulphate Eq to Gentamicin 200mg United States Pharmacopeia RRA Status: Local me-too Available Me Too Status: Gelox-20 Injection Reg. No. 099436 Wimits Pharma Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: Target species: Dogs, cats Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
170	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (NH4-MBD-YSDV, 2024-09-19) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Avi-AD3E Injection** Each ml Contains: VITAMIN A 50,000 IU VITAMIN D3 75,000 IU VITAMIN E 50mg As per Innovators Specification RRA Status: Local me-too Available Me Too Status: Duravit AD3E Injection of M/s Mylab (Pvt) Ltd. Bahawalpur (Reg. No. 074018) Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Target Animals: Calves, Camels, Cats, Cattle, Cows, Equine, Goats, Horses, Sheep Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
171	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (PDU-515-W7U1, 2024-09-16) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Diclocena-50 Injection** Each ml contains: Meloxicam ... 50mg British Pharmacopeia RRA Status: Local me-too Available Me Too Status: Tricam Injection 5% Reg. No. 052307 Cherished Pharmaceutical Lahore Registration Letter Attached Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Target species: Horse, cattle, dogs, cats Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
172	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (QVE-NWU-64X3, 2024-09-16) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Diclocena-5 Injection** Each ml contains: Meloxicam ... 5mg British Pharmacopeia RRA Status: Local me-too Available Me Too Status: Diclostar Super injection of M/s. Star Labs (Reg. No. 053957) Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Target species: Cattle, horse, dogs, cats Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
173	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (RAY-UYQ-ENRP, 2024-09-14) Fee Paid: 37000.0 Paid Date: 2024-09-12 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Gentacen Injection 10%** Each ml Contains: Gentamicin Sulphate Eq to Gentamicin 100mg United States Pharmacopeia RRA Status: Local me-too Available Me Too Status: Gentafas 10% Injection 072659 Intervac Pharma Lahore Pack Size(s): 50ml-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc): Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Evaluation Remarks: Target species: Dogs, cats	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
174	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (RMB-DJP-Q2PB, 2024-09-18) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Avi-GT 100/50 Injection** Each ml Contains: Gentamicin Sulphate Eq to Gentamicin 100mg & Tylosin as Tartrate 50mg As per Innovators Specification RRA Status: Local me-too Available Me Too Status: Gemsin Injection of M/s Grand Pharma (Pvt) Ltd., Islamabad (Reg. No. 111552) Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Target species: Cattle, sheep, goats, dogs, cats Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
175	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (SG1-LT7-WHZT, 2024-09-14) Fee Paid: 37000.0 Paid Date: 2024-09-12 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Gentacen Injection 10%** Each ml Contains: Gentamicin Sulphate Eq to Gentamicin 100mg United States Pharmacopeia RRA Status: Local me-too Available Me Too Status: Gentafas 10% Injection 072659 Intervac Pharma Lahore Pack Size(s): 100ml-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc): Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Evaluation Remarks: Target species: Dogs, cats	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
176	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (SQZ-ZTT-GD1V, 2024-09-19) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Avi-AD3E Fort Injection** Each ml Contains: VITAMIN A 100,000 IU VITAMIN D3 100,000 IU VITAMIN E 50mg As per Innovators Specification RRA Status: Local me-too Available Me Too Status: Vitaden Injection Registration No: 026499 STAR LABORATORIES PVT. LTD. Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: Target Animals: Calves, Camels, Cats, Cattle, Cows, Equine, Goats, Horses, Sheep Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
177	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (SR1-ABM-Y77U, 2024-09-18) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Oxytena Injection 5%** Each ml contains: Oxytetracycline hydrochloride ... 50mg As per Innovators Specification RRA Status: Local me-too Available Me Too Status: Terrarok M 50 Parenteral solution of M/s. Manhattan Pharma (Reg. No. 074043) Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: Target species: cattle Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
178	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (T1L-QMX-83NA, 2024-09-18) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Nitroxena Injection 20%** Each ml contains: Nitroxinil ... 200mg As per Innovators Specification RRA Status: Local me-too Available Me Too Status: Troxy-20% Injection M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. Reg. No. 034596 Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
179	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (TEW-M6P-9JSB, 2024-09-16) Fee Paid: 37000.0 Paid Date: 2024-09-12 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Gentacen Injection 15%** Each ml Contains: Gentamicin Sulphate Eq to Gentamicin 150mg United States Pharmacopeia RRA Status: Local me-too Available Me Too Status: Gentapak 15% Injection 043162 Leads Pharma (Pvt) Ltd. Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: Target species: Dogs, cats Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
180	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (U1R-DVQ-83YR, 2024-09-14) Fee Paid: 37000.0 Paid Date: 2024-09-12 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Avimec Injection 3.15%** Each ml Contains: Ivermectin..... 31.50mg British Pharmacopeia RRA Status: Local me-too Available Me Too Status: Vectin Injection Aamster Lab Rawalpindi 112158 Pack Size(s): 50ml-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Details of Certificates (CoPP/cGMP, Authorization Letter etc): Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Evaluation Remarks: Target species: cattle	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
181	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (U9E-8Q5-5L77, 2024-09-14) Fee Paid: 37000.0 Paid Date: 2024-09-12 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Gentacen Injection 5%** Each ml Contains: Gentamicin Sulphate Eq to Gentamicin..... 50mg United States Pharmacopeia RRA Status: Local me-too Available Me Too Status: Gentasym 5% Injection 022739 Symans Pharma Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Target species: Dogs, cats Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
182	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (UB6-76D-U9JL, 2024-09-16) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Avienro Injection 10%** Each ml contains: Enrofloxacin.....100mg British Pharmacopeia RRA Status: Local me-too Available Me Too Status: Enflox-10% Injection of M/s. Univet Pharmaceuticals, Rawalpindi. (Reg. No. 112212) Pack Size(s): 50ML-De-Controlled
	Evaluation Remarks: Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
183	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (UJA-LMJ-WU8M, 2024-09-16) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Avienro Injection 20%** Each ml contains: Enrofloxacin.....200mg British Pharmacopeia RRA Status: Local me-too Available Me Too Status: Enras-20 Injection of (Reg. No. 057071) M/s Zakfas Pharmaceutical Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
184	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (UZ1-8RS-EJD7, 2024-09-18) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Avi-GT 100/50 Injection** Each mlContains: Gentamicin Sulphate Eq to Gentamicin 100mg &Tylosin as Tartrate 50mg As per Innovators Specification RRA Status: Local me-too Available Me Too Status: Gemsin Injection of M/s Grand Pharma (Pvt) Ltd., Islamabad (Reg. No. 111552) Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: Target species: Cattle, sheep, goats, dogs, cats Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
185	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (V8N-P16-J52A, 2024-09-20) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Flumeg-50 Injection** Each ml Contains: Flunixin as Meglumine....50mg United States Pharmacopeia RRA Status: Local me-too Available Me Too Status: Phoenix Injection (073914) M/s. Mylab (Pvt) Ltd. Bahawalpur Pack Size(s): 10ml-De-Controlled
	Evaluation Remarks: Target species: Horses, cattle Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 10ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
186	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (VJE-G8M-RMJY, 2024-09-19) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Multicena Injection** Each ml Contains: VITAMIN A 100,000 IU VITAMIN D3 40,000 IU VITAMIN E 40mg As per Innovators Specification RRA Status: Local me-too Available Me Too Status: Product Name:: ADE-Max Injection Registration No: 058990 Company Name: Nawan Laboratories Pvt Ltd Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: Target Animals: Calves, Camels, Cats, Cattle, Cows, Equine, Goats, Horses, Sheep Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
187	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (VW4-PSV-H5ZG, 2024-09-20) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Clorver-120 Injection** Each ml contains: Ivermectin...20mg Clorsulon...100mg United States Pharmacopeia RRA Status: Local me-too Available Me Too Status: Actimec DS Injection of M/s Selmore Pharmaceuticals (Pvt) Limited, Lahore. (Reg. No. 101524) Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Target Animals: Calves, Camels, Cattle, Cows, Goats, Sheep Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
188	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (VYT-ERU-N7B3, 2024-09-13) Fee Paid: 37000.0 Paid Date: 2024-09-12 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Avimec Injection 1%** Each ml Contains: Ivermectin..... 10mg British Pharmacopeia RRA Status: Local Me-too Present Me Too Status: Intermectin Injection 1% Reg. No. 073986 Pack Size(s): 100ml-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc): Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Evaluation Remarks: Target species: Cattle	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
189	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (YDJ-13S-45M4, 2024-09-14) Fee Paid: 37000.0 Paid Date: 2024-09-12 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Avimec Injection 1.2%** Each ml Contains: Ivermectin..... 12mg British Pharmacopeia RRA Status: Local me-too Available Me Too Status: Animectin 1.2% Injection 088827 Biolab Islamabad Pack Size(s): 50ml-De-Controlled
	Details of Certificates (CoPP/cGMP, Authorization Letter etc): Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Evaluation Remarks: Target species: cattle	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
190	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (YUL-69J-VENW, 2024-09-16) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Diclocena-20 Injection** Each ml contains: Meloxicam ... 20mg British Pharmacopeia RRA Status: Local me-too Available Me Too Status: Melo Grand 20 Injection of M/s. Grand Pharma (Pvt) Ltd., Islamabad (Reg. No. 111556) Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: Target species: Cattle, horse, dogs, cats Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
191	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (YWP-WA1-PMVZ, 2024-09-19) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Avi-AD3E Fort Injection** Each ml Contains: VITAMIN A 100,000 IU VITAMIN D3 100,000 IU VITAMIN E 50mg As per Innovators Specification RRA Status: Local me-too Available Me Too Status: Vitaden Injection Registration No: 026499 STAR LABORATORIES PVT. LTD. Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Target Animals: Calves, Camels, Cats, Cattle, Cows, Equine, Goats, Horses, Sheep Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 100ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	
192	**AVICENNA LABORATORIES (PVT) LTD** 14-KM Sheikhpura Disstt. Faisalabad Road Bhikki (**000328**) Tracking ID: (ZM2-83A-WW9A, 2024-09-18) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New Section **(Najia Saleem)**	Proposed Name: **Oxytena Injection 20%** Each ml contains: Oxytetracycline hydrochloride ... 200mg As per Innovators Specification RRA Status: Local me-too Available Me Too Status: Terrasym LA-200 Injection Reg. No. 022750 Symans Pharma Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: Target species: cattle Approval of Injectable Vial (LVP) section General was granted vide letter No. 1-18/91-Lic (Vol-IV) dated 20-08-2024, while you have applied for 50ml pack size, submit the approval letter for relevant manufacturing facility.	
	Decision: Deferred The firm shall submit relevant section approval of Injectable Vial (SVP) section General from Licensing Division, DRAP.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
193	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila (**000856**) Tracking ID: (3DJ-VG4-ZB42, 2023-11-27) Fee Paid: 75000.0 Paid Date: 2023-11-22 Case Category: Routine **(Saima Hussain)**	Proposed Name: **Micozon Cream 2% w/w** Each gram of cream contains Miconazole Nitrate....20mg (2% w/w) (As per USP Specs.) United States Pharmacopeia RRA Status: Registered drug by US FDA Daktarin Cream (Miconazole Nitrate Cream), for topical use. Me Too Status: Daktarin Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: 3.2. P.5.1 Please submit the reference of acceptance criteria adopted for the test of pH and viscosity of drug product. In response of above query firm replied that ,As per USP <3> Topical and transdermal drug products-product quality tests, the pH acceptance criteria are stated that; “When applicable, topically applied drug products should be tested for pH. Because some topically applied drug products contain very limited quantities of water or aqueous phase, pH measurements may not always be warranted. This test is generally formulation dependent. Therefore, it is not included in the compendial drug product monograph but is part of the manufacturer's specification for the drug product.” The viscosity criteria are stated that; “Acceptance criteria are product specific and defined to ensure that the apparent viscosity of each batch of semisolid drug product is within the range defined by the product design and is consistent between batches based on the product development specifications and statistical assessment of multiple product batches over the product's shelf life.” Moreover, our results are concordant to commercial marketed drug product as shown in pharma equivalence report and consistent in stability studies. 3.2. P.8.1 Provide a scientific rationale for manufacturing two trial batches, each with a batch size of 500 units, ensuring that the response complies with the CTD guidance document and international guidelines. In response of above query firm replied that, We have selected two batches as per minutes of 293rd meeting of registration board, Implementation of Common Technical Document, 3.2.P.8 Stability, Clause (a), Aerosol and any other specialized preparations 500.	
	Decision: Approved	
194	**Scilife Pharma Private Limited** FD-57/58-A2, Korangi Creek Industrial Park (KCIP) (**000837**) Tracking ID: (777-3ZQ-RS15, 2024-05-15) Fee Paid: 75000.0 Paid Date: 2023-05-17 Case Category: Routine **(Saima Hussain)**	Proposed Name: **Scirica CR 82.5mg Tablet** Each Extended-release tablets contains: Pregabalin.....82.5mg As per Innovators Specification RRA Status: Product is registered in USFDA with brand Name “LYRICA CR” 82.5mg tablet by UPJOHN Me Too Status: N/A for New Drug Product Pack Size(s): 10s-As per SRO,14s-As per SRO,20s-As per SRO,28s-As per SRO,30s-As per SRO,56s-As per SRO,7s-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info

Evaluation Remarks:
Case was deferred in 340th meeting of Registration Board for the submission of shortcomings communicated earlier.

S.no.	Observations/Deficiencies/ Short-comings	Response of the Firm
1.	Assay results of drug substance specified by the drug product manufacturer is as basis and on anhydrous basis while the USP monograph of pregabalin mentioned the limits of assay on dried basis, provide the results of assay according to the recommendation of USP monograph.	Firm submitted the batch analysis report of drug substance in which the results of assay has been mentioned in accordance with USP monograph of pregabalin.
2.	Specification of drug substance mentioned in the COA, given in section 3.2.S.4.1 and recommended by USP monograph of pregabalin is different from the specification on which stability of drug substance has been performed, clarification is required in this regard.	Firm replied that "We would like to inform the Agency that Pregabalin API batches PG120001, PG120002 and PG120003 were initially kept for stability studies as per inhouse Specification and Method of Analysis as Pregabalin monograph was not yet published in any pharmacopeia in 2012. Later on, monograph of Pregabalin was published in year 2016. Accordingly, API Specification and Method of Analysis for Assay and Related substance was revised in-line with the Ph.Eur. monograph. Hence, initial control sample and 48 months stability interval sample of these API batches were analyzed as per revised specification and batches meeting Ph.Eur. Specification. Further, Pregabalin API got official in USP monograph (USP 40-NF_August 01, 2017). However, stability study of these API batches was completed. Hence, initial control sample and stability sample of last interval i.e. 72 months were checked as per USP specification. Accordingly, stability data are attached. Later on, CTX has initiated the accelerated and long-term stability study for API batches PG183002, PG183003 and PG183004 as per Pregabalin USP Specification and Method of Analysis. Kindly find attached 06 months accelerated and 60 months long term stability data of above batches as per USP Specification and Method of Analysis. Conclusion: Based on the above justification, it is concluded that stability study data of Pregabalin API batches PG120001, PG120002 and PG120003 (from the initial and 72 months as provided on page # 2 of stability study) were in-line with the USP specification and Method of Analysis as recommended in USP monograph. Additionally, accelerated and long-term stability data in-line with the Pregabalin USP specification is also attached.
3.	Justify for not including the dissolution data of time point 4hr and 9hr in the CDP report since the innovator literature recommends to include these time points in the dissolution analysis of drug product.	Firm replied that "In response to the query for not including the 4-hour and 9-hour time points in the Comparative Dissolution Profile (CDP) for Pregabalin CR 82.5mg (Test Product) compared to Pregabalin extended release Tablet 82.5 mg (Reference Product) respectively, we would like to clarify the following: The dissolution profile was conducted in accordance with WHO TRS 1003 (2017), Appendix 1: "Recommendations for Conducting and Assessing Comparative Dissolution Profiles." The time points selected for the dissolution profile were at 1, 2, 3, 5, 8, 12, 16, and 24 hours. These time points were chosen based on the guidance provided by the WHO, and as such, the 4-hour and 9-hour time points were not included in the original study. Both the test and reference products were subjected to dissolution testing under identical conditions in three different media, and the drug release profiles were found to be similar and acceptable. The F2 similarity factor for all three media was calculated to be greater than 50, indicating comparable dissolution behavior. However, we have theoretically calculated the drug release at the 4-hour and 9-hour time points using a non-linear polynomial regression model (second order). The predicted release values were determined" However, the reference WHO guidelines stated that "For extended-release FPPs the time-points should be set to cover the entire duration of expected release, e.g. in addition to earlier timepoints: samples at 1, 2, 3, 5 and 8 hours should be collected for a 12-hour release and additional test intervals would be necessary for longer duration of release". It is clear from the guidelines that it does not bound the manufacturer to perform the CDP on the stated sampling time rather it is an example quoted to explain the procedure.
4.	Provide reference used for adjusting the acceptance criteria of percentage moisture content of drug product.	Firm replied that Our product is manufactured using direct compression process, and we have developed an inhouse testing method. Based on the formulation, excipient quantities, loss on drying specifications, and their impact on the product, we initially established an acceptance criterion for the moisture content, which must not exceed 10.00%. However, in fact the stability results of moisture content obtained under different environmental conditions e.g., accelerated and real time which are less than 7% and no signs of degradation, discoloration, hardness changes or changes in the disintegration/dissolution profile so the limit of moisture content has been reduced to "Not more than 7%" that will be followed for all future batches testing and reporting.
5.	Innovator review literature recommends dissolution data at time point 9hrs also to ensure quality control from 55% to complete release, considering the recommendation of innovator you have not included the 9hr in the dissolution specification of applied drug product, so justification is required in this regard.	Firm replied In the initial submission, the dissolution time points of 1, 4, and 24 hours were selected based on the innovator's specification, as reflected in the literature. The 9-hour time point was not included, as it was not part of the specification submitted to the DRAP. However, after reviewing the additional literature and considering the regulatory recommendation, we have revised our dissolution specification to include the 9-hour time point, with a limit of not less than (NLT) 55%. We have also conducted testing on the current stability batches of the drug product, and the results have been provided for your review. This revision ensures alignment with both quality control expectations and innovator specifications.
6.	Provide scientific rational regarding the sudden downward trend observed after the zero month in the percentage moisture content of drug product, since in one of the trial batches its drop from 5.79% to 0.79% within one month.	Firm responds the requisite query.
7.	Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin, since the submitted GMP certificate is expired.	Submitted
8.	Documents for the procurement of API with approval from DRAP (in case of import).	Submitted

Decision: Approved

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
195	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. (**000105**) Tracking ID: (8PU-QAY-4SLJ, 2023-12-01) Fee Paid: 75000.0 Paid Date: 2023-11-17 Case Category: Routine **(Saima Hussain)**	Proposed Name: **Lasmit tablet 100mg** Each tablet contains Lasmiditan..100mg (Equivalent to 115.65mg Lasmiditan Hemisuccinate) As per Innovators Specification RRA Status: REYVOW 100mg (lasmiditan) tablets , Lily, USA Me Too Status: Not available Pack Size(s): 10's, 14's, 20's,28'-As per SRO
	Manufacturer(s): ---	
	Evaluation Remarks: 1. Please submit the complete drug substance part of above registration dossier, for evaluation and further consideration of your application. Firm submitted the drug substance part. 2. Please provide a scientifically-based justification for the rationale and percentage of active ingredient overage used in the formulation, supported by references to relevant international standards and guidelines. For above subject query, it is stated that label claim of Lasmit Tablet 50mg is Lasmiditan as Lasmiditan Hemisuccinate 50mg. Therefore, each tablet contains 57.824mg of Lasmiditan Hemisuccinate equivalent to 50mg of Lasmiditan, reference to this is present in reference product information. FDA literature attached. Hence no overage of active ingredient is used in the formulation. REYVOW 50 mg tablets contain 50 mg lasmiditan (equivalent to 57.824 mg lasmiditan hemisuccinate). Furthermore, 20% excess of only coating material is used to compensate for process loss during coating process. 3. Batch of active ingredient used in the manufacturing of trial batches of drug product was expired on 08th March, 2024 as per commercial invoice attached along the stability data than provide clarification how you have claimed the expiry of trial batches of drug product till 12-2024. For above subject query, it is stated that stability batches of Lasmit Tablet 50mg (630DS01, 630DS02 and 630DS03) were manufactured in December 2022, using API (Lasmiditan Hemisuccinate) with below detail: Manufacturing Date: March 9 2022 Expiration Date: March 8 2024 As per above data, stability batches of drug product were manufactured well before the expiration date of API (Lasmiditan Hemisuccinate). Furthermore, based on satisfactory stability data for a period of 6 months accelerated and real time in proposed container closure system (Alu-PVC Blister), a shelf life of two years is proposed	
	Decision: Approved	
196	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila (**000856**) Tracking ID: (EBW-WBS-24AV, 2023-12-01) Fee Paid: 30000.0 Paid Date: 2023-11-27 Case Category: Routine **(Saima Hussain)**	Proposed Name: **Micozon-V Cream** Each gram of Cream contains Miconazole Nitrate.... 20mg (2% w/w) (As per USP's Specs.) United States Pharmacopeia RRA Status: Registered drug by US FDA, (Miconazole Nitrate Vaginal Cream 2%), for Vaginal use. Me Too Status: Gyno-Daktarin Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: 3.2. P.5.1 Please submit the reference of acceptance criteria adopted for the test of pH and viscosity of drug product. Firm replied that, as per USP <3> Topical and transdermal drug products-product quality tests, the pH acceptance criteria are stated that; "When applicable, topically applied drug products should be tested for pH. Because some topically applied drug products contain very limited quantities of water or aqueous phase, pH measurements may not always be warranted. This test is generally formulation dependent. Therefore, it is not included in the compendial drug product monograph but is part of the manufacturer's specification for the drug product." The viscosity criteria are stated that; "Acceptance criteria are product specific and defined to ensure that the apparent viscosity of each batch of semisolid drug product is within the range defined by the product design and is consistent between batches based on the product development specifications and statistical assessment of multiple product batches over the product's shelf life." Moreover, our results are concordant to commercial marketed drug product as shown in pharma equivalence report and consistent in stability studies. 3.2. P.8.1 Provide a scientific rationale for manufacturing two trial batches, each with a batch size of 500 units, ensuring that the response complies with the CTD guidance document and international guidelines. Firm replied that,we have selected two batches as per minutes of 293rd meeting of registration board, Implementation of Common Technical Document, 3.2.P.8 Stability, Clause (a), Aerosol and any other specialized preparations 500.	
	Decision: Approved	
197	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. (**000105**) Tracking ID: (MH6-RU2-BLMZ, 2023-11-21) Fee Paid: 75000.0 Paid Date: 2023-11-17 Case Category: Routine **(Saima Hussain)**	Proposed Name: **Lasmit tablet 50mg** Each tablet contains Lasmiditan..50mg (Equivalent to 57.824mg Lasmiditan Hemisuccinate) As per Innovators Specification RRA Status: REYVOW (lasmiditan) tablets , Eli Lily, USA Me Too Status: Not available Pack Size(s): 10's, 14's, 20's,28'-Controlled
	Manufacturer(s): ---	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: 1. 1. Please submit the complete drug substance part of above registration dossier, for evaluation and further consideration of your application. 2. 3. Firm submitted the drug substance part. 4. 5. 2. Please provide a scientifically-based justification for the rationale and percentage of active ingredient overage used in the formulation, supported by references to relevant international standards and guidelines. For above subject query, it is stated that label claim of Lasmit Tablet 50mg is Lasmiditan as Lasmiditan Hemisuccinate 50mg. Therefore, each tablet contains 57.824mg of Lasmiditan Hemisuccinate equivalent to 50mg of Lasmiditan, reference to this is present in reference product information. FDA literature attached. Hence no overage of active ingredient is used in the formulation. REYVOW 50 mg tablets contain 50 mg lasmiditan (equivalent to 57.824 mg lasmiditan hemisuccinate). Furthermore, 20% excess of only coating material is used to compensate for process loss during coating process. 3. Batch of active ingredient used in the manufacturing of trial batches of drug product was expired on 08th March, 2024 as per commercial invoice attached along the stability data than provide clarification how you have claimed the expiry of trial batches of drug product till 12-2024. For above subject query, it is stated that stability batches of Lasmit Tablet 50mg (630DS01, 630DS02 and 630DS03) were manufactured in December 2022, using API (Lasmiditan Hemisuccinate) with below detail: Manufacturing Date: March 9 2022 Expiration Date: March 8 2024 As per above data, stability batches of drug product were manufactured well before the expiration date of API (Lasmiditan Hemisuccinate). Furthermore, based on satisfactory stability data for a period of 6 months accelerated and real time in proposed container closure system (Alu-PVC Blister), a shelf life of two years is proposed 1.	
	Decision: Approved	
198	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (8G3-4MS-E4AT, 2024-09-30) Fee Paid: 37000.0 Paid Date: 2024-09-25 Case Category: New License **(Shahid Nawaz)**	Proposed Name: **Belexa** Each film coated tablet contains: Escitalopram Oxalate Eq. to Escitalopram.....5mg United States Pharmacopeia RRA Status: Medicines and Healthcare Regulatory Agency (MHRA Me Too Status: ESPRAM 5mg by pharmatec Pack Size(s): 10's,20's,30's,50's,-As per SRO
	Evaluation Remarks: Your application is found deficient for the following; Proposed pack size shall be submitted. Valid copy of GMP certificate of the drug substance manufacturer shall be submitted. Specifications of the drug substance from drug product manufacturer shall be submitted. Analytical procedures for the drug substance from drug product manufacturers shall be submitted. Stability data has mentioned that drug substance stability data is at 25°C ± 2°C / 60% ± 5%RH while the stability data sheets has mentioned 30°C ± 2°C / 65% ± 5%RH. Clarification shall be submitted. Stability data sheets with inclusion of API lot number shall be submitted. API Loan approval letter from M/s Lisko pharma shall be submitted. Documents for the procurement of API (Clearance certificate) with approval from DRAP (in case of import) shall be submitted. Reply submitted by the firm: Firm has submitted 10’s,20’s,30’s,50’s and 100’s as proposed pack sizes. No GMP certificate is submitted by the firm for drug substance. Firm has submitted specifications of the drug substance. Firm has also submitted analytical procedures of the drug substance as requested. Firm has submitted revised and corrected data sheets from drug substance manufacturer. Firm has submitted API loan letter from M/s Lisko pharma mentioning borrowing of different API for development purpose. Firm has submitted copy of CLEARANCE CERTIFICATE No. E-10249494512617 dated 27-06-2024 mentioning 20 kg of Escitalopram with batch EO045/24 attested by Assistant Director, DRAP Karaci. However, batches manufactured are in November, 2023 while clearance certificate is of June 2024. Also the batch number mentioned in 3.2.S.4.4 is different from that mentioned in clearance certificate.	
	Decision: Deferred Deferred for clarification of the point that trial batches are manufactured in November, 2023 while clearance certificate is of June 2024. Also the batch number mentioned in 3.2.S.4.4 is different from that mentioned in clearance certificate.	
199	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (8ZY-1HR-9DBH, 2024-09-30) Fee Paid: 37000.0 Paid Date: 2024-09-19 Case Category: New License **(Shahid Nawaz)**	Proposed Name: **Belexa** Each film coated tablet contains: Escitalopram Oxalate Eq. to Escitalopram.....20mg United States Pharmacopeia RRA Status: Medicines and Healthcare Regulatory Agency (MHRA Me Too Status: ESPRAM 10mg by pharmatec Pack Size(s): 10's,20's,30's,50's,-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Your application is found deficient for the following; Proposed pack size shall be submitted. Valid copy of GMP certificate of the drug substance manufacturer shall be submitted. Specifications of the drug substance from drug product manufacturer shall be submitted. Analytical procedures for the drug substance from drug product manufacturers shall be submitted. Stability data has mentioned that drug substance stability data is at 25˚C ± 2˚C / 60% ± 5%RH while the stability data sheets has mentioned 30˚C ± 2˚C / 65% ± 5%RH. Clarification shall be submitted. Stability data sheets with inclusion of API lot number shall be submitted. API Loan approval letter from M/s Lisko pharma shall be submitted. Documents for the procurement of API (Clearance certificate) with approval from DRAP (in case of import) shall be submitted. Reply submitted by the firm: Firm has submitted 10's,20's,30's,50's and 100's as proposed pack sizes. No GMP certificate is submitted by the firm for drug substance. Firm has submitted specifications of the drug substance. Firm has also submitted analytical procedures of the drug substance as requested. Firm has submitted revised and corrected data sheets from drug substance manufacturer. Firm has submitted API loan letter from M/s Lisko pharma mentioning borrowing of different API for development purpose. Firm has submitted copy of CLEARANCE CERTIFICATE No. E-10249494512617 dated 27-06-2024 mentioning 20 kg of Escitalopram with batch EO045/24 attested by Assistant Director, DRAP Karaci. However, batches manufactured are in November, 2023 while clearance certificate is of June 2024. Also the batch number mentioned in 3.2.S.4.4 is different from that mentioned in clearance certificate.	
	Decision: Deferred Deferred for clarification of the point that trial batches are manufactured in November, 2023 while clearance certificate is of June 2024. Also the batch number mentioned in 3.2.S.4.4 is different from that mentioned in clearance certificate.	
200	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (D31-15B-QRW9, 2024-11-05) Fee Paid: 30000.0 Paid Date: 2024-08-09 Case Category: New License **(Shahid Nawaz)**	Proposed Name: **Candirid** Each Capsule contains: Fluconazole BP.....150mg British Pharmacopeia RRA Status: Product Name: Fluconazole Capsule 150mg Manufacturer: Ranbaxy (UK) Limited 5th floor, Hyde Park, Hayes 3 11 Millington Road Hayes, UB3 4AZ United Kingdom Reference Regulatory Authority: MHRA Approved drug. Me Too Status: Brand Name: Flucaton Capsule Strength: 150mg Dosage Form: Oral Capsules Pack Size: 1's Regn No. 086580 Manufacturer: Newton Health Care Pvt. Ltd. Pack Size(s): 1x1's-As per SRO
	Evaluation Remarks: Your application is found deficient for the following; • Documents for the procurement of API with approval from DRAP (in case of import) shall be submitted. Reply submitted by the firm: Firm has submitted copy of Form-5 No. K-564888447496 dated 09-06-2022 issued to m/s Orta Laboratories (Pvt.) Limited. However, clearance certificate is not submitted.	
	Decision: Deferred Deferred for submission of clearance certificate for the import of API with approval from DRAP.	
201	**Bio-Labs(Pvt) Ltd** Plot 145, Industrial Triangle, Kahuta Road (**000296**) Tracking ID: (H53-9ER-E4WN, 2023-12-15) Fee Paid: 30000.0 Paid Date: 2023-11-22 Case Category: Routine **(Shahid Nawaz)**	Proposed Name: **Jacxel 5mg** Each film-coated tablet contains: Tofacitinib as citrate 5mg As per Innovators Specification RRA Status: USFDA, Approved. Me Too Status: Tofajek Tablets 5mg by Hiranis Pharma (110057) Pack Size(s): 10s, 20s, 30s-As per SRO
	Evaluation Remarks: Dear applicant your application was evaluated and found deficient for the following; 3.2.S.4.1. Justification shall be submitted for not including citric acid content and chloride content in the specifications of the drug substance as provided by the drug substance manufacturer. 3.2.S.4.2. Gradient method and concentration of sample solution and standard solution are different from drug substance manufacturer. Clarification shall be submitted. 3.2.S.4.4. Justification shall be submitted for not performing Chloride content and Isomer test on drug substance. 3.2.P.1 Qualitative composition of the applied formulation is different from that of the innovator product. Clarification shall be submitted. 3.2.P.8. Complete six-month time stability data along with raw data sheets shall be submitted Value of uniformity of dosage unit test shall be submitted instead of only writing complies.	
	Decision: Deferred Deferred for submission of reply to the above cited shortcoming.	
202	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (MJ7-YH6-XXAT, 2024-08-27) Fee Paid: 30000.0 Paid Date: 2024-08-09 Case Category: New License **(Shahid Nawaz)**	Proposed Name: **Orteso Capsules 20mg** Each Capsule contains: Enteric Coated Pellets of Esomeprazole Magnesium Trihydrate Eq: to Esomeprazole .....20mg United States Pharmacopeia RRA Status: Product Name: Esomeprazole Magnesium Manufacturer: Aurobindo Pharma Reference Regulatory Authority: US FDA Approved drug. Me Too Status: Brand Name: Newzole Capsule Strength: 20mg Dosage Form: Oral Capsules Pack Size: 14's Regn No. 086575 Manufacturer: Newton Health Care Pvt. Ltd. Pack Size(s): 2x7's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Observation communicated: Specifications for the drug substance has mentioned USP specification while monograph is not available in USP. Clarification shall be submitted. Analytical procedures for the drug substance from drug product manufacturers shall be submitted. CDP studies with the comparator product shall be submitted. Stability data sheets with inclusion of API lot number shall be submitted. No differentiation between the 20mg and 40mg capsule in the body of capsules and batches manufactured. Clarification shall be submitted. **Response Submitted by the Firm:** **1. It is a typographical error made by us, actually Esomeprazole EC Pellets are not included in USP monograph. Esomeprazole EC Pellets are manufacturer Specification. Esomeprazole EC Pellets are Semi finished product and ready to fill pellets. While finished product monograph available in USP.** **2. Firm has submitted analytical procedure of the drug substance.** **3. Firm has submitted CDP studies against Newzole 20mg capsule, B. No. 228F, Mfg. date of 12-2023 manufactured by m/s newton Healthcare.** **04. Firm has submitted API lot number of the drug substance only.** **05. firm has submitted that Esomeprazole EC Pellets are ready to fill pellets filled through automatic capsule filling machine, so both capsules 20mg and 40mg filled easily. While the content weight of 20mg and 40mg different.**	
	Decision: Approved	
203	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (QNT-ENB-VL36, 2024-09-30) Fee Paid: 37000.0 Paid Date: 2024-09-19 Case Category: New License **(Shahid Nawaz)**	Proposed Name: **Belexa** Each film coated tablet contains:Escitalopram Oxalate Eq. to Escitalopram.....10mg United States Pharmacopeia RRA Status: Medicines and Healthcare Regulatory Agency (MHRA Me Too Status: ESPRAM 10mg by pharmatec Pack Size(s): 10's,20's,30's,50's,-As per SRO
	Evaluation Remarks: Your application is found deficient for the following; Proposed pack size shall be submitted. Valid copy of GMP certificate of the drug substance manufacturer shall be submitted. Specifications of the drug substance from drug product manufacturer shall be submitted. Analytical procedures for the drug substance from drug product manufacturers shall be submitted. Stability data has mentioned that drug substance stability data is at 25°C ± 2°C / 60% ± 5%RH while the stability data sheets has mentioned 30°C ± 2°C / 65% ± 5%RH. Clarification shall be submitted. Stability data sheets with inclusion of API lot number shall be submitted. API Loan approval letter from M/s Lisko pharma shall be submitted. Documents for the procurement of API (Clearance certificate) with approval from DRAP (in case of import) shall be submitted. Reply submitted by the firm: Firm has submitted 10's,20's,30's,50's and 100's as proposed pack sizes. No GMP certificate is submitted by the firm for drug substance. Firm has submitted specifications of the drug substance. Firm has also submitted analytical procedures of the drug substance as requested. Firm has submitted revised and corrected data sheets from drug substance manufacturer. Firm has submitted API loan letter from M/s Lisko pharma mentioning borrowing of different API for development purpose. Firm has submitted copy of CLEARANCE CERTIFICATE No. E-10249494512617 dated 27-06-2024 mentioning 20 kg of Escitalopram with batch EO045/24 attested by Assistant Director, DRAP Karaci. However, batches manufactured are in November, 2023 while clearance certificate is of June 2024. Also the batch number mentioned in 3.2.S.4.4 is different from that mentioned in clearance certificate.	
	Decision: Deferred Deferred for clarification of the point that trial batches are manufactured in November, 2023 while clearance certificate is of June 2024. Also the batch number mentioned in 3.2.S.4.4 is different from that mentioned in clearance certificate.	
204	**Nahal Pharmaceuticals (Pvt) Ltd.** Plot No. 2, Street No. SS-4, RCCI, Industrial Estate Rawat (**000989**) Tracking ID: (RPB-YEB-HQ51, 2024-11-12) Fee Paid: 37000.0 Paid Date: 2024-11-07 Case Category: New License **(Shahid Nawaz)**	Proposed Name: **Cefoxim 40mg/5ml dry susp** each 5ml reconstituted suspension contains Cefpodoxime as Proxetil --- 40mg United States Pharmacopeia RRA Status: Vatin 40mg/5ml FDA Approved Me Too Status: Prelox 40mg/5ml Pack Size(s): 1x1 s-As per SRO
	Evaluation Remarks: 1.5.4: Proposed pack size shall be submitted. (Proposed pack size shall be 1's x 1.) 1.6.5: Valid copy of GMP certificate of the drug substance manufacturer shall be submitted. (Not submitted, instead they submitted Applicant DML.) 3.2.S.4.1: Specifications of the drug substance from Drug product manufacturer shall be submitted. (Submitted.) 3.2.S.4.2: Analytical procedures of the drug substance from Drug product manufacturer shall be submitted. (Submitted.) 3.2.S.4.3: Analytical method verification studies of the drug substance performed by the Drug product manufacturer shall be submitted. (Submitted.) 3.2.P.2.2: Details of the comparator product i.e. Batch number, Exp. date shall be submitted. Product Name: PRELOX 40MG/5ML Suspension, Batch No. R240450 Mfg. Date: 01/2024 Exp. Date: 12/2025 RN.027156 Marketing Authorization Holder: Bosch Pharmaceuticals(Pvt.) Ltd.,	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
205	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. (**000105**) Tracking ID: (S2R-8RU-5H3M, 2023-12-05) Fee Paid: 30000.0 Paid Date: 2023-11-24 Case Category: Routine **(Shahid Nawaz)**	Proposed Name: **Xelnib 5mg** Each film coated tablet contains;Tofacitinib.....5mg (Equivalent to 8.03mg Tofacitinib citrate)(Innovators Specs.) As per Innovators Specification RRA Status: Xeljanz tablet 5mg USFDA Approved Me Too Status: Tofajak Tablets by Hiranis pharma Pack Size(s): 10's, 20's & 30's-As per SRO
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks: 3.2.S.7.3. Complete real time stability data of the drug substance till claimed shelf life shall be submitted. 3.2.P.8Justification shall be submitted for not performing uniformity of dosage unit test as recommended by the innovator product.	
	Decision: Approved	
206	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (VBZ-JNB-Q396, 2024-08-27) Fee Paid: 30000.0 Paid Date: 2024-08-09 Case Category: New License **(Shahid Nawaz)**	Proposed Name: **Orteso Capsules 40mg** Each Capsule contains: Enteric Coated Pellets of Esomeprazole Magnesium Trihydrate Eq: to Esomeprazole .....40m United States Pharmacopeia RRA Status: Product Name: Esomeprazole Magnesium Manufacturer: Aurobindo Pharma Reference Regulatory Authority: US FDA Approved drug. Me Too Status: Brand Name: Newzole Capsule Strength: 40mg Dosage Form: Oral Capsules Pack Size: 14’s Regn No. 086574 Manufacturer: Newton Health Care Pvt. Ltd. Pack Size(s): 2x7's-As per SRO
	Evaluation Remarks: Your application is found deficient for the following; 01. Specifications for the drug substance has mentioned USP specification while monograph is not available in USP. Clarification shall be submitted. 02. Analytical procedures for the drug substance from drug product manufacturers shall be submitted. 03. CDP studies with the comparator product shall be submitted. 04. Stability data sheets with inclusion of API lot number shall be submitted. 05. No differentiation between the 20mg and 40mg capsule in the body of capsules and batches manufactured. Clarification shall be submitted. Reply Submitted by the Firm: 1. It is a typographical error made by us, actually Esomeprazole EC Pellets are not included in USP monograph. Esomeprazole EC Pellets are manufacturer Specification. Esomeprazole EC Pellets are Semi finished product and ready to fill pellets. While finished product monograph available in USP. 2. Firm has submitted analytical procedure of the drug substance. 3. Firm has submitted CDP studies against Newzole 40mg capsule, B. No. 002F, Mfg. date of 01-2023 manufactured by m/s newton Healthcare. 04. Firm has submitted API lot number of drug substance only. 05. Esomeprazole EC Pellets are ready to fill pellets filled through automatic capsule filling machine, so both capsules 20mg and 40mg filled easily. While the content weight of 20mg and 40mg different.	
	Decision: Approved	
207	**Nahal Pharmaceuticals (Pvt) Ltd.** Plot No. 2, Street No. SS-4, RCCI, Industrial Estate Rawat (**000989**) Tracking ID: (49A-N4M-X4SY, 2024-09-18) Fee Paid: 30000.0 Paid Date: 2024-08-06 Case Category: New License **(Shahrukh Ali)**	Proposed Name: **NEFXON 1 G IV INJECTION** Each Vial contains: Ceftriaxone (as Sodium)....1 g United States Pharmacopeia RRA Status: ROCEFIN , USA,CEFTRIAXONE 1G IV US-FDA APPROVED Me Too Status: Oxidil {Sami Pharmaceuticals} Pack Size(s): 1's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: 1.5.2 label claim not provided" "Each vial contains Ceftriaxone as sodium equivalent to 1 g Ceftriaxone" 3.2.S.4.4. Drug product manufacturer has not performed complete testing of drug substance as per USP monograph. Tests for crystallinity sterility and bacterial endotoxin test have not been performed. Justify According to CoA of drug substance by drug substance manufacturer, the limits for assay are NLT 84% whereas the limit in the USP monograph is NLT 795mcg/mg of Ceftriaxone on anhydrous basis. Justify. · Firm has submitted revised COA with required information 3.2.P.2.1 In Pharmaceutical equivalence of the applied drug with the innovator / reference results of all the quality tests of the developed formulation and the innovator / reference product shall be submitted. In the data provided no quantification of any result of reference product is done including assay, all results are reported as "complies". Particulate matter, crystallinity and water determination tests are not performed. No particulars of reference product batch number, Mfg date and Exp date pictorial evidence was provided. Justify. · · Firm has provided revised pharmaceutical equivalence studies with tests as per pharmacopoeia however reference product details are not provided. 3.2.P.2.6 Compatibility studies with the diluent of reconstitution shall be submitted. Firm has claimed that it is a single use vial 3.2.P.5.4 COA of finish product quantification of results excluding assay are not done, Particulate matter, crystallinity and water determination tests are not performed. Firm has submitted revised COA with required information 3.2.P.5.6 COA for working standard lacks important pharmacopoeia test i.e. Particulate matter, crystallinity and water determination. Specification's set are not as per pharmacopoeia. · Firm has requested the vendor to provide revised COA 3.2.P.8 Justify why the test for bacterial endotoxin, sterility, water contents, constituted solution, pH etc is not performed during stability studies since these tests are very critical and are required to make assessment of the stability profile and shelf life. Bacterial endotoxin& sterility test are marked as not applicable justify. Firm has provided revised data sheet summary with inclusion of these tests Documents for the procurement of API with approval from DRAP (in case of import). Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. Firm has submitted valid copy of DML of the Drug substance manufacturer.	
	Decision: Approved	
208	**Nahal Pharmaceuticals (Pvt) Ltd.** Plot No. 2, Street No. SS-4, RCCI, Industrial Estate Rawat (**000989**) Tracking ID: (7AA-X7P-LBUY, 2024-08-26) Fee Paid: 30000.0 Paid Date: 2024-08-06 Case Category: New License **(Shahrukh Ali)**	Proposed Name: **Nelcef 500 mg Capsule** Each Capsule Contains: 500 mg Cephradine USP United States Pharmacopeia RRA Status: Velosef 500 mg Capsule Me Too Status: ATCOSEF {Atco Laboratories} Pack Size(s): 12's-As per SRO
	Evaluation Remarks: 3.2.S.4.4 COA of drug substance by drug product manufacturer not provided. Firm has Submitted COA of drug substance. 3.2.P.2.2.1 Pharmaceutical equivalence and CDP studies not provided. Firm has now Submitted Pharmaceutical equivalence and CDP studies. 3.2.P.5 Batch analysis COA doesn't B.P Pharmacopoeia specs. Firm has adopted USP Specs 3.2.P.5.4 Firm has mentioned Nahal specs however pharmacopoeia monograph is available and in module 1 firm has adopted BP specs for finish products. LOD, cephalexin and Dihydrocefradine contents not identified Firm has now revised specification's as per USP. 3.2.P.5.6 COA of working standard is not as per pharmacopoeia specs, Cephalexin contents not found, optical rotation is out of specs, water contents are out of specs, dihydro-cephradine contents not found. Specification adopted are not as per pharmacopoeia. Assay limits are not as per pharmacopeial specs. Firm has submitted revised working standard COA with correct information 3.2.P.8 Stability data sheets with inclusion of API lot number as per decision of registration Board in its 293 shall be submitted, calculations of assay as per raw data sheets (CP)(L/1000D)(ru/rs) are not justified, as per data provided assay calculations are quite low instead of 100% as mentioned. Injection volume is not as per Pharmacopoeia specs 10ul used instead of 5ul. correction factor of 1.6 of dihydrocefradine not applied. Firm claimed that they have adopted USP specs.	
	Decision: Approved	
209	**Nahal Pharmaceuticals (Pvt) Ltd.** Plot No. 2, Street No. SS-4, RCCI, Industrial Estate Rawat (**000989**) Tracking ID: (A2U-7UD-JUX1, 2024-08-27) Fee Paid: 30000.0 Paid Date: 2024-08-06 Case Category: New License **(Shahrukh Ali)**	Proposed Name: **Nelcef 250 mg Capsule** Each Capsule Contains: 250 mg Cephradine United States Pharmacopeia RRA Status: CefraCare 250 Capsule(AdvaCare Pharma USA) Me Too Status: Atcosef(Atco Laboratories) Karachi Pack Size(s): 12's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: 1.5.6 Firm has adopted USP specs for oral suspension however B.P specs are available for Cefradine capsules. Firm claimed that specification for oral suspension were mistakenly submitted and now they submitted specification for capsule as per USP. 3.2.S.4.4 COA of drug substance by drug product manufacturer not provided. Firm has Submitted COA of drug substance. 3.2.P.2.2.1 Pharmaceutical equivalence and CDP studies not provided. Firm has now Submitted Pharmaceutical equivalence and CDP studies. 3.2.P.5 Batch analysis COA provided for 500mg capsules and doesn't follow Pharmacopoeia specs. Firm has now submitted COA for 250mg Capsules. 3.2.P.5.4 Firm has mentioned Nahal specs however pharmacopoeia monograph is available and in module 1 firm has adopted USP specs for finish products which are not available. LOD, cephalexin and Dihydrocefradine contents not identified. Firm has now revised spesifications as per USP. 3.2.P.5.6 COA of working standard is not as per pharmacopoeia specs, Cephalexin contents not found, optical rotation is out of specs, water contents are out of specs, dihydro-cephradine contents not found. Specification adopted are not as per pharmacopoeia. Assay limits are not as per pharmacopeial specs. Firm has submitted revised working standard COA with correct information 3.2.P.8 Stability data sheets of 500mg capsules attached without inclusion of API lot number as per decision of registration Board in its 293 shall be submitted. Submitted revised stability data sheets with inclusion of API lot number (00204/072/2023).	
	Decision: Approved	
210	**Genix pharma** Survey No. 186,188,189,204,210,224, 225,294,296,297,119,193 &390 situated in Deh Sharabi, Tapo Landhi, Taluka Ibrahim Hyderi, District Malir Karachi (**000351**) Tracking ID: (N85-PRU-RSUV, 2023-11-22) Fee Paid: 75000.0 Paid Date: 2023-11-17 Case Category: Routine **(Shahrukh Ali)**	Proposed Name: **Depsit** Each film coated tablet contains: Escitalopram oxalate, equivalent to Escitalopram .....15 mg United States Pharmacopeia RRA Status: Cinfa Laboratories, Spain Me Too Status: Not Applicable Pack Size(s): 7s, 10s, 14s, 20s, 2-As per SRO
	Manufacturer(s): ---	
	Evaluation Remarks:	
	Decision: Approved	
211	**Pacific Pharmaceuticals Ltd.** Plot No.384, Sundar Industrial Estate, Raiwind Road, Lahore (**000902**) Tracking ID: (B7L-5AD-2AEU, 2023-12-12) Fee Paid: 30000.0 Paid Date: 2023-11-22 Case Category: New License **(Shahrukh Ali)**	Proposed Name: **Amikacin Sulphate 500 mg/2 ml Injection** Each 2 ml Contains: Amikacin Sulphate ..... 500 mg British Pharmacopeia RRA Status: Amikacin Sulphate 500 mg / 2 ml - Hospira UK Limited Me Too Status: Zomacin Injection Pack Size(s): 2 ml Ampoule-As per SRO
	Evaluation Remarks: 1.3.4: Valid copy of DML certificate of the drug product manufacturer shall be submitted. Firm has submitted receiving of e-application for license renewal • 3.2.P.2.1 Submit the image/picture/snapshot of innovator /reference/comparator pack against which pharmaceutical equivalence have been performed and shall reveal the details of brand name, manufacturer, batch# and expiry date of the innovator /reference/comparator product Pacific's Response: Pharmaceutical Equivalence was performed against reference pack of Amikacin Injection by Hospira Pharma UK but we hadn't any snapshots and retained sample of it now. Details are provided below; Reference Product: Amikacin Injection 500 mg / 2 ml Batch No.: 09A022 Mfg. Date: 02-2022 Exp. Date: 01-2024 Pack Size: 5 x 2 ml Ampoules Shelf Life: 2 Years Innovator Address: Hospira UK Limited, Horizon Honey Lane Hurley Maidenhead SL6 6RJ, UK	
	Decision: Approved	
212	**Genix pharma** Survey No. 186,188,189,204,210,224, 225,294,296,297,119,193 &390 situated in Deh Sharabi, Tapo Landhi, Taluka Ibrahim Hyderi, District Malir Karachi (**000351**) Tracking ID: (U4L-YVX-YWPS, 2023-11-22) Fee Paid: 75000.0 Paid Date: 2023-11-10 Case Category: Routine **(Shahrukh Ali)**	Proposed Name: **Depsit** Each ml of the solution contains: 20 mg escitalopram ..... as 25.56 mg escitalopram oxalate (Each drop contains 1 mg of escitalopram) Manufacturer Specification RRA Status: Escitalopram Kern Pharma, SL Oral Drops 20mg/ml Me Too Status: Not Applicable Pack Size(s): 15ml, 30ml, 60ml-As per SRO
	Manufacturer(s): ---	
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
213	**Nahal Pharmaceuticals (Pvt) Ltd.** Plot No. 2, Street No. SS-4, RCCI, Industrial Estate Rawat (**000989**) Tracking ID: (DY7-6P6-LYAM, 2024-08-20) Fee Paid: 30000.0 Paid Date: 2024-08-06 Case Category: New License **(Shahrukh Ali)**	Proposed Name: **Nelcef 250 mg Dry Suspensionension** Each 5 ml of reconstituted Suspension Contains 250 mg Cephradine (as monohyrate) United States Pharmacopeia RRA Status: ASNPOR {US-FDA} Me Too Status: ATCOSEF {Atco Laboratories} Pack Size(s): 60 ml Suspension in -As per SRO
	Evaluation Remarks: .5.8. Strength is shown as 250mg/ml however in composition it is 125mg/ml. Pack size is mentioned as 1's. Firm was asked about me-too product for the applied formulation wherein they submitted wrong me-too. Now firm has submitted corrected me-too that is velosef 250mg/5ml. 3.2.S.4.4 COA of drug substance by drug product manufacturer not provided. Firm has Submitted COA of drug substance. 3.2.P.5 Batch analysis COA doesn't show water contents as per USP Pharmacopoeia Firm has submitted revised COA wherein water content test is as per USP Pharmacopoeia 3.2.P.5.4 Firm has mentioned Nahal specs however pharmacopoeia monograph is available and in module 1 firm has adopted USP specs. Firm has now revised specification's as per USP. 3.2.P.5.6 COA of working standard is not as per pharmacopoeia specs , Cephalexin contents not found, optical rotation is out of specs, water contents are out of specs, dihydro-cephradine contents not found. Specification adopted are not as per pharmacopoeia. Firm has submitted revised working standard COA with correct information 3.2.P.8 Stability data sheets with inclusion of API lot number as per decision of registration Board in its 293 shall be submitted, calculations of assay as per raw data sheets (CP)(L/1000D)(ru/rs) are not justified, as per data provided assay calculations are 25% instead of 100% as mentioned. Firm has submitted revised calculations however rough calculations are not shared and result of assay is mentioned.	
	Decision: Approved Registration letter will be issued after Submission of 9000/- fee for pre-registration variations as per notification No. S.R.O. 1324(I)/2024 dated 30-08-2024.	
214	**Nahal Pharmaceuticals (Pvt) Ltd.** Plot No. 2, Street No. SS-4, RCCI, Industrial Estate Rawat (**000989**) Tracking ID: (PYA-8Y2-TNGV, 2024-09-18) Fee Paid: 30000.0 Paid Date: 2024-08-06 Case Category: New License **(Shahrukh Ali)**	Proposed Name: **NEFXON 250 MG IM INJECTION** Each Vial contains: Ceftriaxone (as sodium)...250mg United States Pharmacopeia RRA Status: ROCEFIN , USA,CEFTRIAXONE 1G IV US-FDA APPROVED Me Too Status: Oxidil {Sami Pharmaceuticals} Pack Size(s): 1's-As per SRO
	Evaluation Remarks: 1.5.2 Justify the label claim Each Vial contains: Ceftriaxone as Sodium.....250 mg in comparison to reference product claim provided "Each vial contains 298.25mg Ceftriaxone sodium equivalent to 250mg Ceftriaxone" Firm has revised label claim to "Each vial contains 298.25mg Ceftriaxone sodium equivalent to 250mg Ceftriaxone" 3.2.S.4.4. Drug product manufacturer has not performed complete testing of drug substance as per USP monograph. Tests for crystallinity sterility and bacterial endotoxin test have not been performed. Justify According to CoA of drug substance by drug substance manufacturer, the limits for assay are NLT 84% whereas the limit in the USP monograph is NLT 795mcg/mg of Ceftriaxone on anhydrous basis. Justify. Firm has submitted revised COA with inclusion of these tests _3.2.P.2.1 In Pharmaceutical equivalence of the applied drug with the innovator / reference results of all the quality tests of the developed formulation and the innovator / reference product shall be submitted. In the data provided no quantification of any result of reference product is done including assay, all results are reported as "complies". Particulate matter, crystallinity and water determination tests are not performed. No particulars of reference product batch number, Mfg date and Exp date pictorial evidence was provided. Justify. Firm has provided revised pharmaceutical equivalence studies with oxidil Inj by M/s Sami pharmaceutical results are quantified. 3.2.P.2.6 Compatibility studies with the diluent of reconstitution shall be submitted. Firm has claimed that drug is a single use product 3.2.P.5.4 COA of finish product quantification of results excluding assay are not done, Particulate matter, crystallinity and water determination tests are not performed. Firm has submitted revised COA with inclusion of these tests 3.2.P.5.6 COA for working standard lacks important pharmacopoeia test i.e. Particulate matter, crystallinity and water determination. Specification's set are not as per pharmacopoeia. Firm has requested drug substance manufacturer to provide revised COA 3.2.P.8 Justify why the test for bacterial endotoxin, sterility, water contents, constituted solution, pH etc is not performed during stability studies since these tests are very critical and are required to make assessment of the stability profile and shelf life Firm replied that the mentioned test were performed during stability studies but no included in the stability data sheets. Now they submitted revised stability data sheets with inclusion of the above mentioned tests. Documents for the procurement of API with approval from DRAP (in case of import). Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. Firm has provided loan agreement from Nicholas pharmaceutical, Firm has submitted valid copy of Drug manufacturing license of the drug substance manufacturer.	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
215	**Nahal Pharmaceuticals (Pvt) Ltd.** Plot No. 2, Street No. SS-4, RCCI, Industrial Estate Rawat (**000989**) Tracking ID: (TV5-JYB-6MYU, 2024-09-18) Fee Paid: 30000.0 Paid Date: 2024-08-06 Case Category: New License **(Shahrukh Ali)**	Proposed Name: **Nelcef 125 mg Dry Suspension** Each 5 ml of Suspension Contains Cephradine 125 mg (as monohydrate) United States Pharmacopeia RRA Status: ANSPOR 125 MG DRY SUSP. {US-FDA} Me Too Status: BIODINE {BIO LABS} Pack Size(s): 60 ml Suspension in -As per SRO
	Evaluation Remarks: RRA not available 3.2.s.4.4 COA of drug substance by drug product manufacturer, Cephalexin contents not found, optical rotation is out of specs, water contents are out of specs, dihydro-cephradine contents not found. Specification adopted are not as per pharmacopoeia. Firm has submitted revised COA with required information 3.2.P.5 COA doesn't show water contents as per USP Pharmacopoeia Firm has submitted revised COA wherein water content test is as per USP Pharmacopoeia 3.2.P.8 Stability data sheets with inclusion of API lot number as per decision of registration Board in its 293 shall be submitted, calculations of assay as per raw data sheets (CP)(L/1000D) (ru/rs) are not justified, as per data provided assay calculations are 25% instead of 100% as mentioned. Firm has submitted revised calculations however rough calculations are not shared and result of assay is mentioned	
	Decision: Deferred Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
216	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. (**000105**) Tracking ID: (X6G-3UW-L6SU, 2023-12-15) Fee Paid: 30000.0 Paid Date: 2023-11-17 Case Category: Routine **(Shahrukh Ali)**	Proposed Name: **Glytec-M 50mg/850mg Tablet** British Pharmacopeia RRA Status: Janumet 50mg/850mg Tablet {Sitagliptin 50mg (as phosphate monohydrate) and metformin hydrochloride} Me Too Status: Yes (SITA-Met 50/850 Tablet) Pack Size(s): 7’s, 10’s, 14’s, 20’-As per SRO
	Manufacturer(s): ---	
	Evaluation Remarks: 1.6.5: Valid copy of GMP certificate of the drug substance manufacturer (Metformin) issued by concerned/relevant regulatory authority shall be submitted. Firm has submitted GMP certificate valid till 20/06/2026. S.4.4) Analytical specifications of raw material for Sitagliptin phosphate API were in compliance to USP however analytical procedure adopted for Assay are contrary to them in S4.4 in raw material calculation sheet justification is required. Firm has claimed that deviation in analytical testing method of Sitagliptin Phosphate from USP as evaluated by your side. Same GRN was retested as per USP when re-test due on 09-01-2024 and results were with in specified limit. Retest COA, chromatograms and assay calculation sheets are enclosed.	
	Decision: Approved	
217	**Nahal Pharmaceuticals (Pvt) Ltd.** Plot No. 2, Street No. SS-4, RCCI, Industrial Estate Rawat (**000989**) Tracking ID: (ZTY-RSR-NBWY, 2024-09-30) Fee Paid: 30000.0 Paid Date: 2024-08-06 Case Category: New License **(Shahrukh Ali)**	Proposed Name: **NEFXON 500 MG IM INJECTION** Each vial contains: Ceftriaxone (as sodium)..... 500 mg United States Pharmacopeia RRA Status: ROCEFIN , USA,CEFTRIAXONE 1G IV US-FDA APPROVED Me Too Status: Oxidil {Sami Pharmaceuticals} Pack Size(s): 1's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Please update module 3 as one file including COA of drug substance. 1.5.2 label claim not provided" o **Ceftriaxone (as sodium) ……. 500 mg** 3.2.S.4.4. Drug product manufacturer has not performed complete testing of drug substance as per USP monograph. Tests for crystallinity sterility and bacterial endotoxin test have not been performed. Justify According to CoA of drug substance by drug substance manufacturer, the limits for assay are NLT 84% whereas the limit in the USP monograph is NLT 795mcg/mg of Ceftriaxone on anhydrous basis. Justify. Firm has submitted revised COA with inclusion of these tests 3.2.P.2.1 In Pharmaceutical equivalence of the applied drug with the innovator / reference results of all the quality tests of the developed formulation and the innovator / reference product shall be submitted. In the data provided no quantification of any result of reference product is done including assay, all results are reported as "complies". Particulate matter, crystallinity and water determination tests are not performed. No particulars of reference product batch number, Mfg date and Exp date pictorial evidence was provided. Justify. Firm has provided revised pharmaceutical equivalence studies with oxidil Inj by M/s Sami pharmaceutical results are quantified. 3.2.P.2.6 Compatibility studies with the diluent of reconstitution shall be submitted. Firm has claimed that it is a single use formulation 3.2.P.5.4 COA of finish product quantification of results excluding assay are not done, Particulate matter, crystallinity and water determination tests are not performed. Firm has submitted revised COA with inclusion of these test 3.2.P.5.6 COA for working standard lacks important pharmacopoeia test i.e. Particulate matter, crystallinity and water determination. Specification's set are not as per pharmacopoeia. Firm has requested vendor for revised test. 3.2.P.8 Justify why the test for bacterial endotoxin, sterility, water contents, constituted solution, pH etc is not performed during stability studies since these tests are very critical and are required to make assessment of the stability profile and shelf life. Bacterial endotoxin& sterility test are marked as not applicable justify. Firm replied that the mentioned test were performed during stability studies but no included in the stability data sheets. Now they submitted revised stability data sheets with inclusion of the above mentioned tests. Documents for the procurement of API with approval from DRAP (in case of import). Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. Firm has provided loan agreement from Nicholas pharmaceutical Firm has submitted valid copy of Drug manufacturing license of the drug substance manufacturer.
	Decision: Approved	
218	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (13E-G9D-GMXX, 2024-09-18) Fee Paid: 37000.0 Paid Date: 2024-09-09 Case Category: New License **(Tahir Waqas)**	Proposed Name: **Ramargon** Each film coated tablet contains: Mirtazapine ... 45mg United States Pharmacopeia RRA Status: REMERON 45mg Tablet, USFDA. **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons** Me Too Status: Mitaz 45mg Tablets of M/s Glitz Pharma. Pack Size(s): 20's,30's-As per SRO
	Evaluation Remarks: Following shortcomings were communicated vide letter No. F. 2-1/2023-PEC (DD-PEC-XXI) dated 29th November 2024.	

Sr. No.	Observations	Response
01	Please provide evidence of DRAP (I&E) Clearance against submitted Form 5. Also submit evidence of issuance of Loan of API from Importer (i.e. M/s Lisko Pharma, Karachi).	Loan letter from Lisko Pharma has been submitted along with copy of DRAP (I&E) Clearance.
02	Please provide evidence of Reference / Innovator's pack used for Pharmaceutical Equivalence / CDP.	Submitted.
03	The submitted Chromatograms show both entries (i.e. 7.5mg & 45mg Tablets) in a single file. Please justify.	The firm have submitted that both product trial batches were performed simultaneously so its chromatograms and audit trails show in single file.
04	Furthermore, the submitted Audit Trail show entries as 15mg & 30mg Tablets only. Please justify.	The firm have submitted that it was an error and referred to revised audit trail submission (i.e. 7.5mg & 45mg Tablets) in a single file.

	Decision: Approved Registration Board further decided to proceed for onsite investigation to confirm genuineness / authenticity of stability data, related documents, import of API, quality, specification, test analysis, facilities etc., before issuance of registration letter.	
219	**Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. (**000105**) Tracking ID: (5MZ-Z87-TVXP, 2023-11-23) Fee Paid: 75000.0 Paid Date: 2023-09-08 Case Category: Routine **(Tahir Waqas)**	Proposed Name: **DERVIT Scalp Solution 0.005% (50mcg/ml)** Each ml of cutaneous solution contains: Calcipotriol Monohydrate eq. to. Calcipotriol ... 50 micrograms British Pharmacopeia RRA Status: Calcipotriol 50 micrograms/ml Scalp Solution, MHRA approved. Me Too Status: N/A Pack Size(s): 20ml, 30ml and 60ml-Controlled
	Manufacturer(s): ---	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Following shortcomings were communicated vide letter No. F. 2-1/2023-PEC (DD-PEC-XXI) dated 29th November 2024.	

Sr. No.	Observations	Response
1	Please provide valid GMP Certificate of API Manufacturer. The enclosed copy of letter is a written commitment for export and not a GMP Certificate	Firm have referred to copy of License of API Manufacturer, No. Yu20150075, Classification code: BhDh, valid till August 2025.
2	Please specify the name of section in which the applied product is intended for manufacturing.	The firm have submitted that the product will be manufactured in Topical solution section. The firm have further stated that that they have a separate section for manufacturing of topical solution and the Ear drop / Topical Solution as mentioned in the attached letter is a typographical mistake, they have raised the matter with Licensing department, and it will be amended in the next issuance of DML renewal. The application for correction is attached for reference.

	Decision: Deferred Registration board deferred the case for confirmation of Section / Manufacturing Facility for applied formulation.	
220	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (7YZ-LNY-PHUR, 2024-09-13) Fee Paid: 30000.0 Paid Date: 2024-08-26 Case Category: New License **(Tahir Waqas)**	Proposed Name: **Oloft Tablet 100mg** Each film coated tablet contains: Sertraline HCl eq. to Sertraline ... 100mg United States Pharmacopeia RRA Status: ZOLOFT 100mg Tablet, USFDA approved. Me Too Status: Zoloft 100mg by Pfizer Pack Size(s): 20's,30's,50's-As per SRO
	Evaluation Remarks: Following shortcomings were communicated vide letter No. F. 2-1/2023-PEC (DD-PEC-XXI) dated 29th November 2024.	

Sr. No.	Observations	Response
01	Please provide valid GMP of API Manufacturer issued by regulatory authority of country of origin.	Copy of GMP Certificate valid till 22-04-2026 has been submitted.
02	Please provide evidence of DRAP (I&E) Clearance against submitted Form 5. Also submit evidence of issuance of Loan of API from Importer (i.e. M/s Nexus Pharma, Karachi).	Loan letter from Nexus Pharma has been submitted along with copy of DRAP (I&E) Clearance.
03	Please provide evidence of Reference / Innovator's packs used for Pharmaceutical Equivalence / CDP.	Submitted.
04	The submitted Audit Trail & Chromatograms show both entries (i.e. 50mg & 100mg Tablets) in a single file. Please justify.	The firm have submitted that both product trial batches were performed simultaneously so its chromatograms and audit trails show in single file.

	Decision: Approved Registration Board further decided to proceed for onsite investigation to confirm genuineness authenticity of stability data, related documents, import of API, quality, specification, test analysis, facilities etc., before issuance of registration letter.	
221	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (8WG-D72-LAN9, 2024-09-12) Fee Paid: 75000.0 Paid Date: 2024-09-09 Case Category: New License **(Tahir Waqas)**	Proposed Name: **Ramargon Tablets 7.5mg** Each Film Coated Tablet contains: Mirtazapine ... 7.5mg United States Pharmacopeia RRA Status: MIRTAZAPINE 7.5mg Tablets, USFDA approved. Me Too Status: N/A Pack Size(s): 20's & 30's-As per SRO
	Evaluation Remarks: Following shortcomings were communicated vide letter No. F. 2-1/2023-PEC (DD-PEC-XXI) dated 29th November 2024.	

Sr. No.	Observations	Response
01	Please provide evidence of mentioned Me-Too status (i.e. Valta Tablets of M/s Getz Pharma, Karachi).	N/A
02	Please provide evidence of DRAP (I&E) Clearance against submitted Form 5. Also submit evidence of issuance of Loan of API from Importer (i.e. M/s Lisko Pharma, Karachi).	Loan letter from Lisko Pharma has been submitted along with copy of DRAP (I&E) Clearance.
03	Please provide evidence of Reference / Innovator's pack used for Pharmaceutical Equivalence / CDP.	Submitted.
04	The submitted Audit Trail & Chromatograms are of 15mg & 30mg Tablets. Please justify.	The firm have submitted that both product trial batches were performed simultaneously so its chromatograms and audit trails show in single file.

	Decision: Approved Registration Board further decided to proceed for onsite investigation to confirm genuineness authenticity of stability data, related documents, import of API, quality, specification, test analysis, facilities etc., before issuance of registration letter.	
222	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (B8U-9JW-PPQM, 2024-09-06) Fee Paid: 30000.0 Paid Date: 2024-08-26 Case Category: New License **(Tahir Waqas)**	Proposed Name: **Ramargon Tablet 15mg** Each film coated tablet contains: Mirtazapine ... 15mg United States Pharmacopeia RRA Status: REMERON 15mg Tablet, USFDA approved. Me Too Status: Mitaz 15mg Tablets of M/s Glitz Pharma. Pack Size(s): 20's,30's-As per SRO

<table>
<tr><th>Sr. No</th><th>Name of Applicant, Manufacturer & Fee Details</th><th>Product Info</th></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
Following shortcomings were communicated vide letter No. F. 2-1/2023-PEC (DD-PEC-XXI) dated 29th November 2024.

<table>
<tr><th>Sr. No.</th><th>Observations</th><th>Response</th></tr>
<tr><td>1</td><td>Please provide evidence of mentioned Me-Too status (i.e. Valta Tablets of M/s Getz Pharma, Karachi).</td><td>Mitaz 15mg Tablets of M/s Glitz Pharma.</td></tr>
<tr><td>2</td><td>Please provide evidence of DRAP (I&E) Clearance against submitted Form 5. Also submit evidence of issuance of Loan of API from Importer (i.e. M/s Lisko Pharma, Karachi).</td><td>Loan letter from Lisko Pharma has been submitted along with copy of DRAP (I&E) Clearance.</td></tr>
<tr><td>3</td><td>Please provide evidence of Reference / Innovator’s pack used for Pharmaceutical Equivalence / CDP.</td><td>Submitted.</td></tr>
<tr><td>4</td><td>Please provide valid GMP of API Manufacturer issued by regulatory authority of country of origin.</td><td>Copy of GMP Certificate valid till 07-07-2025 has been submitted.</td></tr>
<tr><td>5</td><td>The submitted Audit Trail & Chromatograms show both entries (i.e. 15mg & 30mg Tablets) in a single file. Please justify.</td><td>The firm have submitted that both product trial batches were performed simultaneously so its chromatograms and audit trails show in single file.</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved
Registration Board further decided to proceed for onsite investigation to confirm genuineness authenticity of stability data, related documents, import of API, quality, specification, test analysis, facilities etc., before issuance of registration letter.</td></tr>
<tr><td>223</td><td>Orbis Pharmaceuticals
Plot # K-138 , SITE Super Highway Phase 2 , Karachi (000979)
Tracking ID: (BBY-QJW-1G3E, 2024-09-06)
Fee Paid: 30000.0
Paid Date: 2024-08-26
Case Category: New License
(Tahir Waqas)</td><td>Proposed Name: Ramargon Tablet 30mg
Each film coated tablet contains: Mirtazapine ... 30mg
United States Pharmacopeia
RRA Status: REMERON 30mg Tablet, USFDA approved.
Me Too Status: Mitaz 30mg Tablets of M/s Glitz Pharma.
Pack Size(s): 20's,30's-As per SRO</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:
Following shortcomings were communicated vide letter No. F. 2-1/2023-PEC (DD-PEC-XXI) dated 29th November 2024.

<table>
<tr><th>Sr. No.</th><th>Observations</th><th>Response</th></tr>
<tr><td>1</td><td>Please provide evidence of mentioned Me-Too status (i.e. Valta Tablets of M/s Getz Pharma, Karachi).</td><td>Mitaz 30mg Tablets of M/s Glitz Pharma.</td></tr>
<tr><td>2</td><td>Please provide evidence of DRAP (I&E) Clearance against submitted Form 5. Also submit evidence of issuance of Loan of API from Importer (i.e. M/s Lisko Pharma, Karachi).</td><td>Loan letter from Lisko Pharma has been submitted along with copy of DRAP (I&E) Clearance.</td></tr>
<tr><td>3</td><td>Please provide evidence of Reference / Innovator’s pack used for Pharmaceutical Equivalence / CDP.</td><td>Submitted.</td></tr>
<tr><td>4</td><td>The submitted Audit Trail & Chromatograms show both entries (i.e. 15mg & 30mg Tablets) in a single file. Please justify.</td><td>The firm have submitted that both product trial batches were performed simultaneously so its chromatograms and audit trails show in single file.</td></tr>
</table></td></tr>
<tr><td></td><td colspan="2">Decision: Approved
Registration Board further decided to proceed for onsite investigation to confirm genuineness authenticity of stability data, related documents, import of API, quality, specification, test analysis, facilities etc., before issuance of registration letter.</td></tr>
<tr><td>224</td><td>City Pharmaceutical Laboratories
Plot 12-A, I-5, Sector 5, Korangi Industrial Area, Karachi, Pakistan (000723)
Tracking ID: (YTY-AQB-PYET, 2023-12-18)
Fee Paid: 30000.0
Paid Date: 2023-10-10
Case Category: Routine
(Tahir Waqas)</td><td>Proposed Name: DESLO
Each film coated tablet contains Desloratadine= 5 mg
United States Pharmacopeia
RRA Status: Desloratadine 5mg tablet by ACCORD Healthcare Limited.(UK), MHRA Approved
Me Too Status: DESLAVID 5 mg tab by Abbott Laboratories. Registration Number: 041011
Pack Size(s): 10'S-As per SRO</td></tr>
<tr><td></td><td colspan="2">Evaluation Remarks:</td></tr>
<tr><td></td><td colspan="2">Decision: Deferred Submission of response to communicated shortcomings.</td></tr>
<tr><td>225</td><td>Orbis Pharmaceuticals
Plot # K-138 , SITE Super Highway Phase 2 , Karachi (000979)
Tracking ID: (GUA-H8W-NB83, 2024-09-10)
Fee Paid: 30000.0
Paid Date: 2024-08-26
Case Category: New License
(Tahir Waqas)</td><td>Proposed Name: Oloft Tablet 50mg
Each film coated tablet contains: Sertraline HCl eq. to Sertraline ... 50mg
United States Pharmacopeia
RRA Status: ZOLOFT 50mg Tablet, USFDA approved.
Me Too Status: Zoloft 50mg Tablet of Pfizer
Pack Size(s): 30's,50's-As per SRO</td></tr>
</table>

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Following shortcomings were communicated vide letter No. F. 2-1/2023-PEC (DD-PEC-XXI) dated 29th November 2024.	

Sr. No.	Observations	Response
01	Please provide valid GMP of API Manufacturer issued by regulatory authority of country of origin.	Copy of GMP Certificate valid till 22-04-2026 has been submitted.
02	Please provide evidence of DRAP (I&E) Clearance against submitted Form 5. Also submit evidence of issuance of Loan of API from Importer (i.e. M/s Nexus Pharma, Karachi).	Loan letter from Nexus Pharma has been submitted along with copy of DRAP (I&E) Clearance.
03	Please provide evidence of Reference / Innovator's packs used for Pharmaceutical Equivalence / CDP.	Submitted.
04	The submitted Audit Trail & Chromatograms show both entries (i.e. 50mg & 100mg Tablets) in a single file. Please justify.	The firm have submitted that both product trial batches were performed simultaneously so its chromatograms and audit trails show in single file.

	Decision: Approved Registration Board further decided to proceed for onsite investigation to confirm genuineness authenticity of stability data, related documents, import of API, quality, specification, test analysis, facilities etc., before issuance of registration letter.	
226	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila (**000856**) Tracking ID: (JR7-MQ3-RVEU, 2023-12-04) Fee Paid: 75000.0 Paid Date: 2023-11-24 Case Category: Routine **(Tahir Waqas)**	Proposed Name: **Claseron Cream 1% (w/w)** Each gram of Cream contains: Clascoterone ... 10mg (1% w/w) As per Innovators Specification RRA Status: WINLEVI, 1% CREAM; TOPICAL, USFDA approved. Me Too Status: N/A Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: The following shortcomings / deficiencies have been communicated to the applicant:	

Sr. No.	Observations	Firm's Response
01	Evidence of section approval letter from licensing division.	Section approval letter from licensing division is enclosed.
02	3.2.P.8 Please provide Stability Study Data along with attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc., for 06th Month Testing Interval of all 03 Trials.	Submitted.

	Decision: Approved	
227	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (RB1-6PD-VERS, 2024-09-25) Fee Paid: 30000.0 Paid Date: 2024-08-09 Case Category: New License **(Tahir Waqas)**	Proposed Name: **Magadol Capsule 50mg** Each Capsule contains: Tramadol Hydrochloride BP ... 50mg British Pharmacopeia RRA Status: Tramadol 50 mg Capsules, MHRA approved. Me Too Status: Newtra Capsule 50mg of M/s Newton Health Care Pvt. Ltd. Pack Size(s): 10's-As per SRO
	Evaluation Remarks: Following shortcomings were communicated vide letter No. F. 2-1/2023-PEC (DD-PEC-XXI) dated 29th November 2024.	

Sr. No.	Observations	Response
01	Please provide evidence of mentioned Me-Too status (i.e. Newtra Capsules of M/s Newton Healthcare).	Reg. No. 086582 of M/s Newton Healthcare.
02	Please provide evidence of DRAP (I&E) Clearance against submitted Invoice. Also submit evidence of issuance of Loan of API from Importer (i.e. M/s Safe Pharma, Karachi).	Loan letter from Safe Pharma has been submitted.
03	Please provide evidence of Reference / Innovator's packs used for Pharmaceutical Equivalence / CDP.	Submitted.

	Decision: Approved Registration letter will be issued after submission of evidence of DRAP (I&E) Clearance against submitted Invoice.	
228	**Nahal Pharmaceuticals (Pvt) Ltd.** Plot No. 2, Street No. SS-4, RCCI, Industrial Estate Rawat (**000989**) Tracking ID: (6GY-VSZ-4PXH, 2024-10-25) Fee Paid: 37000.0 Paid Date: 2024-09-27 Case Category: New License **(Waqar Ahmed)**	Proposed Name: **Nefroxil 500 mg Capsule** Each capsule contains: Cefadroxil Monohydrate equivalent to Cefadroxil.....500 mg United States Pharmacopeia RRA Status: Duricef 500 mg capsule USFDA Approved Me Too Status: Duricef 500mg capsule M/s GSK Pack Size(s): 12's-As per SRO
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved	
229	**Nahal Pharmaceuticals (Pvt) Ltd.** Plot No. 2, Street No. SS-4, RCCI, Industrial Estate Rawat (**000989**) Tracking ID: (6SG-DZ3-HS2D, 2024-10-08) Fee Paid: 37000.0 Paid Date: 2024-09-06 Case Category: New License **(Waqar Ahmed)**	Proposed Name: **Nemoxil** each 5ml reconstituted suspension contains: Amoxicillin as (Trihydrate).....125mg British Pharmacopeia RRA Status: Amoxil . FDA MHRA Approved , Trade Mark of GSK Me Too Status: Amoxil Pack Size(s): 1x1 s-As per SRO
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	
230	**Nahal Pharmaceuticals (Pvt) Ltd.** Plot No. 2, Street No. SS-4, RCCI, Industrial Estate Rawat (**000989**) Tracking ID: (8NN-92D-H1MZ, 2024-10-07) Fee Paid: 37000.0 Paid Date: 2024-09-27 Case Category: New License **(Waqar Ahmed)**	Proposed Name: **Nefroxil 125 mg /5ml Dry Suspension** Each 5 ml of reconstituted suspension contains: Cefadroxil monohydrate equivalent to Cefadroxil.....125 mg United States Pharmacopeia RRA Status: Biodroxil 125mg/5ml by Sandoz GMBH,Austria(EMA) Me Too Status: Duricef 125mg /5ml Dry Suspension Reg. 008014 GSK Pack Size(s): 60 ml Suspension in -As per SRO
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	
231	**Nahal Pharmaceuticals (Pvt) Ltd.** Plot No. 2, Street No. SS-4, RCCI, Industrial Estate Rawat (**000989**) Tracking ID: (ABY-23X-MV14, 2024-10-21) Fee Paid: 37000.0 Paid Date: 2024-10-16 Case Category: New License **(Waqar Ahmed)**	Proposed Name: **Nemoxil 500mg Capsule** Each hard Gelatin Capsule Contains Amoxicillin as Trihydrate ----500mg British Pharmacopeia RRA Status: Amoxil . FDA MHRA Approved , Trade Mark of GSK Me Too Status: Amoxil 500 mg capsule Pack Size(s): 1x10s-As per SRO
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	
232	**Nahal Pharmaceuticals (Pvt) Ltd.** Plot No. 2, Street No. SS-4, RCCI, Industrial Estate Rawat (**000989**) Tracking ID: (HSD-YX7-6SH1, 2024-10-02) Fee Paid: 37000.0 Paid Date: 2024-09-27 Case Category: New License **(Waqar Ahmed)**	Proposed Name: **Nemoxil 250mg Capsule** each capsule contains Amoxicillin as Trihydrate---250mg British Pharmacopeia RRA Status: Amoxil . FDA MHRA Approved , Trade Mark of GSK Me Too Status: Amoxil 250mg caps Pack Size(s): 1x10s-As per SRO
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	
233	**Nahal Pharmaceuticals (Pvt) Ltd.** Plot No. 2, Street No. SS-4, RCCI, Industrial Estate Rawat (**000989**) Tracking ID: (UAW-VD7-SRB4, 2024-09-25) Fee Paid: 37000.0 Paid Date: 2024-09-13 Case Category: New License **(Waqar Ahmed)**	Proposed Name: **Nemoxil** Each 5ml Reconstituted Suspension Contains: Amoxicillin as Trihydrate..... 250mg British Pharmacopeia RRA Status: Amoxil . FDA MHRA Approved , Trade Mark of GSK Me Too Status: Amoxil Fort Pack Size(s): 1x1 s-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	
234	**Nahal Pharmaceuticals (Pvt) Ltd.** Plot No. 2, Street No. SS-4, RCCI, Industrial Estate Rawat (**000989**) Tracking ID: (UDD-8LR-8NEH, 2024-10-07) Fee Paid: 37000.0 Paid Date: 2024-09-27 Case Category: New License **(Waqar Ahmed)**	Proposed Name: **Nefroxil 250mg Dry Suspension** Each 5 ml of reconstituted suspension contains: Cefadroxil monohydrate equivalent to Cefadroxil .... 250 mg United States Pharmacopeia RRA Status: Duracef 250mg/5ml Dry Susp{Jute Darma, Spain{EMA} Me Too Status: Duricef 250mg /5ml Dry Suspension M/s GSK Reg.010057 Pack Size(s): 60 ml Suspension in -As per SRO
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks:	
	Decision: Approved	
235	**Horizon HealthCare (Pvt) Ltd** plot no 33 sunder industrial estate lahore (**000782**) Tracking ID: (VY5-14G-YJQ2, 2023-12-13) Fee Paid: 75000.0 Paid Date: 2023-11-22 Case Category: Routine **(Waqar Ahmed)**	Proposed Name: **Epala 50mg Tablet** Each film-coated tablet contains: Epalrestat .....50mg (As per JP specs.) Any Other RRA Status: Approved drug by PMDA of Japan - Epalrestat Tablet (Japanese name: KINEDAK tablets: 50mg) Me Too Status: N/A Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: Dear applicant please provide six-month time point stability data for the applied product. * Firm has provided data for 6 month stability time point.	
	Decision: Approved	
236	**Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi (**000755**) Tracking ID: (ESW-N5X-Q11L, 2023-12-07) Fee Paid: 75000.0 Paid Date: 2023-11-14 Case Category: Routine **(Waqar Ahmed)**	Proposed Name: **Thiorelax Plus** Each tablet contains: Paracetamol.....500mg Thiocolchicoside.....2mg As per Innovators Specificatio RRA Status: Spanish Agency for Medicine and Health products (Adalgur 500mg/2mg Tablet) Me Too Status: None Pack Size(s): 10's-As per SRO
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	
	Evaluation Remarks: Reference of this formulation also available in AIFA Italy with brand name Tyomol 500mg/2mg manufactured by M/s. Bruno Pharmaceuticals SPA.	
	Decision: Approved	

Registration Board 343 Meeting Additional/Supplementary Minutes:

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
1	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (**000978**) Tracking ID: (177-PEQ-D8YT, 2024-11-29) Fee Paid: 30000.0 Paid Date: 2024-09-05 Case Category: New License **(Adil Saeed)**	Proposed Name: **CIP-Q 250mg Tablet** Each film coated tablets contains Ciprofloxacin as HCl.....250mg (USP-SPEC,S) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Ciplet 250mg Tablets Pack Size(s): 1x10s-Controlled
	Evaluation Remarks: API purchased from Pharmagen	
	Decision: Approved	
2	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (**000978**) Tracking ID: (3WZ-BT1-ZNB4, 2024-12-02) Fee Paid: 30000.0 Paid Date: 2024-09-05 Case Category: New License **(Adil Saeed)**	Proposed Name: **Qioloceph 250mg Capsule** Each Hard gelatin Capsule cantains: Cephradine .....250mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Velocef 250 mg capsule Pack Size(s): 2x6's-As per SRO
	Evaluation Remarks: Drug substance purchased from Citi Pharma	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
3	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (54E-EH3-LM37, 2024-09-27) Fee Paid: 37000.0 Paid Date: 2024-09-05 Case Category: New License **(Adil Saeed)**	Proposed Name: **Denla XR Tablet 100mg** Each Extended Release Tablet contains: Desvenlafaxine as Desvenlafaxine Succinate Monohydrate.....100mg Manufacturer Specification RRA Status: Product Name: Pristiq Extended Release Tablet 100mg Manufacturer: PF PRISM Reference Regulatory Authority: FDA Approved drug. Me Too Status: Brand Name: Lafaxine ER Tablets Strength: 100mg Dosage Form: Oral Tablets Pack Size: 14's Regn No. 070459 Manufacturer: Genix Pharma Private Limited. Pack Size(s): 14's , 20's , 50's, -As per SRO
	Evaluation Remarks:	
	Decision: Approved Approved with innovator specifications. Letter shall be issued after submission of fee of Rs. 9000/- for pre-registration variation.	
4	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (**000978**) Tracking ID: (6SN-3EU-U9DQ, 2024-12-02) Fee Paid: 30000.0 Paid Date: 2024-09-05 Case Category: New License **(Adil Saeed)**	Proposed Name: **Qioloceph 125 mg/5ml DS** Each 5ml Reconstituted suspension contain: Cephradine .....125mg (USP Spec,s) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Velocef 125mg/5ml DS Pack Size(s): 1s-Controlled
	Evaluation Remarks: Cephradine 125mg/5ml suspension Drug susbtance purchased from CITI pharma	
	Decision: Deferred Deferred for submission of valid RRA reference.	
5	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (**000978**) Tracking ID: (6YN-EJP-QBUN, 2024-12-02) Fee Paid: 30000.0 Paid Date: 2024-09-05 Case Category: New License **(Adil Saeed)**	Proposed Name: **Qiozole 40mg Capsule** Each Hard gelatin Capsule cantain: Enteric coated Pellets of Esomeprazole Mg Trihydrate USP eq to Esomeprazole .....40 mg (USP Spec,s) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Nexum 40mg Capsule Pack Size(s): 2x7's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Source of Pellets: Vision Pharma	
	Decision: Approved	
6	**Shaigan Pharmaceuticals (Pvt) Ltd** 14Km Adyala Road Post office Dahgal Rawalpindi (**000333**) Tracking ID: (6AS-D5H-3317, 2024-06-14) Fee Paid: 30000.0 Paid Date: 2024-02-15 Case Category: New Section **(Adil Saeed)**	Proposed Name: **HYDRA Sachet** Each sachet contains: sodium chloride.....1.3gm potassium chloride.....0.75gm sodium citrate.....1.45gm dextrose anhydrous.....6.75gm equivalent to sodium 37.5mmol potassium.....10mmol citrate.....5mmol glucose....37.5mmol As per Innovators Specification RRA Status: WHO recommended ORS formulation Me Too Status: osmolar ors atco laboratories Pack Size(s): 10's-As per SRO
	Evaluation Remarks: The case was deferred in 339th meeting of RB for submission of reply. Firm has submitted their response which is given below; Give tabulated comparison of your formulation with WHO recommended formulation indicating their similarity. The WHO recommended formulation is for 1L ORS solution, firm has applied for sachet to be reconstituted in 500ml, concentration of salts per mL is same. The WHO formulation recommends use of Trisodium citrate whereas you have used sodium citrate in your formulation. Firm has stated that sodium citrate and trisodium citrate are sane chemicals. But the sodium citrate salt can be in three forms Mono di and tri sodium citrate, the amount of sodium will be different in all three salts. As per Section 1.5.1, why USP or BP specifications are not adopted, although ORS formulation is same as mentioned in BP. The firm has not addressed the point of applying innovator specs. Clearance certificates of each drug substance (KCl, NaCl, Glucose & Sodium Citrate) are required Local Invoices are submitted. S- part of each drug substance is required. S part of Dextrose, KC and NACL is upload but data in uploaded files is incomplete.	
	Decision: Deferred Deferred for further deliberation.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
7	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (**000978**) Tracking ID: (94A-VE1-RW1D, 2024-11-29) Fee Paid: 30000.0 Paid Date: 2024-09-05 Case Category: New License **(Adil Saeed)**	Proposed Name: **Linzolid 600 mg tablet** Each Film coated tablet contain: Linezolid.....600mg (innovater Spec,s) As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Zevoxid 600 mg Tablet Pack Size(s): 2x7's-Controlled
	Evaluation Remarks: API taken loan from Lawari International	
	Decision: Approved	
8	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (**000978**) Tracking ID: (9BY-A81-ZLVS, 2024-12-02) Fee Paid: 30000.0 Paid Date: 2024-09-05 Case Category: New License **(Adil Saeed)**	Proposed Name: **Qioloceph 500mg Capsule** Each Hard gelatin Capsule cantain: Cephradine .....500mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Velocef 500 mg capsule Pack Size(s): 2x6's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
9	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (**000978**) Tracking ID: (EZN-ZV9-3YZA, 2024-11-29) Fee Paid: 30000.0 Paid Date: 2024-09-05 Case Category: New License **(Adil Saeed)**	Proposed Name: **Qiopride 50mg Tablet** Each tablets contains Levosulpiride.....50mg (Innovater-SPEC,S) As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Vesulpid Tablets 50mg Pack Size(s): 1x10s-Controlled
	Evaluation Remarks: Drug substance taken loan from Lawari International	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
10	**Gray's Pharmaceuticals** Plot NO2, Street No. N-3, RCCI Rawat Islamabad (**000518**) Tracking ID: (EUA-REZ-XPV4, 2024-08-15) Fee Paid: 30000.0 Paid Date: 2024-08-01 Case Category: New Section **(Adil Saeed)**	Proposed Name: **Selden 10mg/ml for oral suspension** Each ml of reconstituted suspension containsSildenafil (as Citrate).....10mg British Pharmacopeia RRA Status: MHRA Me Too Status: NA Pack Size(s): 1's-As per SRO
	Evaluation Remarks: Section approval letter attached is of Sachet section, Product applied is Powder for Oral suspension; please submit evidence of powder for oral suspension (general) section, further evidence that it can be considered as a new section. Firm has shared Oral suspension section approval letter dated 14.12.2023 verifying that application can be considered in new section category. 3.2.P.2, In description of product, its mentioned that it will be granular, innovator product is also mentioned as granular powder, but manufacturing out line does not mention the process of granulation. Please clarify. Firm has stated that it appears granular due to nature of excipients used. 3.2.P.2. The pharmaceutical equivalence is performed against product Sildenafil Citrate 10mg DS batch No. BG21023A having expiry date 08.2023, please justify how product of Bio-Labs having expiry date of 08.2023 was procured or obtained. (registration status of said product needs verification, because as per stated expiry date the product would be manufactured in 2021) In Module 2, the manufacturer of product is claimed as amneal. Having expiry of 07.2025 (Pictorial evidence is attached) Firm has stated that these are typographic mistakes. Reference product used was of M/s Amneal 08.2023 The expiry of batch No 23TRSH002 is mentioned as 08.2023 in 3.2.P.2 section, whereas its mentioned as its manufacturing date in section 3.2.P.3, Firm has stated that its a typo error. Copies of executed BMRs of trial batches are required. Submitted Copy of Clearance certificate of drug substance or its AD attested invoice is required. Submitted S part in Module 3 is not submitted. Submitted Function of ingredients mentioned in every table is incorrect. It is required to correct the Function of each ingredient in Module 2 and Module 3 and again upload the corrected Module 2 and 3 files. Firm has submitted corrected module 2 & 3 physically.	
	Decision: Approved Keeping in view the criticality (pediatric demand & use) of product and to ensure fair competition, the Registration Board advised the PE&R Division to issue the registration Letter of above product without waiting for finalization of minutes.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
11	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (**000978**) Tracking ID: (J9N-54W-4YV5, 2024-11-29) Fee Paid: 30000.0 Paid Date: 2024-09-05 Case Category: New License **(Adil Saeed)**	Proposed Name: **CIP-Q 500mg Tablet** Each film coated tablets contains Ciprofloxacin as HCl.....500mg (USP-SPEC,S) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Ciplet 500mg Tablets Pack Size(s): 1x10s-Controlled
	Evaluation Remarks: APi purchased from Pharmagen	
	Decision: Approved	
12	**Gray's Pharmaceuticals** Plot NO2, Street No. N-3, RCCI Rawat Islamabad (**000518**) Tracking ID: (J66-ZJY-QLMZ, 2024-08-15) Fee Paid: 30000.0 Paid Date: 2024-05-27 Case Category: New Section **(Adil Saeed)**	Proposed Name: **Gray-merz 3 gram sachets** each sachet contains L-ornithine L-aspartate 3 gram As per Innovators Specification RRA Status: Austria AGES Me Too Status: Hepamerz sachets Pack Size(s): 5 sachets-As per SRO
	Evaluation Remarks: 3.2.S.4 Detailed method of Assay of drug substance by drug substance manufacturer is not submitted. Firm has submitted detailed method of testing of drug substance. 3.2.S.7 Stability Summary sheets for drug substance are required. Stability summary sheets are submitted. 3.2.P.2 Description of product is granular but granulation step is not mentioned in manufacturing method. Firm has stated that their product does appear granular and it happens due to addition of excipients like Saccharin Sodium, citric acid etc. 3.2.P.5 Assay is done by potentiometric titration, please clarify why HPLC method is not adopted. (The amino acid ratio is performed on HPLC by the drug substance manufacturer) Firm has submitted response of drug substance manufacturer. They have stated that impurities are checked by HPLC, assay is done by titration. Method of Chinese Pharmacopoeia 2015 is submitted, it is also by titration. Copies of executed BMRs of trial batches are required. Copies are submitted.	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
13	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (**000978**) Tracking ID: (LP3-J18-8SH8, 2024-11-29) Fee Paid: 30000.0 Paid Date: 2024-09-05 Case Category: New License **(Adil Saeed)**	Proposed Name: **Qiopride 25mg Tablet** Each tablets contains Levosulpiride.....25mg (Innovater Spec,s)) As per Innovators Specification RRA Status: USFDA Approved Me Too Status: Vesulpid Tablets 25mg Pack Size(s): 1x10s-Controlled
	Evaluation Remarks: API taken loan from Lawari International	
	Decision: Approved	
14	**Gray's Pharmaceuticals** Plot NO2, Street No. N-3, RCCI Rawat Islamabad (**000518**) Tracking ID: (N41-TH7-DEHQ, 2024-09-16) Fee Paid: 30000.0 Paid Date: 2023-04-04 Case Category: New Section **(Adil Saeed)**	Proposed Name: **Breath 4mg Sachet** Each Sachet contains: Montelukast (as Sodium) ..... 4mg United States Pharmacopeia RRA Status: MHRA Me Too Status: NA Pack Size(s): 1's-As per SRO
	Evaluation Remarks: Differential fee of Rs. 7000/- is required. (Screening was completed in September 2024) Differential fee of Rs. 7000/- vide slip No. 8290399463 is submitted. The Description of drug product is mentioned as granular, but granulation step is not mentioned in manufacturing of the product. Clarification is required. The firm has stated that "The description of drug product is granular powder is not due to granulation process because sachet manufacturing having no granulation process required as per manufacturing process, the physical appearance of Breath 4mg sachet is due to itself composition containing some expedients having granular in description like “Hyprolose” so that why the description of powder is mentioned granular"	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
15	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (QUV-Y33-9ZB1, 2024-09-30) Fee Paid: 37000.0 Paid Date: 2024-09-05 Case Category: New License **(Adil Saeed)**	Proposed Name: **Denla XR Tablet 50mg** Each Extended Release Tablet contains: Desvenlafaxine as Desvenlafaxine Succinate Monohydrate.....50mg Manufacturer Specification RRA Status: Product Name: Pristiq Extended Release Tablet 50mg Manufacturer: PF PRISM Reference Regulatory Authority: FDA Approved drug. Me Too Status: Brand Name: Lafaxine ER Tablets Strength: 50mg Dosage Form: Oral Tablets Pack Size: 14's Regn No. 070458 Manufacturer: Genix Pharma Private Limited. Pack Size(s): 14's,20's,50's,100's-As per SRO
	Evaluation Remarks: Mfg specs are applied	
	Decision: Approved Approved with innovator specifications. Letter shall be issued after submission of fee of Rs.9000/- for pre-registration variation.	
16	**Gray's Pharmaceuticals** Plot NO2, Street No. N-3, RCCI Rawat Islamabad (**000518**) Tracking ID: (TM3-AGR-YDHB, 2024-08-15) Fee Paid: 30000.0 Paid Date: 2023-04-04 Case Category: New Section **(Adil Saeed)**	Proposed Name: **tossa 2 gram sachets** each sachet contains strontium ranelate 2 gram As per Innovators Specification RRA Status: mhra Me Too Status: onita sachet Pack Size(s): 7-Controlled
	Evaluation Remarks: 1. 3.2 S.4 batch analysis of drug substance by drug product manufacturer is required 2. Analysis of Batch No. S202202004 is submitted. 3.2.P.2 Description of product is granular but granulation step is not mentioned in manufacturing method. 3. Firm has stated that "The description of drug product is granular powder is not due to granulation process because sachet manufacturing having no granulation process required as per manufacturing process, the physical appearance of Tossa 2gm sachet is due to itself composition containing some excipients having granular in description like “Maltodextrin” so that why the description of powder is mentioned granular. " 3.2.P.8 Stability Summary sheets along with supporting data are required. 4. Stability data only upto second time point is submitted. 5. Copies of executed BMRs of trial batches are required. 6. BMR are not submitted. 7. Copy of Clearance certificate of drug substance or its AD attested invoice is required. 8. Invoice is submitted.	
	Decision: Approved The letter shall be issued after submission of 3rd time point stability data and executed BMR of the trial batches.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
17	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (**000978**) Tracking ID: (WRG-J3E-LLYT, 2024-11-29) Fee Paid: 30000.0 Paid Date: 2024-09-05 Case Category: New License **(Adil Saeed)**	Proposed Name: **Linzoqio 100 mg/5ml DS** Each 5ml Reconstituted suspension contain: Linezolid .....100mg (Innovator Spec,s) As per Innovators Specification RRA Status: USFDA Approved Me Too Status: NEZKIL 100mg/5ml DS Pack Size(s): 1s-Controlled
	Evaluation Remarks: Drug substance is taken loan from M/s Lawari. The batch No. of drug substance used in trial batches is BLKCR 03423, Clearance certificate of this specific batch of drug substance is required. Firm again submitted clearance certificate of batch different than the one used in manufacturing of trial batches.	
	Decision: Deferred Deferred for submission of clearance of batch of drug substance used in manufacturing of trial batches.	
18	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (**000978**) Tracking ID: (WDM-RSY-9W45, 2024-12-02) Fee Paid: 30000.0 Paid Date: 2024-09-05 Case Category: New License **(Adil Saeed)**	Proposed Name: **Qioloceph 250 mg/5ml DS** Each 5ml Reconstituted Suspension contain: Cephradine .....250mg (USP Spec,s) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Velocef 250mg/5ml DS Pack Size(s): 1s-Controlled
	Evaluation Remarks: API local purchase from CITI Pharma	
	Decision: Approved	
19	**S&K Pharmaceuticals** Plot N0. 252, Sunder Industrial Estate (**000961**) Tracking ID: (5MH-GZY-5122, 2024-10-08) Fee Paid: 30000.0 Paid Date: 2024-08-01 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Diclowell Injection 75mg/3ml** Each 3ml Ampoule contains: Diclofenac Sodium .....75mg As per Innovators Specification RRA Status: MHRA Approved Me Too Status: Dicloran Injection By Sami Pharmaceuticals Karachi Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Instant application has been evaluated and found deficient for following observations: Submit drug substance stability studies as per Zone IV conditions. Submit loan letter from Venus Pharma for the borrowed API. Details of the terminal sterilization shall be submitted.	
	Decision: Deferred For submission of reply to shortcomings shared earlier	
20	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore (**000789**) Tracking ID: (6EU-YQ1-MD4W, 2023-12-27) Fee Paid: 30000.0 Paid Date: 2023-12-05 Case Category: Routine **(Ammar Ashraf Awan)**	Proposed Name: **REGAIN 5% Topical Solution** Each ml Contains: Minoxidil.....50mg United States Pharmacopeia RRA Status: BOSLEY MEN 5 MINOXIDIL TOPICAL SOLUTION M/s Bosley, inc. (USFDA Approved) Made in USA Me Too Status: Hair Max 5% w/v Topical Solution M/s Elko organization (Pvt)Ltd. Reg. No. 027592 Pack Size(s): 1x60ml As per SRO-As per SRO
	Details of Certificates (CoPP/cGMP, Authorization Letter etc): Firm has submitted loan letter and clearance certificate form kanel pharma	
	Evaluation Remarks: Instant application has been evaluated and found deficient for following observations: Details i.e., name of manufacturer, country of origin, of the reference product against which pharmaceutical equivalence has been performed, shall be submitted. The reference product submitted in PE studies also contains biotin while the applied formulation is of Minoxidil only. Clarification shall be submitted in this regard. Firm's response: 1. Pharmaceutical equivalence is performed against Hair Max 5% w/v Topical Solution Manufacturer: Elko organization (Pvt)Ltd Address: Plot # 27 & 28 Sector 12-B North Karachi Industrial Area Karachi, Pakistan. Reg. No. 027592 Batch # AU-50 MFG 07-2023 EXP 07-2025 2. Its a typing error in the PE Studies during typing we used Hair Max 5% w/v Topical Solution	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
21	**Daneen Pharma Pvt Limited** plot no: 27 sunder industrial estate, sunder raiwind road, lahore (**000688**) Tracking ID: (7RT-48B-WRGP, 2023-12-13) Fee Paid: 75000.0 Paid Date: 2023-11-14 Case Category: Routine **(Ammar Ashraf Awan)**	Proposed Name: **TRAMDER** Each film coated tablet contains: Paracetamol ....325mg Tramadol HCl ...37.5mg United States Pharmacopeia RRA Status: Ultracet by Janssen Pharmaceuticals, Inc., USA Me Too Status: Dol-P Tablet by Genix Pharma Pvt Ltd (076424) Pack Size(s): 7's, 10's 14's, 20's-As per SRO
	Manufacturer(s): Manufacturer-GENIX PHARMA (PVT) LTD.PAKISTAN-44, 45B, KORANGI CREEK ROAD, KARACHI. PAKISTAN-	
	Evaluation Remarks:	
	Decision: Approved	
22	**OBS AGP (Private) Limited** Plot no. B-23-C, 2nd Floor S.I.T.E., Karachi (**024**) Tracking ID: (8GP-L9B-UMEQ, 2023-12-29) Fee Paid: 150000.0 Paid Date: 2023-06-21 Case Category: Import **(Ammar Ashraf Awan)**	Proposed Name: **Asporelix** Each Vial Contains: Cetrorelix (as acetate) ..... 250 mcg (Lyophilized) Each Ampoule contains Sterile water for Injection ..... q.s.to 1ml Manufacturers Specification RRA Status: Netherland Approved with brand name Cetrotide 0.25mg Powder and solvent for injection Me Too Status: Generic Drug product, Cetrotide by Martin Dow Pack Size(s): Each Combo Pack of A-As per SRO
	Marketing Authorization Holder (Abroad): M/S. Bharat Serums and Vaccines Limited , Plot No. K-27, K-27 Part and K-27/1, Anand Nagar,Jambivili Village, Additional MIDC, Ambernath (East), Thane 421506,Maharashtra State, India., India **Manufacturer(s):** Manufacturing, Testi-M/S. Bharat Serums and Vaccines Limited-Plot No. K-27, K-27 Part and K-27/1, Anand Nagar,Jambivili Village, Additional MIDC, Ambernath (East), Thane 421506,Maharashtra State, India.-India	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	

Observations	Firm's response
Characterization studies of drug substance to establish the molecular structure and amino acid sequence against the innovator drug product shall be submitted.	Cetrorelix acetate is a synthetically derived low molecular weight peptide molecule and the API manufacturer, Piramal Pharma Limited, has conducted characterization studies of the drug substance to confirm its molecular structure and amino acid sequence using the MS/MS technique, refer section 3.2.$.3.1 Elucidation of structure, enclosed as Annexure 1. The manufacturing process for Cetrorelix acetate is well-established, fully validated, and consistently produces a product with the same molecular structure and amino acid sequence. Since it is synthetically derived low molecular weight peptide molecule, comparative characterization studies with innovator drug product are not necessarily required.
Limits of Peptide content declared in drug substance specification is different from that mentioned in Drug substance COA. justification shall be submitted in this regard	Firm has submitted API COA of 2 batches with limit of peptide content (NLT 87%) as per the specification.
Pharmaceutical equivalence studies against the innovator 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.	Submitted
Justification shall be submitted for the un-conventional limits applied for Assay test i.e., 90%-115% in submitted drug product specifications.	Based on available 24 month stability data of FP, we have the limit for Assay as 95-115%.

	Decision: Approved	
23	**Daneen Pharma Pvt Limited** plot no: 27 sunder industrial estate, sunder raiwind road, lahore (**000688**) Tracking ID: (9W2-EHS-GWDX, 2023-12-08) Fee Paid: 75000.0 Paid Date: 2023-11-03 Case Category: Routine **(Ammar Ashraf Awan)**	Proposed Name: **Ran-F** Each chewable tablet contains: Elemental Iron in the form of iron (III) Hydroxide polymaltose .....100 mg Folic Acid.....0.35mg Manufacturer Specification RRA Status: Ferrum Fol by Vifor France SA Me Too Status: RBC-F Chewable Tablet by Genix Pharma Pvt Ltd (048741) Pack Size(s): 7's, 10's 14's, 20's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Manufacturer(s): Manufacturer-Genix Pharma Pvt Ltd-44 45-B Genix St, Sector 39 Korangi Creek, Karachi, Karachi -	
	Evaluation Remarks: Instant application has been evaluated and found deficient for following observations: Evidence of applied formulation approved by any of the reference regulatory authority shall be submitted, since submitted reference is not verifiable. justification shall be submitted for not performing CDP studies. Justification shall be submitted for not including dissolution test in drug product specifications. Documents confirming procurement/import of Folic acid, issued by DRAP I&E Lahore office, shall be submitted.	
	Decision: Deferred For submission of reply of shortcomings shared earlier.	
24	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (**000978**) Tracking ID: (E8R-ZHA-7JW2, 2024-12-02) Fee Paid: 30000.0 Paid Date: 2024-09-05 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Qiotan 80mg tablet** each film coated tablet contains Valsartan----------80mg (USP Spec,s) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Valtec 80mg tablet Pack Size(s): 1x14s-Controlled
	Evaluation Remarks: Instant application has been evaluated and found deficient for following observations: Documents confirming procurement/import of drug substance, issued by DRAP I&E Office shall be submitted. Firm has submitted loan letter along with clearance certificate issued in name of M/s Lawari	
	Decision: Approved	
25	**S&K Pharmaceuticals** Plot N0. 252, Sunder Industrial Estate (**000961**) Tracking ID: (G64-LGR-QQRB, 2024-10-08) Fee Paid: 30000.0 Paid Date: 2024-08-01 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Skobal Injection** Each 1 ml Ampoule Contains: Cyanocobalamin.....1000mcg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Vitamin B12 Injection by Amros Pharmaceuticals Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Your instant application has been evaluated and found deficient for following observations: Drug substance specifications form drug substance manufacturer shall be submitted. Clarification shall be submitted for the sterlisation procedure applied for the trial batches. Submitted rug product analytical procedure describes US spectrophotometric analytical method for the Assay test, while the analytical record of drug product stability studies is as per HPLC. Justification shall be submitted in this regard. You are therefore advised to submit response to above cited observations at earliest for further processing of the case	
	Decision: Deferred For submission of reply to shortcomings shared earlier	
26	**Sapient Pharma** 123/S Quaid E Azam Industrial Estate Kot Lakhpat (**000207**) Tracking ID: (L76-AG2-HML1, 2023-12-19) Fee Paid: Paid Date: Case Category: Contract Manufacturing **(Ammar Ashraf Awan)**	Proposed Name: **Brisonox** Each Hard Gelatin Capsule Contains: Itraconazole 100mg United States Pharmacopeia RRA Status: Sporanox Capsule by Janssen Pharms Me Too Status: Icon Capsules by Ferozsons Laboratories Pvt. Ltd Pack Size(s): 4's-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-	
	Details of Certificates (CoPP/cGMP, Authorization Letter etc): Firm has submitted fee vide deposit slip# 866673450217	
	Evaluation Remarks: Instant application has been evaluated and found deficient for following observations: Submit drug substance analytical method verification studies performed by M/s Biomark. Submit clarification regarding the test type of dissolution test adopted from USP monograph of applied formulation.	
	Decision: Deferred For submission of reply to shortcomings shared earlier	
27	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (NGE-4U7-973H, 2024-10-01) Fee Paid: 37000.0 Paid Date: 2024-09-19 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Fusimed - H Cream** Each gm contains: Fusidic Acid BP.....20mg Hydrocortisone Acetate USP.....10mg As per Innovators Specification RRA Status: Product Name: Fucidin H Cream 20mg/gm +10mg/gm Market Authorization: LEO Laboratories Limited Maidenhead Berkshire SL6 3UD UK Reference Regulatory Authority: MHRA Approved drug. Me Too Status: Brand Name: Fusimed – H Cream Strength: 20mg/gm& 10mg/gm Dosage Form: Topical Cream Pack Size: 15gm Regn No. 072706 Manufacturer: Medera Pharmaceuticals (Pvt.) Ltd. Pack Size(s): 15gm-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Instant application has been evaluated and found deficient for following observations: Documents confirming procurement/import of drug substance, issued by DRAP I&E Office shall be submitted. In case of borrowing of API, Loan letter shall be submitted. Firm has submitted clearance certificate in name of M/s Medera Pharmaceuticals, Rawat.	
	Decision: Deferred For declaration from M/s Medera Pharmaceuticals regarding grant of loan of drug substance along with evidence of procurement/import issued by DRAP I&E office for the relevant batch.	
28	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore (**000789**) Tracking ID: (P1N-NSQ-9G77, 2023-12-27) Fee Paid: 30000.0 Paid Date: 2023-12-05 Case Category: Routine **(Ammar Ashraf Awan)**	Proposed Name: **REGAIN 2% Topical Solution** Each ml Contains: Minoxidil.....20mg United States Pharmacopeia RRA Status: BOSLEY WOMEN 2 MINOXIDIL TOPICAL SOLUTION M/s Bosley, inc. (USFDA Approved) Made in USA Me Too Status: REGRO 2% w/v Topical Solution M/s Seatle (Private) Limited Reg. No. 038386 Pack Size(s): 1x60ml As per SRO-As per SRO
	Details of Certificates (CoPP/cGMP, Authorization Letter etc): Firm has submitted loan documents along with clearance certificate from M.s Kanel Pharma	
	Evaluation Remarks: Instant application has been evaluated and found deficient for following observations: Details i.e., name of manufacturer, country of origin, of the reference product against which pharmaceutical equivalence has been performed, shall be submitted. Firm has submitted details of Regro 2% solution of M/s Martin Dow	
	Decision: Approved	
29	**3S Pharmaceuticals (Pvt) Ltd.** 5 km off Raiwind Manga Road Lahore. (**000665**) Tracking ID: (P98-7AE-861B, 2023-12-01) Fee Paid: 75000.0 Paid Date: 2023-09-04 Case Category: Routine **(Ammar Ashraf Awan)**	Proposed Name: **Stron Sachet** Each sachet contains: Strontium ranelate .... 2gm As per Innovators Specification RRA Status: Protelos Sachets by Les Laboratories Services - Europe Me Too Status: Onita Sachet by Pharmevo Pvt. Ltd Pack Size(s): 7's, 14's, 28's & 56-As per SRO
	Manufacturer(s): Manufacturing & Pack-Bio-Mark Pharmaceuticals-527 Sundar Industrial Estate, Lahore-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Instant application has been evaluated and found deficient for following observations: Submit evidence of validity of DML of the applicant.	
	Decision: Deferred For confirmation of validity of DML status of the applicant from Licensing Division	
30	**High-Q Pharmaceuticals** Plot# 224 and 225/1, sector 23, Korangi Industrial area, Karachi (**000597**) Tracking ID: (TYG-QAM-N4QL, 2023-12-14) Fee Paid: 30000.0 Paid Date: 2023-11-24 Case Category: Routine **(Ammar Ashraf Awan)**	Proposed Name: **Imeglin** Each Film Coated Tablet Contains: Imeglimin HCl.....500mg Manufacturer Specification RRA Status: Twymeeg 500mg Tablet (PMDA Approved) Me Too Status: Meglim Tablet (Nabi Qasim Pvt Ltd) Pack Size(s): 10’s, 14’s, 20’s, 28-As per SRO
	Evaluation Remarks:	
	Decision: Approved With innovator's specifications. Firm shall submit fee of pre-registration variation i.e., Rs. 9,000/- as per SRO1324 (I)/2024 dated 30-08-2024.	
31	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (Q2A-YQE-SX6D, 2024-09-30) Fee Paid: 37000.0 Paid Date: 2024-09-19 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Fusimed Cream** Each gm contains: Fusidic Acid BP.....20mg British Pharmacopeia RRA Status: Product Name: Fusidic Acid 20mg/gm cream Market Authorization: Focus Pharmaceuticals Ltd Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom. Reference Regulatory Authority: MHRA Approved drug. Me Too Status: Brand Name: Fusimed Cream Strength: 20mg/gm Dosage Form: Topical Cream Pack Size: 15gm Regn No. 073009 Manufacturer: Medera Pharmaceuticals (Pvt.) Ltd. Pack Size(s): 15gm-As per SRO
	Evaluation Remarks: Instant application has been evaluated and found deficient for following observations: Justification shall be submitted for using Fusidic acid as working standard instead of diethanolamine fusidate as recommende dby BP monograph. As per submitted chromatograms the chromatographic conditions of gradient programme as recommended by BP monograph have not been applied. Justification shall be submitted in this regard. Documents confirming procurement/import of drug substance, issued by DRAP I&E Office shall be submitted. In case of borrowing of API, Loan letter shall be submitted.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Deferred For following: Justification for not adopting BP monograph of "Fusidic Acid Cream" for the drug product specifications. Documents confirming procurement/import of relevant batch of drug substances used in manufacturing of trial batches.	
32	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila (**000856**) Tracking ID: (QX5-Z1Z-AN1T, 2023-12-04) Fee Paid: 75000.0 Paid Date: 2023-11-22 Case Category: Routine **(Ammar Ashraf Awan)**	Proposed Name: **Tapiro Cream 1% (w/w)** Each gram of Cream contains Tapinarof ..... 10mg (1% w/w) (As per Innovator's Specs.) As per Innovators Specificatio RRA Status: Registered drug by US-FDA VTAMA Cream 1% (Tapinarof Cream), for topical use. Me Too Status: N/A Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: Instant application has been evaluated and found deficient for following observations: Details of the characterization studies performed to establish the chemical structure of drug substance, shall be submitted. Justification shall be submitted for not including test of Benzoic acid content & Butylated hydroxytoluene content in drug product specifications as recommended by the innovator drug product. Clarification shall be submitted for the performance oof In-Vitro Release studies as recommended by the innovator drug product literature. Drug product stability studies data of 6th month time point shall be submitted. Firm's response: We have performed the IR test and taken the other characterization studies of drug substance from manufacturer. The Infrared spectrum and the evidence of other characterization has been attached We have performed the microbials limit tests as our results falls within limits. Moreover, we have updated our drug product specifications in standard analytical procedure. The updated SAP and Specs are attached We have followed the USP General guidelines for testing of semisolid drug products, <3> TOPICAL AND TRANSDERMAL DRUG PRODUCTS□PRODUCT QUALITY TESTS in which it is stated under the section In-vitro drug release test, "for semisolid dosage forms, in-vitro drug release testing is currently not required for batch release. The 6th Month stability data along with chromatograms and raw data sheets has been attached.	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
33	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi (**000979**) Tracking ID: (S5G-V13-EBYQ, 2024-10-29) Fee Paid: 37000.0 Paid Date: 2024-09-19 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Fusimed - B Cream** Each gm contains: Fusidic Acid BP.....20mg Betamethasone as Valerate USP .....1mg As per Innovators Specification RRA Status: Product Name: Fusidic Acid / Betamethasone Cream 20mg/gm +1mg/gm Market Authorization: Pharmascience International Ltd Lampousas 1 1095 Nicosia Cyprus Reference Regulatory Authority: MHRA Approved drug. Me Too Status: Brand Name: Fusimed – B Cream Strength: 20mg/gm & 1mg/gm Dosage Form: Topical Cream Pack Size: 15gm Regn No. 072707 Manufacturer: Medera Pharmaceuticals Pvt. Limited. Pack Size(s): 15gm -As per SRO
	Evaluation Remarks: Instant application has been evaluated and found deficient for following observations: Documents confirming procurement/import of drug substance, issued by DRAP I&E Office shall be submitted. In case of borrowing of API, Loan letter shall be submitted.	
	Decision: Deferred For Documents confirming procurement/import of drug substance, issued by DRAP I&E Office shall be submitted for the relevant batch of drug substance used for the manufacturing of trial batches.	
34	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (**000978**) Tracking ID: (VAB-BS8-DV13, 2024-12-02) Fee Paid: 30000.0 Paid Date: 2024-09-05 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Qiotan 160 mg tablet** each film coated tablet contains Valsartan----------160mg (USP Spec,s) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Valtec 160mg tablet Pack Size(s): 1x14s-Controlled
	Evaluation Remarks: Instant application has been evaluated and found deficient for following observations: Documents confirming procurement/import of drug substance, issued by DRAP I&E Office shall be submitted. Firm has submitted loan letter along clearance certificate in name of M/s Lawari	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
35	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (**000978**) Tracking ID: (WV1-Y5Q-UYB5, 2024-12-02) Fee Paid: 30000.0 Paid Date: 2024-09-05 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Qiozek 40mg Capsule** Each Hard gelatin Capsule cantain: Omeprazole enteric coated pellets eq. to Omeprazole.....40 mg (USP Spec,s) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Risek 40 mg capsule Pack Size(s): 2x7's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
36	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (**000978**) Tracking ID: (Z7J-DY9-YMTT, 2024-12-02) Fee Paid: 30000.0 Paid Date: 2024-09-05 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Qiozek 20mg Capsule** Each Hard gelatin Capsule cantain: Enteric coated pellets of Omeprazole eq. to Omeprazole.....20 mg (USP Spec,s) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Risek 20 mg capsule Pack Size(s): 2x7's-As per SRO
	Evaluation Remarks:	
	Decision: Approved	
37	**PHARMAQIO RAWALPINDI** 10-Km,Basali Chowk,Chakbeli Road,Rawalpindi. (**000978**) Tracking ID: (ZQ7-415-HPW3, 2024-12-02) Fee Paid: 30000.0 Paid Date: 2024-09-05 Case Category: New License **(Ammar Ashraf Awan)**	Proposed Name: **Qiozole 20mg Capsule** Each Hard gelatin Capsule cantain: Enteric coated Pellets of Esomeprazole Mg Trihydrate USP eq to Esomeprazole.....20 mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Nexum 20mg Capsule Pack Size(s): 2x7's-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Instant application has been evaluated and found deficient for following observations: Revised label claim shall be submitted in section 1.5.2 declaring complete salt form of drug substance. Firm has submitted revised Module I with correction in section 1.5.2	
	Decision: Approved Firm shall submit fee of pre-registration variation i.e., Rs. 9,000/- as per SRO1324 (I)/2024 dated 30-08-2024.	
38	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (D3R-RD1-8GQ4, 2024-08-20) Fee Paid: 30000.0 Paid Date: 2024-07-02 Case Category: New License **(Dr. Farhad Ullah)**	Proposed Name: **Esoren 500mg/ 20mg Tablets** Each modified release tablet contains:Naproxen.....500mg (Enteric coated Core)Esomeprazole as Magnesium Trihydrate.....20mg(Immediate Release Coat)(Innovator's Specifications) As per Innovators Specification RRA Status: VIMOVO 500mg/20mg modified-release tablets MHRA Approved Me Too Status: Glomov 500/20mg Tablet by M/s Global Pharmaceuticals (Pvt.) Ltd (Reg#109338) Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: **Observations** 1.6.5 • Valid GMP certificate / DML of the Drug Substance manufacturer of Naproxen issued by relevant regulatory authority of country of origin is required **Firm's Response** Firm has submitted copy of cGMP certificate of API manufacturer issued by Drug Control Administration, Government of Andhra Pradesh India valid upto 25-06-2027. **Observations** 3.2.P.5 • The dissolution time of esomeprazole mentioned in analytical method (Q after 90min instead of Q at 45min) is different than that of innovator product review document, clarify **Firm's Response** The firm submitted that the dissolution time of esomeprazole mentioned in analytical method is according to the FDA Clinical Pharmacology and Bio-pharmaceutics Review of innovator product Vimovo tablets (esomeprazole magnesium and naproxen) page No 108. The dissolution time for Esomeprazole mentioned is 45 minutes and Naproxen is 60 minutes. **Observations** 3.2.P.8 • Justify the batch size of trial batches against the number of units required for complete testing of drug product during stability study including real time stability study till claimed shelf life • Stability study data of applied drug product at 6^{th} month time point is not submitted • Loan Letter for procurement of Esomeprazole is not submitted • Stability summary sheet of batch No. 24CT21 of applied product at accelerated conditions is not submitted **Firm's Response** The firm submitted that the batch size of the tablets is according to the protocol of stability studies and units requirements for testing is sufficient for stability testing. Stability study data of drug product at 6th month time point is submitted Firm has provided the loan letter for Esomeprazole from M/s Biogen Life Sciences along with procurement documents attested by DRAP in name of M/s Biogen Life Sciences. Stability summary sheet of batch No. 24CT21 of applied product at accelerated conditions is submitted	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
39	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (PM3-SDB-943G, 2024-10-09) Fee Paid: 30000.0 Paid Date: 2024-08-28 Case Category: New License **(Dr. Farhad Ullah)**	Proposed Name: **Azysol Suspension 200mg/5ml** Each reconstituted 5ml contains: Azithromycin (As Dihydrate) .....200mg (USP Specifications) United States Pharmacopeia RRA Status: Zithromax 200/ 5ml Oral suspension, Manufacturer: Haupt Pharma Latina, (NDA):0507 (USFDA Approved)10 Me Too Status: Zetro 200mg/5ml Oral Suspension, Manufacturer:Getz Pharma (Private) Limited. Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: **Observations** Stability study data of applied drug product at 6th month time point is not submitted **Firm's Response** Stability study data of applied drug product at 6th month time point is submitted	
	Decision: Approved	
40	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (T3W-WUD-4XMM, 2024-08-21) Fee Paid: 30000.0 Paid Date: 2024-07-02 Case Category: New License **(Dr. Farhad Ullah)**	Proposed Name: **Esoren 375mg/ 20mg Tablets** Each modified release tablet contains:Naproxen.....375mg (Enteric coated Core)Esomeprazole as Magnesium Trihydrate.....20mg(Immediate Release Coat)(Innovator's Specifications) As per Innovators Specification RRA Status: Vimovo 20mg;375mg Tablet Health Canada Approved Me Too Status: Glomov 375/20mg Tablet by M/s Global Pharmaceuticals (Pvt.) Ltd (Reg#109339) Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: **Observations** 1.6.5 • Valid GMP certificate / DML of the Drug Substance manufacturer of Naproxen issued by relevant regulatory authority of country of origin is required **Firm's Response** Firm has submitted copy of cGMP certificate of API manufacturer issued by Drug Control Administration, Government of Andhra Pradesh India valid upto 25-06-2027. **Observations** 3.2.P.5 • The dissolution time of esomeprazole mentioned in analytical method (Q after 90min instead of Q at 45min) is different than that of innovator product review document, clarify **Firm's Response** The firm submitted that the dissolution time of esomeprazole mentioned in analytical method is according to the FDA Clinical Pharmacology and Bio-pharmaceutics Review of innovator product Vimovo tablets (esomeprazole magnesium and naproxen) page No 108. The dissolution time for Esomeprazole mentioned is 45 minutes and Naproxen is 60 minutes. **Observations** 3.2.P.8 • Justify the batch size of trial batches against the number of units required for complete testing of drug product during stability study including real time stability study till claimed shelf life • Stability study data of drug product at 6th month time point shall be submitted • Loan Letter for procurement of Esomeprazole is not submitted **Firm's Response** The firm submitted that the batch size of the tablets is according to the protocol of stability studies and units requirements for testing is sufficient for stability testing. Stability study data of drug product at 6th month time point is submitted Firm has provided the loan letter for Esomeprazole from M/s Biogen Life Sciences along with procurement documents attested by DRAP in name of M/s Biogen Life Sciences.	
	Decision: Approved	
41	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road (**000971**) Tracking ID: (1VP-HGW-G6WP, 2024-10-23) Fee Paid: 37000.0 Paid Date: 2024-10-01 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Carip 4.5mg Capsule** Each Capsule contains: Cariprazine Hydrochloride equivalent to Cariprazine.....4.5mg As per Innovators Specification RRA Status: VRAYLAR Capsules (USFDA Approved) Me Too Status: Arpizin Capsule by Daneen Pharma Pack Size(s): 1x5's, 1x 10's, 2x6'-As per SRO
	Evaluation Remarks:	
	Decision: Approved .	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
42	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road (**000971**) Tracking ID: (4LA-9H8-T5J2, 2024-10-24) Fee Paid: 37000.0 Paid Date: 2024-10-01 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Carip 3mg Capsule** Each Capsule contains: Cariprazine Hydrochloride equivalent to Cariprazine.....3mg As per Innovators Specification RRA Status: VRAYLAR Capsules (USFDA Approved) Me Too Status: Arpizin Capsule by Daneen Pharma Pack Size(s): 1x5's, 1x 10's, 2x6'-As per SRO
	Evaluation Remarks:	
	Decision: Approved .	
43	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road (**000971**) Tracking ID: (633-LBS-N4VU, 2024-09-30) Fee Paid: 75000.0 Paid Date: 2024-09-12 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Finren 10mg Tablet** Each Film Coated Tablet contains: Finerenone.....10mg As per Innovators Specification RRA Status: KERENDIA 10mg tablet (USFDA Approved) Me Too Status: N/A Pack Size(s): 1 X 10's, 2 X 10's, -As per SRO
	Evaluation Remarks: Finerenone is a nonsteroidal, selective antagonist of the mineralocorticoid receptor (MR) that is claimed to attenuate inflammation and fibrosis mediated by MR overactivation. 1. The innovator's product has used drug substance with a controlled particle size. Clarify if your drug substance has controlled particle size or otherwise. Response: Firm has submitted COA which specifies that particle size test is included in the specification. 2. The innovator's product has adopted 15 mins for dissolution test, while your specifications specify dissolution test in 30 mins. Clarification is required in this regard. Response: The Dissolution results obtained at 15 minutes time point is above 75% in CDP which was considered as baseline benchmark for the immediate release dosage form while We are just taking general limit of dissolution Test i.e. NLT 75%(Q) in 30 minutes. 3. Submit valid GMP certificate / DML of API manufacturer. Response: GMP certificate is Submitted by the firm	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Decision: Approved . Firm shall revise its dissolution specifications to NLT 75% (Q) within 15 minutes as per the innovator's product along with submission of requisite fee before issuance of Registration letter.	
44	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road (**000971**) Tracking ID: (687-7P6-SBXU, 2024-10-03) Fee Paid: 30000.0 Paid Date: 2023-12-13 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Cyprodol 2mg/0.035mg Tablet** Each Sugar coated tablet contains: Cyproterone acetate.....2mg, Ethinyl Estradiol.....0.035mg British Pharmacopeia RRA Status: DIANE-35 of M/s Bayer Australia, (TGA-Australian Approved) Me Too Status: Diane 35 Tablet of M/s Bayer Pakistan Pack Size(s): As per SRO / DPC-As per SRO
	Evaluation Remarks: DIANE-35 ED tablets are available in blister packs of 28 tablets. Each blister contains 21 round beige active tablets followed by 7 round white placebo tablets. Firm has Tablet section (Hormone) steroidal. Firm has also used placebo tablet. Shortcoming: Submit evidence of BP monograph for applied product, since you have claimed BP specifications while BP monograph could not be traced. Response by the firm: The BP monograph of applied product is available with the title Co-cyprindlol Tablets	
	Decision: Approved .	
45	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road (**000971**) Tracking ID: (6J4-5SW-73Y2, 2024-08-21) Fee Paid: 30000.0 Paid Date: 2023-12-13 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Levonor-D Tablet** Each Sugar Coated Tablet Contains: Levonorgestrel.....0.15mg, Ethinylestradiol .....0.03mg British Pharmacopeia RRA Status: Levest 150/30mcg Tablet (MHRA Approved) Me Too Status: Familia 28 Tablet of M/s Zafa Pharmaceutical Laboratories Pack Size(s): As per SRO / DPC-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Firm has Tablet section (Hormone) steroidal Submit documents for procurement of Levonorgestrol along with copy of GMP certificate / DML of its API manufacturer. Response: Firm has submitted procurement documents and GMP certificate of API manufacturer.	
	Decision: Approved .	
46	**Nagarsons Pharmaceuticals Pvt Ltd** Plot no 34 Street NS-2 National Industrial zone Rawat Islamabad (**000927**) Tracking ID: (8ZJ-1NA-WBDV, 2024-09-27) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **BETANAG 0.05% OINTMENT** Each gram of ointment contains: Betamethasone as Dipropionate.....5mg (0.05%w/w) United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Betadip Ointment by M/s Zafa Pharmaceuticals Pack Size(s): 15g, 20g, 30g / As p-As per SRO
	Evaluation Remarks: 1. Submit 6 month's stability study data 2. Submit loan letter from Global Pharma (No response received from the firm)	
	Decision: Deferred for following submissions: 1. 6 month's stability study data 2. Loan letter from Global Pharma	
47	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road (**000971**) Tracking ID: (9LV-HBM-WE8W, 2024-10-24) Fee Paid: 37000.0 Paid Date: 2024-10-01 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Carip 1.5mg Capsule** Each Capsule contains: Cariprazine (as cariprazine hydrochloride) .....1.5mg As per Innovators Specification RRA Status: VRAYLAR Capsule (USFDA Approved) Me Too Status: Arpizin Capsule by Daneen Pharma Pack Size(s): 1x5’s, 1x6’s, 2x7’s,-As per SRO
	Evaluation Remarks:	
	Decision: Approved .	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
48	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road (**000971**) Tracking ID: (H89-GWM-4J1T, 2024-10-24) Fee Paid: 37000.0 Paid Date: 2024-10-01 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Carip 6mg Capsule** Each Capsule contains: Cariprazine Hydrochloride equivalent to Cariprazine.....6mg As per Innovators Specification RRA Status: VRAYLAR Capsules (USFDA Approved) Me Too Status: Arpizin Capsule by Daneen Pharma Pack Size(s): 1x5's, 1x 10's, 2x6'-As per SRO
	Evaluation Remarks:	
	Decision: Approved .	
49	**Nagarsons Pharmaceuticals Pvt Ltd** Plot no 34 Street NS-2 National Industrial zone Rawat Islamabad (**000927**) Tracking ID: (JRR-XXV-TJ72, 2024-09-26) Fee Paid: 37000.0 Paid Date: 2024-09-19 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Fudinag Cream** Each gram of cream contains:Fusidic acid.....20mg (2%w/w) British Pharmacopeia RRA Status: Fucidin 20mg/g Cream HPRA Ireland Approved Me Too Status: Fuderm Cream by Seraph pharma Pack Size(s): 15g / As per SRO / D-As per SRO
	Evaluation Remarks:	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
50	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road (**000971**) Tracking ID: (G6E-9DL-X6S6, 2024-09-30) Fee Paid: 75000.0 Paid Date: 2024-09-12 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Finren 20mg Tablet** Each Film Coated Tablet contains: Finerenone.....20mg As per Innovators Specification RRA Status: KERENDIA 20mg tablet (USFDA Approved) Me Too Status: N/A Pack Size(s): 1 X 10's, 2 X 10's, -As per SRO
	Evaluation Remarks: Finerenone is a nonsteroidal, selective antagonist of the mineralocorticoid receptor (MR) that is claimed to attenuate inflammation and fibrosis mediated by MR overactivation 1. The innovator's product has used drug substance with a controlled particle size. Clarify if your drug substance has controlled particle size or otherwise. Response: Firm has submitted COA which specifies that particle size test is included in the specification. 2. The innovator's product has adopted 15 mins for dissolution test, while your specifications specify dissolution test in 30 mins. Clarification is required in this regard. Response: The Dissolution results obtained at 15 minutes time point is above 75% in CDP which was considered as baseline benchmark for the immediate release dosage form while We are just taking general limit of dissolution Test i.e. NLT 75%(Q) in 30 minutes. 3. The innovator's product has used Acetate buffer pH 4.5 + 0.1% Tween 20 as a dissolution medium while you have not used tween 20. Clarification is required in this regard. Response: The innovator's product has used Acetate buffer pH 4.5 + 0.1% Tween 20 as a dissolution medium while We also used tween 20 its a typing error we revised the method of Analysis and attached. 4. Submit valid GMP certificate / DML of API manufacturer. Response: GMP certificate is Submitted by the firm	
	Decision: Approved . Firm shall revise its dissolution specifications to NLT 75% (Q) within 15 minutes as per the innovator's product along with submission of requisite fee before issuance of Registration letter.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
51	**Skywin Pharmaceutical** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road (**000971**) Tracking ID: (XWE-5P5-EVVJ, 2024-10-31) Fee Paid: 75000.0 Paid Date: 2024-10-01 Case Category: New License **(Dr. Muhmmad Haseeb Tariq)**	Proposed Name: **Maltofer 30mg Capsule** Each Capsule contains: Iron (as Ferric Maltol).....30mg As per Innovators Specification RRA Status: ACCRUFeR (Ferric Maltol) 30mg capsules of M/s Shield Therapeutics Inc. (USFDA Approved) Me Too Status: N/A Pack Size(s): 1x6's, 2x7's, 1 x 10-As per SRO
	Evaluation Remarks: Submit loan documents from wimits pharma. Response: Firm has submitted loan letter dated 25-10-2023 from Wimits pharma. Firm has also submitted copy of drug import license dated 27-06-2023.	
	Decision: Approved	
52	**Nutrion private limited** plot no S 186-187-192-193 Industrial area Mir Pur A.J.K Pakistan (**000983**) Tracking ID: (1SD-NA6-VY7D, 2024-12-02) Fee Paid: 37000.0 Paid Date: 2024-12-02 Case Category: New License **(Najia Saleem)**	Proposed Name: **Florikol-11** Each 100ml Contains: Flofenicol ..... 11gm Colistin Sulphate 50MIU As per Innovators Specification RRA Status: - Me Too Status: FLORFARM Liquid (Reg. # 097997) M/S Farmaid Group Hattar Pack Size(s): 1x100ml 1X250ml -De-Controlled
	Evaluation Remarks: Liquid syrup (General-Vet) section was granted vide letter No. F. 1-17/2017-Lic dated 11-11-2024	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
53	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (2DU-GEN-SR4W, 2024-10-10) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **META PRED INJECTION** Each ml contains (As Per Innovator Spec.) Prednisolone as acetate.....7.5mg Dexamethasone as sodium phosphate.....2.5mg As per Innovators Specification RRA Status: N/A Me Too Status: DURACORT INJECTION (073913) MY LAB BAHAWALPUR Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
54	**Nutrion private limited** plot no S 186-187-192-193 Industrial area Mir Pur A.J.K Pakistan (**000983**) Tracking ID: (384-XB9-W7U9, 2024-12-02) Fee Paid: 37000.0 Paid Date: 2024-12-02 Case Category: New License **(Najia Saleem)**	Proposed Name: **MENTIBROX-60** Each ml contains: Menthol ..... 40mg Bromhexine HCl ..... 20mg As per Innovators Specification RRA Status: - Me Too Status: BROMO-PLUS Oral Liquid (Reg. # 073917) m/s eLEGANCE pHARMACEUTICALS Pack Size(s): 1x100ml 1X250ml -De-Controlled
	Evaluation Remarks: Liquid syrup (General-Vet) section was granted vide letter No. F. 1-17/2017-Lic dated 11-11-2024	
	Decision: Approved	
55	**Nutrion private limited** plot no S 186-187-192-193 Industrial area Mir Pur A.J.K Pakistan (**000983**) Tracking ID: (3L6-14D-VB9X, 2024-12-02) Fee Paid: 37000.0 Paid Date: 2024-12-02 Case Category: New License **(Najia Saleem)**	Proposed Name: **Netriflox-C 45** Each 100ml contains Enrofloxacin ..... 20gm Colistin sulphate ..... 50 MIU As per Innovators Specification RRA Status: - Me Too Status: FLOXICOL Oral Liquid (Reg. # 058966) M/s Biogen Pharma Pack Size(s): 1000ml-De-Controlled,100ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Liquid syrup (General-Vet) section was granted vide letter No. F. 1-17/2017-Lic dated 11-11-2024	
	Decision: Approved	
56	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (275-ZBL-4EWY, 2024-10-10) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **BRODEX INJECTION** Each ml contains (As Per Innovators Spec.) Colistin Sulphate ..... 1250mg Tylosin as tartrate .....10mg Bromhexine HCl.....100mg Dexamethasone as Sodium Phosphate ....50 mg As per Innovators Specification RRA Status: N/A Me Too Status: COLITYLO PLUS INJECTION (052336) ALINA COMBINE KARACHI Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
57	**Nutrion private limited** plot no S 186-187-192-193 Industrial area Mir Pur A.J.K Pakistan (**000983**) Tracking ID: (3TE-LHX-X6QZ, 2024-12-02) Fee Paid: 37000.0 Paid Date: 2024-12-02 Case Category: New License **(Najia Saleem)**	Proposed Name: **Netriflor-25** Each 100ml contains: Flofenicol ..... 25% As per Innovators Specification RRA Status: - Me Too Status: FLORFENICOL Oral Liquid (Reg. # 075707) ms Attabak Pharmaceuticals Isb Pack Size(s): 1000ml-De-Controlled,100ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
	Evaluation Remarks: Liquid syrup (General-Vet) section was granted vide letter No. F. 1-17/2017-Lic dated 11-11-2024	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
58	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (486-NBL-14E3, 2024-10-09) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **P-RED 25 INJECTION** Each ml contains Prednisolone Acetate..... 25mg British Pharmacopeia RRA Status: N/A Me Too Status: PREDISON INJECTION 2.5% (035091) MANHATTAN PHARMA KARACHI Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
59	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (4WG-735-7WAL, 2024-10-11) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **KANASONE INJECTION** Each ml contains(As Per Innovators Spec.) Kanamycin Sulphate .....50mg Colistine Sulphate .....100,000IU Neomycin Sulphate.....50mg Dexamethasone Sodium Phospahte .....0.5 mg As per Innovators Specification RRA Status: N/A Me Too Status: KONODEX INJECTION (052347) ALINA COMBINE KARACHI Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
60	**Nutrion private limited** plot no S 186-187-192-193 Industrial area Mir Pur A.J.K Pakistan (**000983**) Tracking ID: (5TE-9VS-MHT8, 2024-12-02) Fee Paid: 37000.0 Paid Date: 2024-12-02 Case Category: New License **(Najia Saleem)**	Proposed Name: **Vertix 10 Oral Drench** Each ml contain Ivermectin ..... 10mg As per Innovators Specification RRA Status: - Me Too Status: ORAMECTIN Liquid (Reg. # 062141 m/s Attabak Pharma Pack Size(s): 1000ml-De-Controlled,100ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
	Evaluation Remarks: Liquid syrup (General-Vet) section was granted vide letter No. F. 1-17/2017-Lic dated 11-11-2024	
	Decision: Approved	
61	**Nutrion private limited** plot no S 186-187-192-193 Industrial area Mir Pur A.J.K Pakistan (**000983**) Tracking ID: (63B-W2N-D2BV, 2024-12-02) Fee Paid: 37000.0 Paid Date: 2024-12-02 Case Category: New License **(Najia Saleem)**	Proposed Name: **Netriflox-C 40** 100ml contains: Enrofloxacin ..... 20gm Colistin sulphate ... 20 MIU As per Innovators Specification RRA Status: - Me Too Status: EC Skill-40 Oral Liquid (Reg. # 111255) m/s Bio Skil Pharmaceuticals Pack Size(s): 1000ml-De-Controlled,100ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
	Evaluation Remarks: Liquid syrup (General-Vet) section was granted vide letter No. F. 1-17/2017-Lic dated 11-11-2024	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
62	**Nutrion private limited** plot no S 186-187-192-193 Industrial area Mir Pur A.J.K Pakistan (**000983**) Tracking ID: (65J-13X-352H, 2024-12-02) Fee Paid: 37000.0 Paid Date: 2024-12-02 Case Category: New License **(Najia Saleem)**	Proposed Name: **ENCOBROX Oral Liquid** Each 100ml contain Enrofloxacin (BP Vet) 10 gm Colistin sulphate 50 MIU Bromhexine HCl 5gm as per innovators specifications As per Innovators Specification RRA Status: - Me Too Status: INTER FLOX Oral Liquid (Reg. # 078241) Pack Size(s): 1x100ml 1X250ml -De-Controlled
	Evaluation Remarks: Liquid syrup (General-Vet) section was granted vide letter No. F. 1-17/2017-Lic dated 11-11-2024	
	Decision: Approved	
63	**Nutrion private limited** plot no S 186-187-192-193 Industrial area Mir Pur A.J.K Pakistan (**000983**) Tracking ID: (6WJ-LP9-4EUG, 2024-12-02) Fee Paid: 37000.0 Paid Date: 2024-12-02 Case Category: New License **(Najia Saleem)**	Proposed Name: **Wheeze - 5 Oral Liquid** Each ml contain Bromhexine HCl ..... 50mg As per Innovators Specification RRA Status: - Me Too Status: BROMOMONT Oral Liquid (Reg. # 063742) m/s Westmont Pharma Pack Size(s): 1000ml-De-Controlled,100ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
	Evaluation Remarks: Liquid syrup (General-Vet) section was granted vide letter No. F. 1-17/2017-Lic dated 11-11-2024	
	Decision: Approved	
64	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (6J6-15W-G7R4, 2024-10-11) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **TRIPELSONE INJECTION** Each ml contain (As Per Innovator Spec.) Oxytetracycline HCl.....150mg Dexamethasone Sodium Phosphate..... 0.5mg Tripelennamine HCl.....10mg As per Innovators Specification RRA Status: N/A Me Too Status: DECALINE INJECTION (028543) HILTON PHARMA KARACHI Pack Size(s): 10ml-De-Controlled

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
65	**Nutrion private limited** plot no S 186-187-192-193 Industrial area Mir Pur A.J.K Pakistan (**000983**) Tracking ID: (86Y-T4V-Q3H6, 2024-12-02) Fee Paid: 37000.0 Paid Date: 2024-12-02 Case Category: New License **(Najia Saleem)**	Proposed Name: **Netriflox-C 50** Each 100ml contain Enrofloxacin ..... 25gm Colistin sulphate ..... 50 MIU As per Innovators Specification RRA Status: - Me Too Status: VITAFLOX-C 25% Oral Liquid (Reg. # 079276) m/s Vetz Pharmaceuticals Pack Size(s): 1000ml-De-Controlled,100ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
	Evaluation Remarks: Liquid syrup (General-Vet) section was granted vide letter No. F. 1-17/2017-Lic dated 11-11-2024	
	Decision: Approved	
66	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (964-3M4-X9AE, 2024-10-10) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **DEXSONE INJECTION** Each 100ml contains (As Per Innovator Spec.) Tylosin as tartrate .....15gm Gentamycin as Sulphate.....6gm Dexamethasone as sodium phosphate....0.0265gm Chlorpheniramine Maleate.....0.75gm As per Innovators Specification RRA Status: N/A Me Too Status: GENTA COMBISONE INJECTION (046696) LEADS PHARMA Pack Size(s): 10ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
67	**Nutrion private limited** plot no S 186-187-192-193 Industrial area Mir Pur A.J.K Pakistan (**000983**) Tracking ID: (9SJ-V2A-QZG1, 2024-12-02) Fee Paid: 37000.0 Paid Date: 2024-12-02 Case Category: New License **(Najia Saleem)**	Proposed Name: **Netriflor-23** Each 100ml contain Flofenicol ..... 23% As per Innovators Specification RRA Status: - Me Too Status: NEFLOX Oral Liquid (Reg. # 049647) m/s Selmore Pharma Lahore Pack Size(s): 1000ml -De-Controlled,100ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
	Evaluation Remarks: Liquid syrup (General-Vet) section was granted vide letter No. F. 1-17/2017-Lic dated 11-11-2024	
	Decision: Approved	
68	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (9U5-DU2-2YAV, 2024-10-11) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **TYLONE 75 INJECTION** Each ml contains (As Per Innovator Spec.) Prednisolone Acetate.....7.55mg :- Tylosin Tartrate.....100mg Oxytetracycline HCL.....50mg As per Innovators Specification RRA Status: N/A Me Too Status: TYLOX-P INJECTION (063789) BREEZE PHARMA Pack Size(s): 10ml-De-Controlled
	Evaluation Remarks: Me-too/generic status could not be confirmed	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
69	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (97W-9LM-2P4U, 2024-10-11) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **KANASONE INJECTION** Each ml contains (As Per Innovators Spec.) Kanamycin Sulphate .....50mg Colistine Sulphate .....100,000IU Neomycin Sulphate.....50mg Dexamethasone Sodium Phospahte .....0.5 mg As per Innovators Specification RRA Status: N/A Me Too Status: KONODEX INJECTION (052347) ALINA COMBINE KARACHI Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
70	**Nutrion private limited** plot no S 186-187-192-193 Industrial area Mir Pur A.J.K Pakistan (**000983**) Tracking ID: (A29-B95-6DM9, 2024-12-02) Fee Paid: 37000.0 Paid Date: 2024-12-02 Case Category: New License **(Najia Saleem)**	Proposed Name: **MENTIBROX-90** Each ml contain Menthol ..... 40mg Bromhexine HCl..... 50mg As per Innovators Specification RRA Status: - Me Too Status: Manster B-90 Oral Liquid (Reg. # 101499) m/s Aamster Laboratories, Rawat Pack Size(s): 1X250ml -De-Controlled,1000ml-De-Controlled,1x100ml-De-Controlled,500ml-De-Controlled
	Evaluation Remarks: Liquid syrup (General-Vet) section was granted vide letter No. F. 1-17/2017-Lic dated 11-11-2024	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
71	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (AR8-WNV-QU5Z, 2024-10-08) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **P-RED 10 INJECTION** Each ml contains Prednisolone Acetate..... 10mg British Pharmacopeia RRA Status: N/A Me Too Status: GP-Pred Injection (111541) M/s Grand Pharma (Pvt) Ltd., Islamabad Pack Size(s): 10ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
72	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (ASH-XUJ-W2PX, 2024-10-10) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **BRODEX INJECTION** Each ml contains (As Per Innovators Spec.) Colistin Sulphate ..... 1250mg Tylosin as tartrate .....10mg Bromhexine HCl.....100mg Dexamethasone as Sodium Phosphate ....50 mg As per Innovators Specification RRA Status: N/A Me Too Status: COLITYLO PLUS INJECTION (052336) ALINA COMBINE KARACHI Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
73	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (BNR-67A-39L2, 2024-10-11) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **TYLONE 50 INJECTION** Each ml contains (As Per Innovator Spec.) Prednisolone Acetate..... 5mg :- Tylosin Tartrate.....100mg Oxytetracycline HCL.....50mg As per Innovators Specification RRA Status: N/A Me Too Status: TOP-VET INJECTION (059180) BREEZE PHARMA Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
74	**Nutrion private limited** plot no S 186-187-192-193 Industrial area Mir Pur A.J.K Pakistan (**000983**) Tracking ID: (BUS-WL9-Q5GZ, 2024-12-02) Fee Paid: 37000.0 Paid Date: 2024-12-02 Case Category: New License **(Najia Saleem)**	Proposed Name: **Florikol-25** Each 100ml contains: Flofenicol ..... 25% Colistin Sulphate ..... 50MIU As per Innovators Specification RRA Status: - Me Too Status: TYE-FOL Oral Liquid (Reg. # 092176) M/S Farm Aid Group Pack Size(s): 1x100ml 1X250ml -De-Controlled
	Evaluation Remarks: Submit revised master formula stating correct quantities of APIs.	
	Decision: Approved Firm shall submit revised master formula stating correct quantities of APIs along with fee of Rs.9000/- vide SRO 1324 dated 30-08-2024 before issuance of registration letter.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
75	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (D4U-A4Q-9R26, 2024-10-11) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **TRIPELSONE INJECTION** Each ml contain (As Per Innovator Spec.) Oxytetracycline HCl.....150mg Dexamethasone Sodium Phosphate..... 0.5mg Tripelennamine HCl.....10mg As per Innovators Specification RRA Status: N/A Me Too Status: DECALINE INJECTION (028543) HILTON PHARMA KARACHI Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
76	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (DJD-MV7-69XL, 2024-10-10) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **P PHEN 35 INJECTION** Each ml contains Prednisolone acetate .....25mg Chlorpheniramine Maleate.....10mg As per Innovators Specification RRA Status: N/A Me Too Status: PREDMINE INJECTION (057084) CHERISHED PHARMA LAHORE Pack Size(s): 10ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
77	**Nutrion private limited** plot no S 186-187-192-193 Industrial area Mir Pur A.J.K Pakistan (**000983**) Tracking ID: (DJE-248-Z6NG, 2024-12-02) Fee Paid: 37000.0 Paid Date: 2024-12-02 Case Category: New License **(Najia Saleem)**	Proposed Name: **MENTIBROX-30** Each ml contains: Menthol..... 20mg Bromhexine HCl ..... 10mg As per Innovators Specification RRA Status: - Me Too Status: BROMOTIN Oral Liquid (Reg. # 073999) Elegence Pharmaceuticals Pack Size(s): 1x100ml 1X250ml -De-Controlled
	Evaluation Remarks: Liquid syrup (General-Vet) section was granted vide letter No. F. 1-17/2017-Lic dated 11-11-2024	
	Decision: Approved	
78	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (GVE-9MH-J9TB, 2024-10-11) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **THIASIN RED INJECTION** Each ml contains (As Per Innovator Spec.) Thiamphenicol.....200mg Prednisolone as Acetate .....5mg Tylosin as Tartrate ..... 57.5mg As per Innovators Specification RRA Status: N/A Me Too Status: TRIOX-P INJECTION (069638) S.J FAZUL ELLAHI, KARACHI Pack Size(s): 20ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
79	**Hirra Pharmaceutical Laboratories (Pvt) Ltd** 3A, 2nd floor, Queen's Center, Queen's Road, (**000449**) Tracking ID: (J5V-9JT-999D, 2024-12-02) Fee Paid: 37000.0 Paid Date: 2024-12-02 Case Category: New Section **(Najia Saleem)**	Proposed Name: **HIRRA LINCO-AMOXTIN WATER SOLUBLE POWDER** Each 100GM Contains: AMOXICILLIN AS TRIHYDRATE ..... 20gm LINCOMYCIN AS HCL ..... 09gm SPECTINOMYCIN 2HCL..... 8.8gm As per Innovators Specification RRA Status: N/A Me Too Status: LINCO MOXTIN Water soluble powder ,M/S ORION Pharma (Pvt.) Ltd Pack Size(s): 01 KG-De-Controlled,50 GM-De-Controlled
	Evaluation Remarks: Target species: cattle, sheep, and poultry	
	Decision: Approved	
80	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (H8D-UAW-3QJD, 2024-10-11) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **DEXSONE INJECTION** Each 100ml contains (As Per Innovator Spec.) Tylosin as tartrate .....15gm Gentamycin as Sulphate.....6gm Dexamethasone as sodium phosphate....0.0265gm Chlorpheniramine Maleate.....0.75gm As per Innovators Specification RRA Status: N/A Me Too Status: GENTA COMBISONE INJECTION (046696) LEADS PHARMA Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
81	**Nutrion private limited** plot no S 186-187-192-193 Industrial area Mir Pur A.J.K Pakistan (**000983**) Tracking ID: (LRW-4EP-AAQU, 2024-12-02) Fee Paid: 37000.0 Paid Date: 2024-12-02 Case Category: New License **(Najia Saleem)**	Proposed Name: **Netriflor-20** Each 100ml containFlofenicol ..... 20% As per Innovators Specification RRA Status: - Me Too Status: PRI-FLORCOL Oral Liquid (Reg. # 080928) M/s Prix Pharmaceuticals Pack Size(s): 1000ml-De-Controlled,100ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
	Evaluation Remarks: Liquid syrup (General-Vet) section was granted vide letter No. F. 1-17/2017-Lic dated 11-11-2024	
	Decision: Approved	
82	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (MDT-1B3-J7DQ, 2024-10-09) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **MEDEX 2 INJECTION** Each 2 ml contains Dexamethasone Sodium Phosphate Eq. to 4mg Dexamethasone Base British Pharmacopeia RRA Status: N/A Me Too Status: DEXAMETHASONE INJECTION (017071) ELKO ORGANIZATION KARACHI Pack Size(s): 10ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
83	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (L6U-JHQ-GU5A, 2024-10-10) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **BRODEX INJECTION** Each ml contains (As Per Innovators Spec.) Colistin Sulphate ..... 1250mg Tylosin as tartrate .....10mg Bromhexine HCl.....100mg Dexamethasone as Sodium Phosphate ....50 mg As per Innovators Specification RRA Status: N/A Me Too Status: COLITYLO PLUS INJECTION (052336) ALINA COMBINE KARACHI Pack Size(s): 10ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
84	**Nutrion private limited** plot no S 186-187-192-193 Industrial area Mir Pur A.J.K Pakistan (**000983**) Tracking ID: (MU6-7V1-2NTR, 2024-12-02) Fee Paid: 37000.0 Paid Date: 2024-12-02 Case Category: New License **(Najia Saleem)**	Proposed Name: **Florikol-23** Each 100ml contain Flofenicol .....23% Colistin Sulphate..... 50MIU As per Innovators Specification RRA Status: - Me Too Status: MAXIFLOR PLUS Oral Liquid (Reg. # 075617 M/S Biogen Pharma Pack Size(s): 1x100ml 1X250ml -De-Controlled
	Evaluation Remarks: Submit evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
	Decision: Deferred Firm shall submit evidence of applied formulation/drug, **in the applied strength**, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
85	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (NVP-NH2-SUTA, 2024-10-08) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **P-RED 10 INJECTION** Each ml contains Prednisolone Acetate..... 10mg British Pharmacopeia RRA Status: N/A Me Too Status: ACETOSOL INJECTION (099030) INTERNATIONAL PHARMA Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
86	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (P33-HP4-GQDS, 2024-10-11) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **TYLONE 75 INJECTION** Each ml contains (As Per Innovator Spec.) Prednisolone Acetate.....7.55mg :- Tylosin Tartrate.....100mg Oxytetracycline HCL.....50mg As per Innovators Specification RRA Status: N/A Me Too Status: TYLOX-P INJECTION (063789) BREEZE PHARMA Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: Me-too/generic status could not be confirmed	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
87	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (PUE-G28-RRNA, 2024-10-11) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **THIASIN RED INJECTION** Each ml contains (As Per Innovator Spec.) Thiamphenicol.....200mg Prednisolone as Acetate .....5mg Tylosin as Tartrate ..... 57.5mg As per Innovators Specification RRA Status: N/A Me Too Status: TRIOX-P INJECTION (069638) S.J FAZUL ELLAHI, KARACHI Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
88	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (Q3N-ABL-UVM8, 2024-10-10) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **P PHEN 14 INJECTION** Each ml contains Prednisolone as Acetate ..... 10mg Chlorpheniramine Maleate..... 4mg As per Innovators Specification RRA Status: N/A Me Too Status: SOLOMIN INJECTION (049642) SELMORE PHARMA LAHORE Pack Size(s): 10ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
89	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (QGJ-JX6-2Y7G, 2024-10-11) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **TRIPELSONE INJECTION** Each ml contains (As Per Innovator Spec.) Oxytetracycline HCl.....150mg Dexamethasone Sodium Phosphate..... 0.5mg Tripelennamine HCl.....10mg As per Innovators Specification RRA Status: N/A Me Too Status: DECALINE INJECTION (028543) HILTON PHARMA KARACHI Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
90	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (QGT-AV2-LVNR, 2024-10-11) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **TYLONE 50 INJECTION** Each ml contains (As Per Innovator Spec.) Prednisolone Acetate..... 5mg :- Tylosin Tartrate.....100mg Oxytetracycline HCL.....50mg As per Innovators Specification RRA Status: N/A Me Too Status: TOP-VET INJECTION (059180) BREEZE PHARMA Pack Size(s): 10ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
91	**Nutrion private limited** plot no S 186-187-192-193 Industrial area Mir Pur A.J.K Pakistan (**000983**) Tracking ID: (S47-ZP1-T9D4, 2024-12-02) Fee Paid: 37000.0 Paid Date: 2024-12-02 Case Category: New License **(Najia Saleem)**	Proposed Name: **Wheeze-10 Oral Liquid** Each ml contain Bromhexine HCl ..... 100mg As per Innovators Specification RRA Status: - Me Too Status: Ebrom Lytic 10% Oral Liquid (Reg. # 099317) M/S VETEC Laboratories Rawat Pack Size(s): 1000ml-De-Controlled,100ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
	Evaluation Remarks: Liquid syrup (General-Vet) section was granted vide letter No. F. 1-17/2017-Lic dated 11-11-2024	
	Decision: Approved	
92	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (NBW-YDU-RY76, 2024-10-10) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **DEXSONE INJECTION** Each 100ml contains (As Per Innovator Spec.) Tylosin as tartrate .....15gm Gentamycin as Sulphate.....6gm Dexamethasone as sodium phosphate....0.0265gm Chlorpheniramine Maleate.....0.75gm As per Innovators Specification RRA Status: N/A Me Too Status: GENTA COMBISONE INJECTION (046696) LEADS PHARMA Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
93	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (S6D-DBA-Q1YH, 2024-10-09) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **MEDEX 4 INJECTION** Each ml contains Dexamethasone Sodium Phosphate ..... 4mg British Pharmacopeia RRA Status: N/A Me Too Status: B.G DEXAMETH INJECTION (072646) BIOGEN PHARMA RAWAT Pack Size(s): 10ml-De-Controlled
	Evaluation Remarks: The official monograph of applied formulation does not exist in BP vet	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
94	**Nutrion private limited** plot no S 186-187-192-193 Industrial area Mir Pur A.J.K Pakistan (**000983**) Tracking ID: (SM4-AN3-4WGE, 2024-12-02) Fee Paid: 37000.0 Paid Date: 2024-12-02 Case Category: New License **(Najia Saleem)**	Proposed Name: **Vertix 0.8 Oral Drench** Each ml contain Ivermectin 0.8mg/ml As per Innovators Specification RRA Status: - Me Too Status: IVOTEK DRENCH (Reg. # 026541) m/s Star Laboratories Lahore Pack Size(s): 1000ml-De-Controlled,100ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
	Evaluation Remarks: Liquid syrup (General-Vet) section was granted vide letter No. F. 1-17/2017-Lic dated 11-11-2024	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
95	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (T58-Q56-AYTE, 2024-10-10) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **META PRED INJECTION** Each ml contains (As Per Innovator Spec.) Prednisolone as acetate.....7.5mg Dexamethasone as sodium phosphate.....2.5mg As per Innovators Specification RRA Status: N/A Me Too Status: DURACORT INJECTION (073913) MY LAB BAHAWALPUR Pack Size(s): 10ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
96	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (TH2-M4X-U7U1, 2024-10-10) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **P PHEN 14 INJECTION** Each ml contains Prednisolone as acetate .....10mg Chlorpheniramine Maleate.....4mg As per Innovators Specification RRA Status: N/A Me Too Status: SOLOMIN INJECTION (049642) SELMORE PHARMA LAHORE Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
97	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (THD-BDD-XHEZ, 2024-10-09) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **MEDEX 2 INJECTION** Each 2 ml contains Dexamethasone Sodium Phosphate Eq. to 4mg Dexamethasone Base British Pharmacopeia RRA Status: N/A Me Too Status: DEXAMETHASONE INJECTION (017071) ELKO ORGANIZATION KARACHI Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
98	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (TVV-278-XT2U, 2024-10-10) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **MEDEX 5 INJECTION** Each ml contains Dexamethasone as Sodium Phosphate ..... 5mg British Pharmacopeia RRA Status: N/A Me Too Status: F-Dex 5 Injection 114934 of M/s Farm Aid Group, Haripur. Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: The monograph of the applied formulation does not exist in BP vet.	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
99	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (RG4-H18-2TJV, 2024-10-10) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **MEDEX 4 INJECTION** Each ml contains Dexamethasone Sodium Phosphate ..... 4mg British Pharmacopeia RRA Status: N/A Me Too Status: B.G DEXAMETH INJECTION (072646) BIOGEN PHARMA RAWAT Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: The official monograph of applied formulation does not exist in BP vet. Standardization of formulation in line with pharmacopeial monograph in USP along with fee.	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
100	**Nutrion private limited** plot no S 186-187-192-193 Industrial area Mir Pur A.J.K Pakistan (**000983**) Tracking ID: (V2L-P93-Q1HM, 2024-12-02) Fee Paid: 37000.0 Paid Date: 2024-12-02 Case Category: New License **(Najia Saleem)**	Proposed Name: **FLOFAX ORAL LIQUID** Each 100ml Contain: Ofloxacin ..... 10 gm As per Innovators Specification RRA Status: - Me Too Status: OFLOBAK Oral Liquid (Reg. # 063829 Pack Size(s): 1x100ml 1X250ml -De-Controlled
	Evaluation Remarks: Liquid syrup (General-Vet) section was granted vide letter No. F. 1-17/2017-Lic dated 11-11-2024	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
101	**Nutrion private limited** plot no S 186-187-192-193 Industrial area Mir Pur A.J.K Pakistan (**000983**) Tracking ID: (VSP-S9E-E1BB, 2024-12-02) Fee Paid: 37000.0 Paid Date: 2024-12-02 Case Category: New License **(Najia Saleem)**	Proposed Name: **REVOXAL ORAL LIQUID** Each 100ml contain OXOLINIC ACID ..... 10 gm As per Innovators Specification RRA Status: - Me Too Status: Vet Oxol Oral Liquid (Reg. # 046668) Leeds pharma Pack Size(s): 1000ml-De-Controlled,100ml-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
	Evaluation Remarks: Liquid syrup (General-Vet) section was granted vide letter No. F. 1-17/2017-Lic dated 11-11-2024	
	Decision: Approved	
102	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (W7T-WRJ-99TD, 2024-10-09) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **MEDEX 1 INJECTION** Each ml contains Dexamethasone (as sodium phosphate) .....1 mg British Pharmacopeia RRA Status: N/A Me Too Status: DEXAMETHASONE 1MG/ML INJECTION (031511) VENUS PHARMA Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
103	**Hirra Pharmaceutical Laboratories (Pvt) Ltd** 3A, 2nd floor, Queen's Center, Queen's Road, (**000449**) Tracking ID: (RS9-13Y-G26P, 2024-12-02) Fee Paid: 37000.0 Paid Date: 2024-12-02 Case Category: New Section **(Najia Saleem)**	Proposed Name: **HIRRA LIZO PLUS WATER SOLUBLE POWDER** Each gm Contains: AMOXICILLIN AS TRIHYDRATE----------50MG LYSOZYME HCL----------10MG GUAIFENESIN----------35MG As per Innovators Specification RRA Status: N/A Me Too Status: Lyzomox Water Soluble Powder M/S DECCENT PHARMA (Pvt.) Ltd. (REG,NO,079842) Pack Size(s): 1000gm-De-Controlled,100gm-De-Controlled,20 gm-De-Controlled,250gm-De-Controlled,25kg-De-Controlled,500 gm-De-Controlled,5kg-De-Controlled
	Evaluation Remarks: Target species: Horses, dogs, cats	
	Decision: Approved	
104	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (WTU-DLZ-5SQZ, 2024-10-10) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **MEDEX 4 INJECTION** Each ml contains Dexamethasone Sodium Phosphate ..... 4mg British Pharmacopeia RRA Status: N/A Me Too Status: B.G DEXAMETH INJECTION (072646) BIOGEN PHARMA RAWAT Pack Size(s): 50ml-De-Controlled
	Evaluation Remarks: The official monograph of applied formulation does not exist in BP vet. Standardization of formulation in line with pharmacopeial monograph in USP along with fee.	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
105	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (XY4-NM5-3TVV, 2024-10-10) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **META PRED INJECTION** Each ml contains (As Per Innovator Spec.) Prednisolone as acetate.....7.5mg Dexamethasone as sodium phosphate.....2.5mg As per Innovators Specification RRA Status: N/A Me Too Status: DURACORT INJECTION (073913) MY LAB BAHAWALPUR Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
106	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (XZJ-W7Q-JZR5, 2024-10-11) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **TYLONE 75 INJECTION** Each ml contains (As Per Innovator Spec.) Prednisolone Acetate.....7.55mg :- Tylosin Tartrate.....100mg Oxytetracycline HCL.....50mg As per Innovators Specification RRA Status: N/A Me Too Status: TYLOX-P INJECTION (063789) BREEZE PHARMA Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: Me-too/generic status could not be confirmed	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
107	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (Y7T-43B-ND4A, 2024-10-10) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **P PHEN 14 INJECTION** Each ml contains Prednisolone as Acetate ..... 10mg Chlorpheniramine Maleate..... 4mg As per Innovators Specification RRA Status: N/A Me Too Status: SOLOMIN INJECTION (049642) SELMORE PHARMA LAHORE Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
108	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (Y9M-NYP-YV17, 2024-10-09) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **P-RED 25 INJECTION** Each ml contains Prednisolone Acetate..... 25mg British Pharmacopeia RRA Status: N/A Me Too Status: PREDISON INJECTION 2.5% (035091) MANHATTAN PHARMA KARACHI Pack Size(s): 10ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
109	**Nutrion private limited** plot no S 186-187-192-193 Industrial area Mir Pur A.J.K Pakistan (**000983**) Tracking ID: (ZAQ-9MX-EG5D, 2024-12-02) Fee Paid: 37000.0 Paid Date: 2024-12-02 Case Category: New License **(Najia Saleem)**	Proposed Name: **CYPRON** 1 ml contains: Cypermethrin .... 100mg As per Innovators Specification RRA Status: - Me Too Status: ECTORID SOLUTION (Reg. # 078372) M/S Symans Pharmaceuticals, Lahore Pack Size(s): 1x10ml, 1x20ml, 1x50-De-Controlled
	Evaluation Remarks: Liquid syrup (General-Vet) section was granted vide letter No. F. 1-17/2017-Lic dated 11-11-2024 while the applied formulation is topical solution.	
	Decision: Rejected The instant application is for topical solution while the firm was granted DML (afresh) with only Liquid Syrup (General-Vet) section. Moreover, firm's quota of priority consideration against the new DML will also be deducted in leiu of consideration of instant application.	
110	**Hirra Pharmaceutical Laboratories (Pvt) Ltd** 3A, 2nd floor, Queen's Center, Queen's Road, (**000449**) Tracking ID: (ZGH-BTT-TH6G, 2024-12-02) Fee Paid: 37000.0 Paid Date: 2024-12-02 Case Category: New Section **(Najia Saleem)**	Proposed Name: **HIRRA PSB-100 POWDER** Each Kg Contains: Procaine Penicillin ..... 12gm Streptomycin Sulphate ..... 36gm Zinc Bacitracin (10%) ..... 52gm As per Innovators Specification RRA Status: N/A Me Too Status: PSB-100 Powder, M/S Nawan Pharmaceutical Laboratories (Pvt.) Ltd Pack Size(s): 2.5 Kg-De-Controlled,25.0 kg-De-Controlled,5.0 kg-De-Controlled,500 gm-De-Controlled
	Evaluation Remarks: Target species: cattle, calves, sheep	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
111	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (ZXJ-TVJ-GJXV, 2024-10-10) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **MEDEX 5 INJECTION** Each ml contains Dexamethasone as Sodium Phosphate ..... 5mg British Pharmacopeia RRA Status: N/A Me Too Status: F-Dex 5 Injection 114935 of M/s Farm Aid Group, Haripur. Pack Size(s): 100ml-De-Controlled
	Evaluation Remarks: The monograph of the applied formulation does not exist in BP vet.	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	
112	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK (**000991**) Tracking ID: (ZZ4-38E-JDWA, 2024-10-10) Fee Paid: 37000.0 Paid Date: 2024-09-24 Case Category: New License **(Najia Saleem)**	Proposed Name: **P PHEN 35 INJECTION** Each ml contains (As Per Innovator Spec.) Prednisolone acetate .....25mg Chlorpheniramine Maleate.....10mg As per Innovators Specification RRA Status: N/A Me Too Status: PREDMINE INJECTION (057084) CHERISHED PHARMA LAHORE Pack Size(s): 20ml-De-Controlled
	Evaluation Remarks:	
	Decision: Deferred Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
113	**Global Pharmaceuticals Pakistan** Plot # 8, Street # S-8, RCCI, Industrial Estate Rawat, Islamabad-Pakistan (**000724**) Tracking ID: (1DE-6UP-3BBV, 2023-12-05) Fee Paid: 75000.0 Paid Date: 2023-11-22 Case Category: Routine **(Saima Hussain)**	Proposed Name: **Relinco 600mg Injection** Each 2ml ampoule contains: Lincomycin (as HCl).....600mg United States Pharmacopeia RRA Status: USFDA Approved Me Too Status: Licomycin 600mg/2ml Injection by Iqra Pharmaceuticals, Islamabad Pack Size(s): 1's-As per SRO,10's-As per SRO,25's-As per SRO,50's-As per SRO
	Manufacturer(s): Formulation-Global Pharmaceuticals (Pvt) Ltd.-Plot # 204-205 Industrial Triangle, Kahuta Road, Islamabad-Pakistan.-	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: 1.Justify for not including the Bacterial endotoxin test in the specification of drug substance by drug product manufacturer, since the USP monograph of Lincomycin Hydrochloride recommends the Bacterial Endotoxin test for API. • Bacterial Endotoxin Test is mentioned in Specifications of Drug Substance. 2.Assay limit specify in the USP for API Lincomycin Hydrochloride is 790 µg of lincomycin (C18 H34 N2 O6 S) per mg, while the assay acceptance limit mentioned in the batch analysis report of API by the drug product manufacturer is NLT 79%(AIB) and 96%-102% (OAB), clarify for adopting different acceptance criteria for assay from that recommended by USP. Keeping in view molecular weight, the anhydrous (OAB) Potency is 443.01/461.02 x 100 = 96% that is set to lower limit and upper limit was set to 102% as per USP practice for API monographs. As is Basis Potency as per USP is NLT 790ug/mg that in terms of percentage can be converted as 0.79/1 x 100 = 79% and both are equivalent. 3.Justify for using 14.2 mg/ml of benzyl alcohol as a preservative in the applied formulation when the innovator products used 9.45mg/ml of benzyl alcohol as a preservative. As per Hand Book of Pharmaceutical Excipients: “Benzyl alcohol is an antimicrobial preservative used in cosmetics, foods, and a wide range of pharmaceutical formulations, including oral and parenteral preparations, at concentrations up to 2.0%” In product 28.40mg/2ml or 14.2mg/ml is used, that in terms of percentage becomes 1.42% and is allowed. 4.Provide a justification for how the sterility of the finished product was maintained, given that neither a sterile Active Pharmaceutical Ingredient (API), as per the Certificate of Analysis (COA) of the API was used in the manufacturing of the liquid injection, nor was terminal sterilization performed during the manufacturing process of the sterile injectable. As per USP monograph of Lincomycin HCl, in labeling, it mentions that it must be subjected to further processing during the preparation of injectable dosage forms. During manufacturing of Dosage form, sterilization was not performed via autoclave because the product is aseptic and degrades on temperature, therefore filtration method was followed for terminal sterilization as per guidance document of WHO Annex 6 “WHO good manufacturing practices for sterile pharmaceutical products”. Attached as Annexure 2.1 & Filtration evidence from BMR is attached as 2.2.	
	Decision: Approved	
114	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (5J3-RAD-3NT5, 2024-10-30) Fee Paid: 37000.0 Paid Date: 2024-10-28 Case Category: New License **(Saima Hussain)**	Proposed Name: **Aromater 2.5mg Tablets** Each film coated tablet contains: Letrozole…….2.5mg (USP Spec’s) United States Pharmacopeia RRA Status: Femara 2.5mg Tablets, Company: Novartis Pharmaceutical corporation, (NDA): 020726, USFDA Approved Me Too Status: Selet 2.5mg Tablets, Seraph Pharmaceutical Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks:	
	Decision: Approved	
115	**Global Pharmaceuticals Pakistan** Plot # 8, Street # S-8, RCCI, Industrial Estate Rawat, Islamabad-Pakistan (**000724**) Tracking ID: (WW3-A7J-AMTB, 2023-12-05) Fee Paid: 75000.0 Paid Date: 2023-11-22 Case Category: Routine **(Saima Hussain)**	Proposed Name: **Nuben 20mg Injection** Each Ampoule (1ml) contains: Nalbuphine Hydrochloride .....20mg As per Innovators Specificatio RRA Status: USFDA Me Too Status: Cenalbine Injection 20mg/mlby Mediate Pharmaceuticals, Karachi Pack Size(s): 1's-As per SRO,10's-As per SRO
	Manufacturer(s): Formulation-Global Pharmaceuticals (Pvt) Ltd.-Plot # 204-205 Industrial Triangle, Kahuta Road, Islamabad-Pakistan.-	
	Evaluation Remarks: 1.Justify the manufacturing of finished drug product without terminal sterilization. Terminal sterilization has been performed. Record of terminal sterilization from BMR is attached as Annexure 01. 2.Justify for keeping the limit of pH of drug product between 3.0 to 4.5 considering the pH limit of innovator product i.e. between 3.5 to 3.7. Innovator is providing range to set pH 3.5 to 3.7 during manufacturing while the limit of pH as per innovator is 3.0 to 4.5. Evidence attached as Annexure 02.	
	Decision: Approved	
116	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (2L5-RWQ-AQ43, 2024-08-29) Fee Paid: 30000.0 Paid Date: 2024-08-13 Case Category: New License **(Shahid Nawaz)**	Proposed Name: **Eszole 40mg Capsules** Each capsule contains: Enteric-coated pellets of Esomeprazole magnesium trihydrate equivalent to Esomeprazole.....40mg (USP Spec's) United States Pharmacopeia RRA Status: NEXIUM 40MG Capsules, Company: Astrazeneca, (NDA):021153, (USFDA Approved) Me Too Status: NEXUM 40mg Capsules, Manufacturer: Getz Pharma (Pvt.) Limited Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Firm has submitted reply against the observation and is as follows; · 1.5.4: Proposed pack size shall be submitted. Pack size is required as per SRO, i.e. 14s (2x7s), 21s (3x7s) and 10s is required for this product that are already available in the market. · 3.2.P.8: Six-month time point stability data shall be submitted. Submitted. · API lot number mentioned in the submitted stability data sheets is different from that provided in 3.2.S.4.4. clarification shall be submitted. API lot number mentioned on the stability sheet is corrected as per documents of procurement submitted in module-III, 3.2.P.8 · Uniformity of dosage unit test is not performed as recommended by the USP monograph. Uniformity of dosage units is performed according to the USP monograph and enclosed in test report Module-III, 3.2.P.8.	
	Decision: Approved	
117	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (99U-W88-X18W, 2024-09-27) Fee Paid: 150000.0 Paid Date: 2024-07-02 Case Category: New License **(Shahid Nawaz)**	Proposed Name: **Stomrex 20mg Capsules** Each capsule contains: Enteric coated pellets of Omeprazole Equivalent to Omeprazole.....20mg (USP Spec's) United States Pharmacopeia RRA Status: Losec 20mg capsule, Manufacturer: Astrazeneca UK Ltd. (Registered in United Kingdom) Me Too Status: Risek 20mg capsules, Manufacturer: Getz Pharma (Pvt.) Limited Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: Your application is found deficient for the following; · 1.5.4: Proposed pack size shall be submitted. Pack size is required as per SRO, i.e. 14's (2x7s), 21's (3x7s) and 10's is required for this product that are already available in the market · 1.6.5: License Submitted in 1.6.5 for Drug substance manufacturer and address of the DS mentioned in module III are completely different from each other. The physical address mentioned on DML and GMP of the drug substance manufacture is same. However the address mentioned 3.2.S.2.1 was according to the clearance from DRAP that is the address of sale office of manufacturer. · 3.2.P.8: Comparator product against which CDP and PE studies are performed has the same batch number. Clarification shall be submitted. The Batch number provided for 40 mg was given as batch number for 20 mg of reference product. Corrected in revised Module III. · Uniformity of dosage unit test is not performed as recommended by the USP monograph. Uniformity of dosage units is performed according to the USP monograph for 20 mg capsules and enclosed in test report Module-III, 3.2.P.8 for 20 mg capsules CTD. · Address of drug substance manufacturer mentioned on clearance certificate is also different from submitted GMP certificate. Clarification shall be submitted. Corrected in revised Module III as per above question.	
	Decision: Approved	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
118	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (LZ4-X7H-LY6D, 2024-09-30) Fee Paid: 150000.0 Paid Date: 2024-07-02 Case Category: New License **(Shahid Nawaz)**	Proposed Name: **Stomrex 40mg Capsules** Each capsule contains:Enteric coated pellets of OmeprazoleEquivalent to Omeprazole.....40mg(USP Spec's) United States Pharmacopeia RRA Status: Losec 40mg capsules, Manufacturer: Astrazeneca UK Ltd. (Registered in United Kingdom) Me Too Status: Risek 40mg capsules, Manufacturer: Getz Pharma (Pvt.) Limited Pack Size(s): As per SRO-As per SRO
	Evaluation Remarks: Your application is found deficient for the following; · 1.5.4: Proposed pack size shall be submitted. Pack size is required as per SRO, i.e. 14's (2x7s), 21's (3x7s) and 10's is required for this product that are already available in the market · 1.6.5: License Submitted in 1.6.5 for Drug substance manufacturer and address of the DS mentioned in module III are completely different from each other. The physical address mentioned on DML and GMP of the drug substance manufacture is same. However the address mentioned 3.2.S.2.1 was according to the clearance from DRAP that is the address of sale office of manufacturer. · 3.2.P.8: Comparator product against which CDP and PE studies are performed has the same batch number. Clarification shall be submitted. The Batch number provided for 40 mg was given as batch number for 20 mg of reference product. Corrected in revised Module III. · Uniformity of dosage unit test is not performed as recommended by the USP monograph. Uniformity of dosage units is performed according to the USP monograph for 20 mg capsules and enclosed in test report Module-III, 3.2.P.8 for 20 mg capsules CTD. · Address of drug substance manufacturer mentioned on clearance certificate is also different from submitted GMP certificate. Clarification shall be submitted. Corrected in revised Module III as per above question.	
	Decision: Approved	
119	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (ML3-BGS-84SD, 2024-08-28) Fee Paid: 30000.0 Paid Date: 2024-08-13 Case Category: New License **(Shahid Nawaz)**	Proposed Name: **Eszole 20mg Capsules** Eszole 20mg Capsules Composition: Each capsule contains: Enteric-coated pellets of Esomeprazole magnesium trihydrate equivalent to Esomeprazole.....20mg (USP Spec's) United States Pharmacopeia RRA Status: NEXIUM 20MG Capsules, Astrazeneca UK Ltd. (NDA): 021153 (USFDA Approved) Me Too Status: NEXUM 20mg Capsules, Manufacturer: Getz Pharma (Pvt.) Limited Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Firm has submitted reply against the observation and is as follows; · 1.5.4: Proposed pack size shall be submitted. Pack size is required as per SRO, i.e. 14s (2x7s), 21s (3x7s) and 10s is required for this product that are already available in the market. · 3.2.P.8: Six-month time point stability data shall be submitted. Submitted. · API lot number mentioned in the submitted stability data sheets is different from that provided in 3.2.S.4.4. clarification shall be submitted. API lot number mentioned on the stability sheet is corrected as per documents of procurement submitted in module-III, 3.2.P.8 · Uniformity of dosage unit test is not performed as recommended by the USP monograph. Uniformity of dosage units is performed according to the USP monograph and enclosed in test report Module-III, 3.2.P.8.	
	Decision: Approved	
120	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (1EZ-QQH-5W9D, 2024-08-26) Fee Paid: 30000.0 Paid Date: 2024-08-13 Case Category: New License **(Shahrukh Ali)**	Proposed Name: **Metzon 5mg Tablets** Each tablet contains; Metolazone.....5mg (USP Specifications) United States Pharmacopeia RRA Status: METOLAZONE 5MG TABLET, Company: GD SEARLE LLC., (NDA): 018535 (USFDA Approved) Me Too Status: Metxone Tablets 5 mg, Manufacturer:Genome Pharmaceutical (Pvt.)Limited Pack Size(s): As per SRO-As per SRO

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: 1.5.2 Firm has claimed Composition as Each Tablet Contains: Metolazone.....5mg (USP specs) as uncoated tablet however in module 3 claimed as film coated Firm has corrected module 1& 3 as uncoated tablet 3.2.S.4.1 Drug Substance Specification set by Drug substance manufacturer for loss on drying test the limit is set as NMT 1.0 however its 0.5 as provided by USP pharmacopoeia, assay limits are defined as NLT 97.0% & NMT 102.0% on the dried basis whereas in USP it is NLT 98.0% & NMT 102.0%, Chromatographic conditions for Detector are UV 254 nm however in pharmacopeia its at UV 226 nm. Firm has provided updated USP monograph 2024. Specification's adopted are in line to monograph now. 3.2.S.4.4 COA of API provided by drug substance manufacturer and drug product manufacturer have claimed USP specs but specification's set are not as per pharmacopeia as described above Firm has provided updated USP monograph 2024. Specification's adopted are in line to monograph now. 3.2. P2.1 In Pharmaceutical equivalence of the applied drug with the innovator / reference, No particulars of reference product batch number, Mfg date and Exp date pictorial evidence was provided. weight of tablets mentioned of subject product was 150mg however reference product was 203mg. Firm has claimed that they have used same excipients as innovator. 3.2.P.5.2 In Analytical procedures chromatographic conditions for assay detector: UV 235 nm Column: 3.9-mm x 15-cm; packing LI Flow rate: 1.1 mL/min Injection volume: 100 µL are not in compliance to USP monograph. In dissolution Test 1 was adopted Apparatus 2: 75 rpm instead of 100 rpm and Time is selected as 120 min instead of 60 min and Tolerances: NLT 75% (Q) instead of 60(Q) Firm has provided updated USP monograph 2024. Specification's adopted are in line to monograph now. 3.2P5.4 Coa of finish product the dissolution method adopted is not as per pharmacopeia, coated tablets mentioned, Firm has corrected module 1& 3 as uncoated tablet 3.2.P.8.3 Stability data of 6-month time point for accelerated and real time are not provided. Chromotagram shows detector wavelength as 236nm instead of monograph 226nm and inj volume as 100ul instead of 20ul. Thickness of tablets is out of specs in 3rd time point stability studies COA Firm has provided Stability data of 6-month time point for accelerated and real time	
	Decision: Approved	
121	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, (**000992**) Tracking ID: (JL5-SBB-B67L, 2024-08-29) Fee Paid: 30000.0 Paid Date: 2024-08-13 Case Category: New License **(Waqar Ahmed)**	Proposed Name: **Strot 2g Sachet** Each sachet contains; Strontium ranelate.....2g (Innovator Specifications) As per Innovators Specification RRA Status: Strontium ranelate Aristo 2g sachet, Manufacturer: Aristo Pharma Limited (Registered in UK) Me Too Status: Osstium Powder 2 gm Sachet, Manufacturer: Atco Laboratories Ltd. Pack Size(s): As per SRO-As per SRO
	Details of Certificates (CoPP/cGMP, Authorization Letter etc):	

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
	Evaluation Remarks: Dear applicant please provide six months timepoint stability data for the applied product. * Firm has provided data for 6 month stability time point.	
	Decision: Approved	

Case no.: 01 Applications submitted on Form 5F by way of contract-manufacturing

1.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Aspin Pharma Pvt Ltd.** **Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi 74900, Pakistan**
	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)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 24688 dated 10-10-2023 Rs.75,000/- dated 05-12-2022
	The proposed proprietary name / brand name	**Monsuka 4mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Montelukast Sodium Eq. to Montelukast…4mg
	Pharmacotherapeutic Group of (API)	Leukotriene receptor antagonists
	The status in reference regulatory authorities	MHRA approved
	For generic drugs (me-too status)	Myteka Sachet of M/s Hilton
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	BP specifications

Evaluation by PEC[II]:

Sr.#	Observations	Firm's reply
1.	Justification shall be submitted for using Montelukast sodium working standard instead of montelukast dicyclohexylamine, as recommended by BP monograph for drug product Assay test.	
2.	As evident from submitted chromatograms, the chromatographic conditions of gradient mobile phase programme have not been followed for the performance of Assay test in drug product stability studies. Justification shall be submitted in this regard.	

Decision: Deferred for submission of reply to above cited shortcomings.

2.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Pharmedic Laboratories Pvt Ltd.** **16-km, Multan Road Lahore, Pakistan**
	Name, address of Manufacturing site.	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 22055 dated 07-09-2023 Rs.75,000/- dated 08-08-2023

	The proposed proprietary name / brand name	**Moxef 400mg/250ml Infusion**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 250ml Contains: Moxifloxacin HCl Eq. to Moxifloxacin…400mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	The status in reference regulatory authorities	MHRA approved
	For generic drugs (me-too status)	Moxiget of M/s Getz Pharma
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's specifications

Evaluation by PEC[II]: Applied formulation is in LDPE Bottle. Stability conditions applied were as under:

- Real Time (30±2˚C & 65±5% RH)
- Accelerated Conditions (40±2˚C & 75±5% RH)

Firm has submitted GMP certificate issued basis of inspection conducted on declaring availability of "Large Volume Parenterals" (Blow fill seal technology) section.

Decision: Approved.

3.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R:2, Industrial Estate Gadoon, Swabi**
	Name, address of Manufacturing site.	M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 26020 dated 27-10-2023 Rs.30,000/- dated 03-09-2023
	The proposed proprietary name / brand name	**Welrox 500/20 mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Modified Release Tablet Contains: Naproxen…500mg Esomeprazole as Magnesium Trihydrate…20mg
	Pharmacotherapeutic Group of (API)	NSAID with PPI
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Glomov Tablets by Global Pharma
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's specifications

Evaluation by PEC[II]:

Sr.#	Observations	Firm's reply
1.	Revise your label claim as per the innovator's product along with submission of requisite fee.	
2.	Submit specifications and analytical method of API from API manufacturer as well as drug product manufacturer in section 3.2.S.4.1 and 3.2.S.4.2 fir both drug substances.	
3.	Justify the performance of specificity test for naproxen API in the light of ICH Q2 guidelines.	
4.	Submit COA of relevant batch of API from API manufacturer as well as product manufacturer in section 3.2.S.4.4 for both drug substances	

5.	Justify why particle size distribution test is not performed by drug product manufacturer for naproxen API since particle size is a critical quality attribute for the applied product.	
6.	Submit real time stability study data of esomeprazole API till claimed shelf life since the submitted data is till 6 months only.	
7.	Submit quantity of esomeprazole added in drug product per unit keeping in view salt factor and magnesium content etc.	
8.	Justify why pharmaceutical equivalence and CDP studies are not conducted against innovator's product.	
9.	Submit details of dissolution parameters used in comparative dissolution profile studies.	
10.	USFDA review documents reveals that for acid stage testing of naproxen tablet, 475ml dissolution medium is to be used with 75rpm paddle speed, while you have used 100rpm paddle speed. Clarification is required in this regard.	
11.	USFDA review documents reveals that for buffer stage testing of naproxen tablet, 900ml of 0.05 M phosphate buffer pH 7.4 dissolution medium is to be used with 75rpm paddle speed, while you have used 100rpm paddle speed. Clarification is required in this regard.	
12.	Submit valid GMP certificate of both API manufacturer	
13.	Submit documents for procurement of both API including DRAP clearance certificate.	
14.	Submit complete analytical record of stability testing of all batches including chromatograms for assay and dissolution test for each time point with proper separators.	

Decision: Deferred for submission of reply to above cited shortcomings.

4.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Unimark Pharmaceuticals Pvt Ltd.** **Plot No. 7--A, Street No. S-7, National Industrial Zone, Rawat, Islamabad, Pakistan**
	Name, address of Manufacturing site.	M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 25271 dated 17-10-2023 Rs.75,000/- dated 12-07-2023
	The proposed proprietary name / brand name	**Vomfran 8mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Ondansetron as Hcl Dihydrate…8mg
	Pharmacotherapeutic Group of (API)	Serotonin (5HT3) antagonists ATC Code: A04AA01
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Zofran 8mg/4ml Injection Reg. No. 020669

		M/s GSK Karachi.
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	USP
Evaluation by PEC[II]:		
Decision: Approved.		
5.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Getz Pharma Pvt Ltd. 29-30/27, Korangi Industrial Area, Karachi.**
	Name, address of Manufacturing site.	M/s GlaxoSmithKline Pakistan Limited. Plot No. 5, Sector-21, Korangi Industrial Area, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 21679 dated 01-09-2023 Rs.75,000/- dated 27-02-2023
	The proposed proprietary name / brand name	**Sterile Water for Injection 10ml**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Water for Injection…10ml
	Pharmacotherapeutic Group of (API)	Serotonin (5HT3) antagonists ATC Code: A04AA01
	The status in reference regulatory authorities	Sterile water for injection (1ml, 2ml, 3.2ml, 5ml and 10ml) ampule Glass class I. MHRA approved
	For generic drugs (me-too status)	Water for Injection (sterile) 10ml in ampule. Reg. No. 076972
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	USP
Evaluation by PEC[II]:		
Decision: Approved.		
6.	**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 Islam Pharmaceuticals. 7 km, Pasrur Road, Sialkot
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 21679 dated 01-09-2023 Rs.75,000/- dated 27-02-2023
	The proposed proprietary name / brand name	**Strona 2gm Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Strontium Ranelate……2gm
	Pharmacotherapeutic Group of (API)	Anti-osteoporotic agent
	The status in reference regulatory authorities	EMA Approved
	For generic drugs (me-too status)	Onita® for M/s PharmEvo
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator Specification

Evaluation by PEC[II]:

Sr.#	Observations	Firm's response
1.	Submit valid coy of DML/GMP certificate of the drug substance manufacturer issued by relevant regulatory authority of country of origin.	
2.	Submit justification for applying UV Spectrophotometric method for the analysis of Assay test.	
3.	Submit documents confirming procurement/ Import of drug substance, issued by DRAP I&E Office.	

Decision: Deferred for submission of reply t above cited shortcomings.

7.	**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 Islam Pharmaceuticals. 7 km, Pasrur Road, Sialkot
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 19978 dated 11-08-2023 Rs.75,000/- dated 29-05-2023
	The proposed proprietary name / brand name	**Omeprafast 20/1680 mg Sachet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sachet Contains: Omeprazole…20mg Sodium Bicarbonate…1680mg
	Pharmacotherapeutic Group of (API)	PPI
	The status in reference regulatory authorities	US FDA Approved
	For generic drugs (me-too status)	Risek Insta Sachet of M/ Getz
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	--

Evaluation by PEC[II]:

Sr.#	Observations	Firm's response
1.	Reference of finished drug product specifications shall be submitted	
2.	Valid DML/GMP certificate of drug substance manufacturers shall be submitted.	
3.	Submit documents confirming procurement/ Import of drug substance, issued by DRAP I&E Office.	
4.	Justification shall be submitted for applying UV spectrophotometric method for analysis of Omeprazole in drug product.	

Decision: Deferred for submission of reply t above cited shortcomings.

8.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Sapient Pharma** **123/S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore**
	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)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 20806 dated 23-08-2023 Rs.75,000/- dated 02-08-2023
	The proposed proprietary name / brand name	**Guill 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Nimesulide……100mg
	Pharmacotherapeutic Group of (API)	NSAID
	The status in reference regulatory authorities	Approved by AIFA of Italy
	For generic drugs (me-too status)	Nims tablet of M/ Sami
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's speculations

Evaluation by PEC[II]:

Sr.#	Observations	Firm's response
1.	Valid DML/GMP certificate of drug substance manufacturers shall be submitted.	

Decision: Approved. Firm shall submit valid DML/GMP certificate of drug substance manufacturer, issued by the relevant regulatory authority of country of origin, before issuance of registration letter.

9.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Islam Pharmaceuticals. 7 km, Pasrur Road, Sialkot**
	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)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 21411 dated 30-08-2023 Rs.75,000/- dated 11-07-2023
	The proposed proprietary name / brand name	**Nimon 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Nimesulide……100mg
	Pharmacotherapeutic Group of (API)	NSAID
	The status in reference regulatory authorities	Approved by AIFA of Italy
	For generic drugs (me-too status)	Nims tablet of M/ Sami
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's speculations

Evaluation by PEC[II]:

Sr.#	Observations	Firm's response
1.	Valid DML/GMP certificate of drug substance manufacturers shall be submitted.	

Decision: Registeration Board declared the instant case as disposed of, since same formulaton has been applied by applicant by the way of self manufacturing and applications is rejected.

10.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Mcolson Research Laboratories (Pvt) Ltd. 26-km Lahore Sharikhpur Road, District Sheikhupura.**
	Name, address of Manufacturing site.	M/s. Mcolson Research Laboratories (Pvt) Ltd.

		26-km Lahore Sharikhpur Road, District Sheikhupura.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 25738 dated 24-10-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 9097737484 dated 04-10-2023.
	The proposed proprietary name / brand name	**Upadacitinib SR 15mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Sustained Release Tablet Contains: Upadacitinib as hemihydrate ……. 15mg
	Pharmacotherapeutic Group of (API)	Janus Kinsase (JAK) inhibitor
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Rinvoq 15mg Tablet. Abbvie Inc. Limited. US FDA Approved.
	For generic drugs (me-too status)	--
	Proposed Pack size	Pack size 30's, MRP As per SRO.
Evaluation by PEC :		
Decision: Approved.		
11.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Sigma pharma International Pvt Ltd. Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan**
	Name, address of Manufacturing site.	M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy.No 24999 dated 13-10-2023 Rs.75,000/- dated 21-09-2022
	The proposed proprietary name / brand name	**D-Raise 5mg/ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 1ml Ampoule Contains: Cholecalciferol…5mg
	Pharmacotherapeutic Group of (API)	Vitamin D
	The status in reference regulatory authorities	MHRA approved
	For generic drugs (me-too status)	Indrop-D of M/s Neutro
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	Innovator's specifications

Evaluation by PEC^{II}:

- Valid GMP certificate/DML of the drug substance manufacturer shall be submitted.
- Drug substance analytical method verification studies from drug product manufacturer shall be submitted.

Decision: Approved. Registration letter will be issued upon submission of following:

- **Valid DML/GMP certificate of drug substance manufacturer, issued by the relevant regulatory authority of country of origin.**
- **Drug substance analytical method verification studies from drug product manufacturer shall be submitted.**

Case no.: 02 Deferred cases

12.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s McOlson Research Laboratories Pvt., Ltd**
	Name, address of Manufacturing site.	**M/s McOlson Research Laboratories Pvt., Ltd**
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 8554: 29-03-2023.
	Details of fee submitted	Slip No:15739021 PKR 30,000/-
	The proposed proprietary name / brand name	Aprin Tablet (Starter Pack)
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**APRIN 10MG TABLETS** Each Film Coated Tablet Contains: Apremilast ……10mg **APRIN 20MG TABLETS** Each Film Coated Tablet Contains: Apremilast ……20mg **APRIN 30MG TABLETS** Each Film Coated Tablet Contains: Apremilast ……30mg
	Pharmacotherapeutic Group of (API)	Selective immunosuppressants L04AA32
	Reference to Finished product specifications	Innovators Specification
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	(not provided)
	Proposed Pack size	14 days starter pack,28 days starter pack. As per SRO.

Evaluation by PEC-V:

The application had been presented in 339th meeting, wherein it was deferred for following observations to which firm has replied as detailed against each

S. No	Sections	Observations/Deficiencies/ Short-comings	Firm's reply
1.	1.1	Submit Me too or fee of new molecule.	
2.	1.3.4	Submit copy of valid Drug Manufacturing License (DML) issued by Licensing Division, DRAP.	Firm has submitted copy of receipt of application for renewal of DML.
3.	1.3.5	Submit valid GMP inspection report/ GMP certificate of the manufacturing unit issued within the last three years.	Firm has submitted copy of inspection report dated 04-06-2022 concluding good level of GMP compliance.
4.	1.6	Submit miscellaneous information as per guidance document.	Submitted
5.	2.3.R.1	Submit production documentation.	Firm has submitted batch production record
6.	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	Firm has submitted drug Drug substance specifications and analytical

		substance /Active Pharmaceutical Ingredient by Drug Product manufacturer.	procedures of drug substance from M/s Mcolson
7.	3.2.S.4.3	Submit analytical test method for assay by drug product manufacturer.	Submitted
8.	3.2.S.4.4	Justification is required for not performing the enantiomeric purity test while analyzing the quality of drug substance by drug product manufacturer. Since, it is the critical test for apremilast because the active substance exhibits stereoisomerism due to presence of a single chiral centre, with the (S)-enantiomer being pharmacologically active. A discussion and justification shall be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer.	We, Lewens Labs Private Limited, hereby declare that the chirality observed in the drug substance is inherently due to the chirality of the key starting material used in its synthesis. This chirality is well-controlled and maintained within the specified limits as outlined in the specification of the key starting material. As the chirality is tightly regulated through the starting material specifications, no additional control for chirality is required within the release specification of the drug substance. The analytical tests performed, including description, solubility, identification, water content, residue on ignition, heavy metals, related substances, and assay, align with standard practices for the characterization of drug substances. These tests are critical in establishing the identity, purity, and quality of the API. The API manufacturer has performed additional tests, including residual solvents, in accordance with current regulatory standards. This approach ensures comprehensive compliance with ICH guidelines and recognizes the manufacturer's capabilities and facilities, which are specifically designed for these analyses. Our facility currently lacks the specialized equipment necessary to perform residual solvent testing. However, we have a robust quality assurance process that verifies and validates the results obtained from the API

			manufacturer. Their testing is conducted under strict Good Manufacturing Practices (GMP) and is subject to thorough review and documentation It is our commitment to adhere to all regulatory guidelines, and we believe that the submitted data, combined with the manufacturer's comprehensive analysis, provides sufficient justification for the quality and safety of the drug substance
9.	3.2.P.2.2.1	The dissolution media as per USFDA is 0.15% SLS and paddle speed is 60 rpm whereas, the test method provided by you mentions SLS 0.3 % and paddle speed 75rpm.	We used dissolution method as mentioned in drug assessment report for Apremilast Tablets. Firm has submitted revised method.
10.	3.2.P.5.1	a) The weight of tablets of all three strengths of innovator brand increase with empirical ratio as per the review report of USFDA, while the weight of tablet of all three applied strength varies irrespective of their increase quantity of active ingredient. b) The innovator uses UPLC for the test whereas, you have used HPLC. c) The test of degradation products and microbial limits have not been included.	Both HPLC (High-Performance Liquid Chromatography) and UPLC (Ultra-Performance Liquid Chromatography) are robust chromatographic techniques. While UPLC allows for faster analysis and may provide better resolution due to smaller particle sizes in the column, HPLC is still widely accepted for pharmaceutical analysis and can deliver equivalent analytical performance in terms of accuracy, precision, linearity, and sensitivity for determining the assay of Apremilast tablets. Validation data of Aprin Tablets demonstrate that HPLC provides acceptable results in line with regulatory standards (e.g., accuracy, precision, linearity, robustness), proving that the method is suitable for its intended use. Selection of HPLC was based on the method's validation, availability of equipment, and its ability to provide reliable and reproducible results for Apremilast assay

			determination. Testing method meets all regulatory requirements, even though a different technology was employed by the innovator. Furthermore, since HPLC is more commonly available, it can ease the method transfer process to different laboratories for future testing and quality control without requiring specialized UPLC equipment UPLC, though faster and more efficient, often requires more expensive equipment, specific columns, and consumables compared to HPLC. For many manufacturers, especially in routine quality control and testing environments, HPLC is the more cost-effective solution without compromising on accuracy or precision. Degradation testing is a crucial part of stability studies, and we have incorporated it into our stability testing protocol. Additionally, forced degradation studies were performed as part of the assay validation process. This assessment not only identifies potential degradation products but also establishes the specificity of the assay method. The results from these stability studies and forced degradation analyses demonstrate that the product maintains its quality over its intended shelf life, and any identified degradation products are within acceptable limits. We acknowledge the importance of microbial testing in ensuring product safety and quality. While the initial specifications did not include a microbial limits test, we have since revised our standard testing methods

			to incorporate this critical assessment. The updated specifications now include a microbial limits test, which ensures that the finished product meets all necessary safety criteria. Attached are the microbial test reports that confirm compliance with regulatory requirements (Standard Testing Method and revised specifications for Microbial Limit Test and Microbial Test Report of Finished Products are submitted
	3.2.P.5.3	The detection limit and quantitation limit has not been performed for assay validation. The dissolution media as per USFDA is 0.15% SLS and paddle speed is 60 rpm whereas, the test method provided by you mentions SLS 0.3 % and paddle speed 75rpm.	According to the United States Pharmacopeia (USP) guidelines, the determination of detection and quantitation limits is not a requisite for assay validation. In our assay validation, we focused on parameters that are critical for establishing the method's accuracy, precision, specificity, linearity, and robustness. These attributes are fundamental to ensuring the assay's reliability for routine quality control purposes. As the assay is designed for quantifying the active pharmaceutical ingredient (API) within specified concentration ranges, the absence of DL and QL does not compromise the validity of the method for its intended use. We used dissolution method as mentioned in drug assessment report for Apremilast Tablets. Dissolution Method and acceptance criteria is submitted
11.	3.2.P.7	The applied starter pack presentation mentioned in section 3.2.P.7 should be as per the innovator brand the starter, pack is of 2 weeks which consist of 13-tablet blister titration pack containing:(4) 10-mg, (4) 20-mg, and (5) 30-mg tablets with an additional (14) 30mg tablets. Justify the rationality of your starter pack presentation with reference to the innovator.	

Decision: Approved. Furtehrmore, Registration Board in order to standardize the drug as per dosage regimen of the innovator's drug product as approved by reference regulatory authorities, the Board decided to approve the pack size as per decision of its 321st meeting.		
13.	**Name, address of Applicant / Importer**	**M/s RG Pharmaceutica (Pvt) Ltd.** BF1-01 First floor gate no. 1, Bahria Orchard Main Raiwind Road, District Lahore
	Details of Drug Sale License of importer	License No: 05-352-0066-059010D Address: BF1-01 First floor gate no. 1, Bahria Orchard Main Raiwind Road, District Lahore Address of Godown: NA Validity: 27-08-2027. Status: License to sell drugs as distributor
	Name and address of marketing authorization holder (abroad)	M/s Livzon Group Pharmaceutical Factory. No. 38 Chuangye Road North, Jinwan District, Zhuhai, PR China
	Name, address of manufacturer(s)	M/s Nanjing King-Friend Biochemical Pharmaceutical Co. Ltd. No. 16, Xuefu Road, Nanjing High and new technology Development zone, Nanjing, Jiangsu China.
	Name of exporting country	China.
	Status of the applicant	☐ Manufacturer ☒ Importer ☐ Is involved in none of the above (contract giver)
	Application Form, Dy. No / Tracking ID & date of submission	Form 5F: Dy.No 7166 dated 13-03-2023
	Details of fee submitted	Rs.150,000/- dated 16-12-2022
	The proposed proprietary name / brand name	**Cetroject Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cetrorelix Acetate Powder (calculated as Cetrorelix)…0.25mg
	Pharmacotherapeutic Group of (API)	anti-gonadotropin-releasing hormones, ATC code: H01CC02
	Reference to Finished product specifications	As per Innovator
	The status in reference regulatory authorities	US FDA Approved
	For generic drugs (me-too status)	--
	Proposed Pack size & Price	1's
	Container closure of drug product	Glass vial with rubber stopper
	Detail of certificates attached (CoPP, Freesale certificate, GMP certificate)	**CoPP:** Firm has submitted copy of legalized CoPP (No. 20220128) valid upto 23-08-2024 issued by medical product Administration of Guangdong Province. The certificate confirms the free sale status of the product in exporting country along with GMP status of the manufacturer ide inspection once a year. **GMP:** Firm has also submitted GMP compliance declaration issued by Jiangsu Medical Product Administration in name of M/s Nanjing King-Friend Biochemical Pharmaceutical Co. Ltd. No. 16, Xuefu Road, Nanjing High and new technology Development zone, Nanjing, Jiangsu China on for "Lyophilized Powder for injection vial production line, on basis of inspection conducted on 04-08-2021.

		Firm has also submitted legalized copy of contract manufacturing agreement of Cetrorelix acetate injection between M/s Livzon Group pharmaceutical Factory & M/s Nanjing King-Friend Biochemical Pharmaceutical Co. Ltd.
	Details of letter of authorization / sole agency agreement	Firm has submitted copy of "Cooperation & Distribution Agreement" between M/s RG Pharmaceutica (Pvt) Ltd. & M/s Livzon Group Pharmaceutical Factory for applied formulation.
	Pharmaceutical Equivalence & CDP studies	Firm has submitted comparison against the innovator drug product Cetrotide injection
	Drug product stability studies	Firm has submitted Long term stability studies data (36 months) and accelerated stability data (6 months) have been submitted as per Zone IVb conditions.

Decision of 339th meeting: Deferred for submission of reply to below cited shortcomings for which frim has replied as under:

Evaluation by PEC[II]:

Section #	Observations	Firm's response
1.5.2	Submitted label claim shall be revised to declare the strength in terms of the Cetrorelix base along with submission of fee for revision of label claim.	Firm has submitted revised label claim as under: "Each vial of Cetrorelix acetate for injection 0.25 mg contains 0.26-0.27mg Cetrorelix acetate equivalent to 0.25 mg Cetrorelix and 54.80mg Mannitol.
3.2.S.3	Characterization studies of drug substance to establish the molecular structure and amino acid sequence against the innovator drug product.	Firm has submitted details of following studies from "Chinese peptide Company: • Mass spectrum • Amino acid analysis • Sequence analysis • IR analysis • NMR • Chiral amino acid analysis
3.2.S.4	Drug substance specification, analytical procedure and analytical method verification studies shall be submitted form the drug product manufacturer.	Submitted
3.2.P.1	Details of the reconstitution diluent shall be submitted.	We acknowledge the Agency's comments and would like to clarify that our product only contains the Cetrorelix Acetate for injection (Lyophilized Powder) without reconstitution diluent. The diluent for brand Cetrotide (innovator drug) is lmL of Sterile water for injection which is to reconstitute the drug product prior to administration. 'Thus, the generic Cetrorelix Acetate for Injection need additional purchase 1 ml of Sterile water for injection for to reconstitute the lyophilized powder.
3.2.P.2.6	Compatibility study with the reconstitution diluent shall be submitted.	Submitted.
3.2.P.5.1	Justification shall be submitted for not including following tests in drug product specifications: • Filled weight per unit vial	• Filled weight per unit vial: Filling range is already monitored during

	• Withdrawal volume form reconstituted injection.	manufacturing and process controls. The Filled weight per vial is studied as development data. • Filled weight per unit vial of validation batches is equivalent to the innovator drug, which is not proposed to include in the specification of Cetrorelix acetate for Injection. • Withdrawal volume from reconstituted injection: According to the RLD labeling, USP<1151> and ISO 11040-8: 2016, the development data of injectable amount with regard to withdrawal volume (deliverable volume) has been investigated. The analysis procedure includes three steps: reconstitution, withdrawal and injection. Deliverable volume is studied by detecting the Cetrorelix content of final injection liquid, which is draw out by syringes. The collective data is provided below • The test results show that injectable amount of validation batches is consistent with the innovator drug product, and NLT 0.23 mg of Cetrorelix can be administered to patients. The deliverable volume is proposed not to test in the specification. In addition, the test items of content uniformity and assay can ensure that the dosage of the drug administration is stable.

Decision of 340th meeting: Deferred for further deliberation upon the class of the drug whether Pharmaceutical or Biological.

Firm's response: Firm has submitted following declarations:

- Cetrorelix acetate API is a chemically synthetic decapeptide.
- Synthetic peptide is not biological product according to FDA. On February 21, 2020, FDA published a final rule that defines "biological product " except any chemically synthetic polypeptide.
- The Innovator drug and generic drugs of Cetrorelix acetate were all classified as chemical drugs during the application for marketing authorization in China, the United States

Firm has submitted route of synthesis of drug substance and also referred to the US FDA Orange Book database for classification of drug.

Decision: Approved as per policy of inspection of manufacturer abroad. Registration letter will be issued upon submission of analytical record for the submitted drug product stability data including chromatograms/spectrums etc and submission of fee for pre-registration variation for correction of label claim as per SRO 1324(I)/2024 dated 30-08.

Agenda of Dr. Muhammad Haseeb Tariq

Contract manufacturing cases

14.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate, Kot Lakhpat,Lahore**

	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 35-A, Small Industrial Estate, Taxila
	GMP status of drug product manufacturer	GMP certifacte: Inspection date 13-02- 2020
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25898: 26-10-2023
	Details of fee submitted	PKR 75,000/- : 21-12-2022
	The proposed proprietary name / brand name	**MPS Dry Powder Injection 40mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Methylprednisolone as Sodium Succinate…40mg
	Pharmacotherapeutic Group of (API)	Glucocorticoids
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Solu Medrol Injectionof Pfizer
	Proposed Pack size	As per SRO
	Name and address of API manufacturer.	BIOFER S.p.A, Italy
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Solomed Injection of Pharmasol
	Details of stability studies of drug product	2000 Vials / 2 batches
	Documents for the procurement of API with approval from DRAP (in case of import).	AD cleared commercial invoice dated 14-01-2022

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	GMP certificate / inspection report of product manufacturer	
2.	Evidence of approval of required manufacturing facility / section approval letter from Licensing Division.	
3.	Clarify why PE studies are not performed against innovator's product	
4.	Submit in-use stability studies.	
5.	Submit valid GMP certificate of API manufacturer.	
6.	Submit BMR of stability batches.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

15.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate, Kot Lakhpat,Lahore**
	Name, address of Manufacturing site.	M/s Horizon Healthcare (Pvt) Ltd. Plot No. 35-A, Small Industrial Estate, Taxila
	GMP status of drug product manufacturer	GMP certifacte: Inspection date 13-02- 2020
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25899: 26-10-2023
	Details of fee submitted	PKR 75,000/- : 21-12-2022
	The proposed proprietary name / brand name	**MPS Dry Powder Injection 125mg**

	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Methylprednisolone as Sodium Succinate…125mg
	Pharmacotherapeutic Group of (API)	Glucocorticoids
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Solu Medrol Injectionof Pfizer
	Proposed Pack size	As per SRO
	Name and address of API manufacturer.	BIOFER S.p.A, Italy
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Solomed Injection of Pharmasol
	Details of stability studies of drug product	2000 Vials / 2 batches
	Documents for the procurement of API with approval from DRAP (in case of import).	AD cleared commercial invoice dated 14-01-2022

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	GMP certificate / inspection report of product manufacturer	
2.	Evidence of approval of required manufacturing facility / section approval letter from Licensing Division.	
3.	Clarify why PE studies are not performed against innovator's product	
4.	Submit in-use stability studies.	
5.	Submit valid GMP certificate of API manufacturer.	
6.	Submit BMR of stability batches.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

16.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s 3S Pharmaceuticals Pvt Ltd. 5-km off Raiwind Road, Manga Road, Lahore**
	Name, address of Manufacturing site.	M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate,Lahore
	GMP status of drug product manufacturer	GMP certifacte: Inspection date 13-02- 2020
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 25270: 17-10-2023
	Details of fee submitted	PKR 75,000/- : 04-09-2023
	The proposed proprietary name / brand name	**DEFLU 5mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Desloratadine…5mg
	Pharmacotherapeutic Group of (API)	Antihistamine
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	USFDA Approved.
	For generic drugs (me-too status)	Neo antial Tablet of Sami
	Proposed Pack size	As per SRO
	Name and address of API manufacturer.	Morepen Laboratories Limited, India.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Neo-Antial Tablet of Sami

	Details of stability studies of drug product	100000 tablet / 2 batches
	Documents for the procurement of API with approval from DRAP (in case of import).	AD cleared commercial invoice dated 31-05-2021

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	GMP certificate / inspection report of product manufacturer	
2.	Submit valid GMP certificate of API manufacturer.	
3.	Submit BMR of stability batches.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings, along with evidence of validity of DML of the applicant.

17.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk**
	Name, address of Manufacturing site.	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar
	GMP status of drug product manufacturer	GMP certifacte: Inspection date 11-12- 2020
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 20065: 15-08-2023
	Details of fee submitted	PKR 75,000/- : 04-08-2023
	The proposed proprietary name / brand name	**SALBACT 1gm IV/IM Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cefoparazone ss Sodium…500mg Sulbactam ss Sodium…500mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	JP
	The status in reference regulatory authorities	PMDA Japan
	For generic drugs (me-too status)	Cebac Injection by Bosch
	Proposed Pack size	1's: As per SRO
	Name and address of API manufacturer.	Suzhou dawnrays pharmaceutical Co., Ltd China.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Cebac injection of Bosch.
	Details of stability studies of drug product	4000 vials / 3 batches
	Documents for the procurement of API with approval from DRAP (in case of import).	Clarance certificate dated 01-09-2022

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit GMP certificate / inspection report of product manufacturer	
2.	Submit API specifications and analytical method from API manufacturer.	
3.	Submit verification studies of drug substance, performed by drug product manufacturer in section 3.2.S.4.3	
4.	Submit details of the product including exp date and batch number against which PE studies were conduced.	
5.	Submit in-use stability studies.	

6.	Submit valid GMP certificate of API manufacturer.	
7.	Submit BMR of stability batches.	
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.		
18.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Athan Pharmaceuticals. Plot 84/1, Block B, Phase 5, Industrial Estate, Hattar, Kpk**
	Name, address of Manufacturing site.	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar
	GMP status of drug product manufacturer	GMP certifacte: Inspection date 11-12- 2020
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 20066: 15-08-2023
	Details of fee submitted	PKR 75,000/- : 04-08-2023
	The proposed proprietary name / brand name	**SALBACT 2gm IV/IM Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cefoparazone ss Sodium…1000mg Sulbactam ss Sodium…1000mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	JP
	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)	Cebac Injection by Bosch
	Proposed Pack size	1's: As per SRO
	Name and address of API manufacturer.	Suzhou dawnrays pharmaceutical Co., Ltd China.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Cebac injection of Bosch.
	Details of stability studies of drug product	4000 vials / 3 batches
	Documents for the procurement of API with approval from DRAP (in case of import).	Clarance certificate dated 01-09-2022

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit GMP certificate / inspection report of product manufacturer	
2.	Submit API specifications and analytical method from API manufacturer.	
3.	Submit verification studies of drug substance, performed by drug product manufacturer in section 3.2.S.4.3	
4.	Submit details of the product including exp date and batch number against which PE studies were conduced.	
5.	Submit in-use stability studies.	
6.	Submit valid GMP certificate of API manufacturer.	
7.	Submit BMR of stability batches.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.		
19.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura**
	Name, address of Manufacturing site.	M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura
	GMP status of drug product manufacturer	Not submitted.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 19523: 07-08-2023
	Details of fee submitted	PKR 75,000/- : 23-02-2023
	The proposed proprietary name / brand name	**AZOSON 250mg Capsule**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Capsule Contains: Azithromycin Dihydrate Eq. to Azithromycin…250mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	(USFDA Approved)
	For generic drugs (me-too status)	Azomax capsule by Novartis
	Proposed Pack size	6's, 10's: As per SRO
	Name and address of API manufacturer.	Hebei Guolong Pharma China.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Azomax Capsule.
	Details of stability studies of drug product	20000 cap / 3 batches
	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit GMP certificate / inspection report of product manufacturer	
2.	Submit verification studies of drug substance, performed by drug product manufacturer in section 3.2.S.4.3	
3.	Applied specs are USP, while analytical method for assay is based on HPLC with UV detector while USP recommends amperometric electrochemical detector.	
4.	Dissolution test specified by the firm specifes Apparatus I while USP recommends Apparatus 2.	
5.	Documents for the procurement of API with approval from DRAP (in case of import).	
6.	Submit valid GMP certificate of API manufacturer.	
7.	Submit BMR of stability batches.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.		
20.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura**

	Name, address of Manufacturing site.	M/s Variant Pharmaceuticals Pvt Ltd. Plot No.5, M2-Pharma Zone Lahore, Sharikpur Road, Sheikhupura
	GMP status of drug product manufacturer	Not submitted.
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 19524: 07-08-2023
	Details of fee submitted	PKR 75,000/- : 23-02-2023
	The proposed proprietary name / brand name	**AZOSON 500mg Tbalet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin…500mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	(USFDA Approved)
	For generic drugs (me-too status)	Azomax Tablet by Novartis
	Proposed Pack size	6's,: As per SRO
	Name and address of API manufacturer.	Hebei Guolong Pharma China.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Azomax Tablet.
	Details of stability studies of drug product	20000 cap / 3 batches
	Documents for the procurement of API with approval from DRAP (in case of import).	Not submitted

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit GMP certificate / inspection report of product manufacturer	
2.	Submit verification studies of drug substance, performed by drug product manufacturer in section 3.2.S.4.3	
3.	Documents for the procurement of API with approval from DRAP (in case of import).	
4.	Submit valid GMP certificate of API manufacturer.	
5.	Submit BMR of stability batches.	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

21.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Martin Dow Limited. Plot No. 37, Sector 19, Korangi Industrial Area, Karachi**
	Name, address of Manufacturing site.	M/s Martin Dow Marker Limited. 7, Jail Road, Quetta
	GMP status of drug product manufacturer	GMP certifacte: Inspection date 26, 27 February, 2021
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 20796: 23-08-2023

	Details of fee submitted	PKR 75,000/- : 27-07-2023
	The proposed proprietary name / brand name	**DEXMITIN 200mcg/2ml injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml Ampoule Contains: Dexmedetomidine HCl Eq. to Dexmedetomidine…200mcg
	Pharmacotherapeutic Group of (API)	Other hypnotics and sedatives
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	PRECEDEX Injection (USFDA Approved)
	For generic drugs (me-too status)	Precidex Injection by Brookes
	Proposed Pack size	2ml x 5's: As per SRO
	Name and address of API manufacturer.	Jiangsu Hengrui Pharmaceutical Co Ltd. China.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Precedex Injection of Hospira Inc.
	Details of stability studies of drug product	2500 Amp / 3 batches
	Documents for the procurement of API with approval from DRAP (in case of import).	AD cleared commercial invoice dated 21-10-2021

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm
1.	Submit 6th month stability study data	
2.	Submit contract manufacturing agreement	

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

22.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Balochistan**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	GMP status of drug product manufacturer	GMP certifacte: Inspection date 11-12- 2020
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22607: 14-09-2023
	Details of fee submitted	PKR 75,000/- : 07-11-2022
	The proposed proprietary name / brand name	**AVEBECTUM 1gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cefoparazone ss Sodium…500mg Sulbactam ss Sodium…500mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	JP
	The status in reference regulatory authorities	PMDA Japan
	For generic drugs (me-too status)	Cebac Injection by Bosch
	Proposed Pack size	1's: As per SRO

Evaluation by PEC[3]:

Sr. No	Shortcomings communicated	Response by the firm

1. Submit GMP certificate / inspection report of product manufacturer 2. Submit API specifications and analytical method from API manufacturer as well as product manufacturer 3. Submit verification studies of drug substance, performed by drug product manufacturer in section 3.2.S.4.3 4. Submit details of the product including exp date and batch number against which PE studies were conduced. 5. Submit in-use stability studies. 6. Submit valid GMP certificate of API manufacturer. 7. Submit evidence of import of drug substance. 8. Submit BMR of stability batches.		
Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.		
23.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Balochistan**
	Name, address of Manufacturing site.	M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar
	GMP status of drug product manufacturer	GMP certifacte: Inspection date 11-12- 2020
	Status of the applicant	☐ Manufacturer ☐ Importer ☒ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 22608: 14-09-2023
	Details of fee submitted	PKR 75,000/- : 07-11-2022
	The proposed proprietary name / brand name	**AVEBECTUM 1gm Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Vial Contains: Cefoparazone ss Sodium…1000mg Sulbactam ss Sodium…1000mg
	Pharmacotherapeutic Group of (API)	Antibiotic
	Reference to Finished product specifications	JP
	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)	Cebac Injection by Bosch
	Proposed Pack size	1's: As per SRO
	Name and address of API manufacturer.	Suzhou dawnrays pharmaceutical Co., Ltd China.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Cebac injection of Bosch.
	Details of stability studies of drug product	4000 vials / 3 batches
	Documents for the procurement of API with approval from DRAP (in case of import).	Clarance certificate dated 01-09-2022
Evaluation by PEC[3]:		
Sr. No	**Shortcomings communicated**	**Response by the firm**

1.	Submit GMP certificate / inspection report of product manufacturer
2.	Submit API specifications and analytical method from API manufacturer.
3.	Submit verification studies of drug substance, performed by drug product manufacturer in section 3.2.S.4.3
4.	Submit details of the product including exp date and batch number against which PE studies were conduced.
5.	Submit in-use stability studies.
6.	Submit valid GMP certificate of API manufacturer.
7.	Submit BMR of stability batches.

Decision: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Agenda of Dr. Farhadullah

Case No. 01; Deferred Registration application on Form 5F

24.	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)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy.No 17166 dated 10-07-2023
	Details of fee submitted	Rs.30,000/- dated 15-06-2023 (Deposit slip#71593585)
	The proposed proprietary name / brand name	**Daysita 100mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Film Coated Tablet Contains: Sitagliptin Phosphate Monohydrate Eq. to Sitagliptin……..…100mg
	Pharmacotherapeutic Group of (API)	Dipeptidyl peptidase 4 (DPP-4) Inhibitors
	Reference to Finished product specifications	USP
	The status in reference regulatory authorities	Januvia (25mg, 50mg, 100mg) film coated tablet USFDA Approved
	For generic drugs (me-too status)	Trevia 100mg Tablet by M/s Getz Pharma (Reg# 55437)
	Proposed Pack size and unit price	As per SRO

Evaluation by PEC[XI]:

Section	Observations	Response
3.2.S.7	• Stability study data of 3 batches of drug substance at real time conditions shall be submitted	• Stability study data of 3 batches of drug substance at real time conditions is submitted

3.2.P.5	• Justification shall be submitted for not selecting specifications for dissolution test in finished product specifications • Sumit method for disintegration test in analytical procedure without referring to USP monograph • Justification shall be submitted for selecting different limit of assay test (90%-110%) in batch analysis of dug product than that submitted in finished product specifications (95%-105%)	• The firm submitted that sitagliptin tablet is pharmacopeial product. In USP Monograph of sitagliptin tablet dissolution test is not mentioned. For reference USP monograph of sitagliptin tablet is submitted • Disintegration test in analytical procedure is adopted from USP monograph of sitgliptin tablet. • The firm submitted that assay limit of drug product is 95%-105%. Revised report is submitted. Fee Rs. 7500/- has been submitted for typographical error vide challan No#082153142296.
3.2.P.8	• Complete procurement documents including form 3, form 7 shall be submitted to establish batch number of drug substance used for manufacturing of submitted drug product stability batches since different COAs of APIs have been submitted against same invoice in application of 50mg and 100mg strength • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	• The firm submitted that we were unable to use the same COA and raw material for sitagliptin 100mg test trial because the raw material which was issued under form 6, has been fully utilized for the preparation of the sitagliptin 50mg test trial. Instead, we proceeded with testing based on drug import license form 5, which was intended for commercial purposes (sitagliptin tablets were already registered for export. The firm submitted that we used this raw material for test analysis of sitagliptin 100mg tablets for local test trials and submitted all relevant documents form 3, form 7 and form 5 and commercial invoice. • However, commercial invoice is not attested by AD (I&E) DRAP. • Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) is submitted

Previous Decision (340th-DRB): Deferred for submission of clearance certificate or commercial invoice attested by AD/DD (I&E) DRAP

Firm's Response:
Firm has submitted copy of commercial invoice cleared 02-02-2022 specifying 170kg Sitagliptin Phosphate monohydrate. The invoice is cleared by AD (I&E) DRAP.

Decision: Approved.

Case No. 02; Deferred Registration application on Form 5

1.	Name and address of manufacture / Applicant	M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	Brand Name + Dosage Form and Strength	Dipsar Tablet 10mg/20mg
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate.…10mg Olmesartan Medoxomil.…20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6709 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Calcium channel blockers/Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Azor 10mg/20mg film coated tablets of (USFDA Approved)

	Me-too-status	Olesta AM 10/20mg by M/s Searle Pakistan (Reg#076189)
	GMP Status	The firm was inspected on 18-08-2017 and Conclusion of inspection was: Keeping in view the above facts, overall GMP compliance found GOOD as of today the management has been advised to continue the process of up gradation and submit the compliance report on the observations made within two weeks positively especially sterile area.
	Remark of the Evaluator [XI]	• The firm submitted duly signed 1st page of Form 5
	Previous Decision (M-295th-DRB)	Deferred for signatures as per requirement
	Firm's Response	• Firm has submitted complete form 5 duly signed by the applicant
	Decision: Approved with innovator's specifications. Registration Board further decided that Registration letter will be issued after submission of following: **i. Fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(l)2024 dated 30-08-2024**	
2.	Name and address of manufacture / Applicant	M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	Brand Name + Dosage Form and Strength	Dipsar Tablet 10mg/40mg
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate.…10mg Olmesartan Medoxomil…..40mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6710 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Calcium channel blockers/Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Azor 10mg/40mg film coated tablets of (USFDA Approved)
	Me-too-status	Olesta AM 10/40mg by M/s Searle Pakistan (Reg#076190)
	GMP Status	The firm was inspected on 18-08-2017 and Conclusion of inspection was: Keeping in view the above facts, overall GMP compliance found GOOD as of today the management has been advised to continue the process of up gradation and submit the compliance report on the observations made within two weeks positively especially sterile area.
	Remark of the Evaluator [XI]	• The firm submitted duly signed 1st page of Form 5
	Previous Decision (M-295th-DRB)	Deferred for signatures as per requirement
	Firm's Response	• Firm has submitted complete form 5 duly signed by the applicant
	Decision: Approved with innovator's specifications **Registration Board further decided that Registration letter will be issued after submission of following:** **i. Fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(l)2024 dated 30-08-2024**	
3.	Name and address of manufacture / Applicant	M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan

	Brand Name + Dosage Form and Strength	Dipsar Tablet 5/20mg
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate…5mg Olmesartan Medoxomil…20mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6712 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Calcium channel blockers/Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Azor 5mg/20mg film coated tablets of (USFDA Approved)
	Me-too-status	Olesta AM 5/20mg of M/s Searle Pakistan (Reg#076187)
	GMP Status	The firm was inspected on 18-08-2017 and Conclusion of inspection was: Keeping in view the above facts, overall GMP compliance found GOOD as of today the management has been advised to continue the process of up gradation and submit the compliance report on the observations made within two weeks positively especially sterile area.
	Remark of the Evaluator [XI]	• The firm submitted duly signed 1st page of Form 5
	Previous Decision (M-295th-DRB)	Deferred for signatures as per requirement
	Firm's Response	• Firm has submitted complete form 5 duly signed by the applicant
	Decision: Approved with innovator's specifications **Registration Board further decided that Registration letter will be issued after submission of following:** **i. Fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(l)2024 dated 30-08-2024**	
4.	Name and address of manufacture / Applicant	M/s Biogen Pharma. 8-Km, Chakbeli Road, Rawat, Rawalpindi, Pakistan
	Brand Name + Dosage Form and Strength	Dipsar Tablet 5/40mg
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate…5mg Olmesartan Medoxomil…40mg
	Dairy No. date of R &I fee	Form-5 Dy.No 6711 dated 15-02-2019 Rs.20,000/- Dated 15-02-2019
	Pharmacological Group	Calcium channel blockers/Angiotensin II receptor blockers (ARBs)
	Type of form	Form 5
	Finished product specifications	Manufacturer's specifications
	Pack size and Demand Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Azor 5mg/40mg film coated tablets of (USFDA Approved)
	Me-too-status	Olesta AM 5/40mg of M/s Searle Pakistan (Reg#076188)
	GMP Status	The firm was inspected on 18-08-2017 and Conclusion of inspection was: Keeping in view the above facts, overall GMP compliance found GOOD as of today the management has been advised to continue the process

		of up gradation and submit the compliance report on the observations made within two weeks positively especially sterile area.
	Remark of the Evaluator [XI]	• The firm submitted duly signed 1st page of Form 5
	Previous Decision (M-295th-DRB)	Deferred for signatures as per requirement
	Firm's Response	• Firm has submitted complete form 5 duly signed by the applicant
	Decision: Approved with innovator's specifications **Registration Board further decided that Registration letter will be issued after submission of following:** **i. Fee of Rs. 9000/- for correction/pre-approval change/ in product specifications, as per S.R.O. 1324(l)2024 dated 30-08-2024**	

Agenda of Ms. Maham Misbah

Previously deferred cases of Form 5F (CTD)

29.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Islam Pharmaceuticals.** **7 km, Pasrur Road, Sialkot**
	Name, address of Manufacturing site.	M/s Islam Pharmaceuticals. 7 km, Pasrur Road, Sialkot
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy.No. 16645 : 04-07-2023
	Details of fee submitted	PKR 30,000/- : 7630379987
	The proposed proprietary name / brand name	Nesul 100mg Tablet
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Nimesulide…100mg
	Pharmacotherapeutic Group of (API)	Other antiinflammatory and antirheumatic agents, non-steroids
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	EMA Approved
	For generic drugs (me-too status)	Unix 100mg Tablet by M/s Hilton Pharma (Pvt) Ltd (Reg. No. 023397)
	Proposed Pack size	20's
Evaluation by PEC (No.XXIII): *Registration Board in its 271st meeting keeping in view the approval status of Nimesulide 100mg tablet in EMA, the Registration Board approved the formulation of Nimesulide Tablets 100mg with a pack size for 15 days as per recommendations of EMA only for the following clinical indications as a second-line choice.* *a) Treatment of acute pain* *b) Primary dysmenorrhea*		
Decision of 340th meeting of RB: Deferred for submission of satisfactory response to afore-mentioned shortcomings.		
Response of applicant/Remarks of evaluator:		
Serial No.	**Module/ Section**	**Shortcomings** / **Response of applicant**

	1.	3.2.P.8	Results and associated data of real time and accelerated stability studies for six-month time point shall be submitted for all three stability batches.	Submitted
	2.	3.2.P.8	Documents for the procurement of APIs with approval from DRAP (in case of import). DRAP attested invoice for clearance of imported raw materials shall be submitted.	Applicant has submitted Invoive No. SAMP/1002/20-21 dated 23/10/2020 for import of API. The clearance certificate dated 04-12-2020 is granted by DRAP field office.
	3.	3.2.P.8	Approval of API/ DML/GMP certificate of API manufacturer (M/s Aarti, India) issued by concerned regulatory authority of country of origin shall be submitted.	Copy of GMP certificate having validity 02-2025 is submitted.

Decision: Approved.

30.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Maxitech Pharma Private Limited Plot No. E-178, S.I.T.E, Phase II, Super Highway, Karachi**
	Name, address of Manufacturing site.	M/s Maxitech Pharma Private Limited Plot No. E-178, S.I.T.E, Phase II, Super Highway, Karachi
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No. 36122: 12-12-2022
	Details of fee submitted	PKR 30,000/- : Deposit Slip No.:16452579167
	The proposed proprietary name / brand name	**DEXA 0.1% eye drops**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Dexamethasone……1mg
	Pharmacotherapeutic Group of (API)	Antiinflammatory Agents, Corticosteroids, plain
	Reference to Finished product specifications	USP
	Proposed Pack size	1 x 5ml
	The status in reference regulatory authorities	Maxidex eye drops (MHRA approved)
	For generic drugs (me-too status)	Vegadex Eye drops By M/a Vega (Reg. No. 33870)

Evaluation by PEC (No…XXIII):

Decision of 336th meeting of RB: Deferred for submission of satisfactory response to above-cited shortcomings.

Decision of 339th meeting of RB: Deferred for submission of satisfactory response to afore-mentioned shortcomings.

Response of applicant/Remarks of evaluator:

Sr. No.	Module/Section	Observations/Deficiencies/ Short-comings	Response of applicant

1.		Executed BMRs of stability batches shall be submitted	Submitted
2.	3.2.S.4.3	Analytical method verification of drug substance conducted by drug product manufacturer shall be submitted	Submitted
3.	3.2.P.8	Documents of import and clearance of API shall be submitted.	Applicant has submitted Invoice No. TM20E0007 dated 06/05/2020 for import of API. The clearance certificate dated 25-06-2020 is issued by DRAP field office.

Decision: Approved.

Deferred cases (Form 5) (Veterinary)

31.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutica Pvt Ltd. Plot No 5, Pharmacity, 30-km Multan Road, Lahore (DML No. 000587) Veterinary Liquid Injectable Section
	Brand Name +Dosage Form + Strength	Pri-Cyanofos Injection 10ml
	Composition	Each ml Contains: Toldimphos Sodium…200mg Cyanocobalamin…0.05mg
	Diary No. Date of R& I & fee	Dy.No 34227 dated 31-12-2021; Rs.30,000/- vide Deposit Slip No. 4390103071
	Pharmacological Group	Vet Nutritional supplement
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10ml Glass vial; Decontrolled
	Me-too status	Not available in applied pack size
	GMP status	Not provided
	Remarks of the Evaluator[xxiii].	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm in the applied PACK SIZE i.e. 10ml is required. • Latest GMP inspection report against inspection conducted within the last three years is required.
	Decision of 330th meeting of RB: Deferred for submission of the following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm in the applied PACK SIZE i.e. 10ml • Latest GMP inspection report against inspection conducted within the last three years The Board further decided that the applicant shall submit response within 1 month after publication of the minutes.	
	Response of applicant: • Me-too status: Tonovit Injection (Registration no. 033253) registered in the name of Selmore Pharmaceuticals, PACK SIZE 10mL. • GMP certificate No. 179/2024-DRAP (AD-627190613556) dated 24-09-2024 issued on the basis of evaluation conducted on 08-05-2024 is submitted for Liquid Injectable (Vet) Section (General). Vial section is confirmed from inspection report.	
	Remarks of evaluator:	
	Decision: Approved.	

32.	Name and address of manufacturer / Applicant	M/s Hirra Pharmaceutical Laboratories (Pvt) Ltd., 1.3 K.M.Asil Raiwind Road,(Ladhaky Bhular) Lahore Cantt.Pakistan
	Brand Name +Dosage Form + Strength	HIRRA-AMOXICLAV POWDER
	Composition	Each 100gm contains: Amoxicillin Trihydrate …… 20gm Clavulanic Acid ……. 04gm Colistin Sulphate…….. 04gm
	Diary No. Date of R& I & fee	Tracking ID UX6-EAV-Z714 dated 02-12-2024; Rs.37,000/- (64561741932)
	Pharmacological Group	Penicillin antibiotic
	Type of Form	Form 5
	Finished product Specifications	As per Innovators Specification
	Pack size & Demanded Price	500gm, 1Kg; Decontrolled
	Me-too status	Moxilav-C Powder of M/s Leads Pharma (Pvt) Ltd., Islamabad. (Reg. No. 082791)
	GMP status	
	Remarks of the Evaluator	The instant application was submitted through e-app portal; initially form-5 attachment was missing and the same was communicated to the firm. In response, the firm has submitted hard copy of complete dossier stating that they were unable to attach the file on portal.
	Decision: Approved.	

Agenda of Mr. Tahir Waqas

Agenda Item No. 01: Routine Applications of Human Drugs (Locally Manufactured) applied on Form - 5F.

33.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Horizon HealthCare (Pvt.) Ltd., Plot No. 33 Sunder Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Horizon HealthCare (Pvt.) Ltd., Plot No. 33 Sunder Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 26031 dated 27-10-2023
	Details of fee submitted	PKR 75,000/- dated 16-10-2023 Challan / Receipt # 9466180096
	The proposed proprietary name / brand name	**GLYCOPEP 1.7mg OD Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Orally disintegrating tablet contains: Glycopyrrolate … 1.7mg
	Pharmacotherapeutic Group of (API)	Anticholinergic to reduce symptoms of a peptic ulcer
	Reference to Finished product specifications	Innovator's specifications
	The status in reference regulatory authorities	DARTISLA ODT 1.7mg TABLET, Orally Disintegrating. (USFDA, **Discontinued**).
	For generic drugs (me-too status)	N/A
	Proposed Pack size	As per SRO

	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

i. The enclosed GMP Certificate (M/s Melody Healthcare (Pvt.) Ltd., India) was valid till March 2023. However, License has been retained till 2027.

ii. Marketing status in USFDA has been mentioned 'Discontinued'. The reason of discontinuation cannot be verified.

iii. Pharmaceutical Equivalence & CDP Performed with DARTISLA ODT 1.7mg, Exp. Oct 2023, Batch No.4813271A.

iv. Stability Study Results along with supporting data for 6th Month Time Point (Real Time and Accelerated) required.

v. Enclosed GMP Certificate of FPP Manufacturer was valid till 10-2023.

The firm had submitted Stability Study Results along with supporting data for 6th Month Time Point (Real Time and Accelerated).

Decision: The Registration Board deferred the case for submission of evidence of approval from any other reference regulatory authority as adopted by Registration Board in its 75th meeting, since submitted reference product has been declared as "Discontinued" by US FDA.

34.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals (Pvt.) Ltd., 129-Sunder Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd., 129-Sunder Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 26131 dated 30-10-2023
	Details of fee submitted	PKR 30,000/- dated 01-09-2023 Challan / Receipt # 8377445952
	The proposed proprietary name / brand name	**PRILOSEC 325mg/40mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated modified release tablet contains: Aspirin (enteric coated) … 325mg Omeprazole (immediate release) … 40mg
	Pharmacotherapeutic Group of (API)	Aspirin (an anti-platelet agent) and (omeprazole, a proton pump inhibitor -PPI).
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Aspirin 81mg/omeprazole 40mg and aspirin 325mg/omeprazole 40 mg delayed-release tablets (USFDA, Tentative Approval).
	For generic drugs (me-too status)	OMO/ASPER 325mg/40mg Tablet of M/s Helix Pharma, Karachi.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

i. Evidence of submitted Me-too status (OMO/ASPER 325mg/40mg Tablet of M/s Helix Pharma, Karachi) is required.

ii. Submitted Long Term Stability Study Data of API (25℃±2℃/60%±5%RH) is not as per Zone – IV.

iii. Omeprazole (1Kg) Loan of API from M/s Pharmazone Chemicals (Pvt.) Ltd, dated 19th July, 2022.

Decision: The Registration Board deferred the case for submission of following points:

i) Reason for submitted Long Term Stability Study Data of API on 25℃±2℃/60%±5%RH instead of Zone – IV.
ii) Jusification of borrowing Omeprazole from a semi basic manufacturer i.e., M/s Pharmazone Chemicals (Pvt.) Ltd, Pakistan, instead of commercial purchase from the same.

35.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals (Pvt.) Ltd., 129-Sunder Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd., 129-Sunder Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 26130 dated 30-10-2023
	Details of fee submitted	PKR 30,000/- dated 01-09-2023 Challan / Receipt # 732759243
	The proposed proprietary name / brand name	**PRILOSEC 81mg/40mg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated modified release tablet contains: Aspirin (enteric coated) … 81mg Omeprazole (immediate release) … 40mg
	Pharmacotherapeutic Group of (API)	Aspirin (an anti-platelet agent) and (omeprazole, a proton pump inhibitor -PPI).
	Reference to Finished product specifications	Innovator's Specifications
	The status in reference regulatory authorities	Aspirin 81mg/omeprazole 40mg and aspirin 325mg/omeprazole 40 mg delayed-release tablets (USFDA, Tentative Approval).
	For generic drugs (me-too status)	OMO/ASPER 81mg/40mg Tablet of M/s Helix Pharma, Karachi.
	Proposed Pack size	As per SRO
	Proposed unit price	As per SRO

Evaluation by PEC (XXI):

i. Evidence of submitted Me-too status (OMO/ASPER 81mg/40mg Tablet of M/s Helix Pharma, Karachi) is required.
ii. Submitted Long Term Stability Study Data of API (25℃±2℃/60%±5%RH) is not as per Zone – IV.
iii. Omeprazole (1Kg) Loan of API from M/s Pharmazone Chemicals (Pvt.) Ltd, dated 19th July, 2022.

Decision: The Registration Board deferred the case for submission of:
i) Reason for submitted Long Term Stability Study Data of API on 25℃±2℃/60%±5%RH instead of Zone – IV.
ii) Jusification of borrowing Omeprazole from a semi basic manufacturer i.e., M/s Pharmazone Chemicals (Pvt.) Ltd, Pakistan, instead of commercial purchase from the same.

36.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Wimits Pharmaceuticals (Pvt.) Ltd., 129-Sunder Industrial Estate, Lahore.**
	Name, address of Manufacturing site.	M/s Wimits Pharmaceuticals (Pvt.) Ltd., 129-Sunder Industrial Estate, Lahore.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)

	Application Form Dy. No / Tracking ID & date of submission & details of fee submitted	Form-5F Dy. No 24573 dated 06-10-2023 Rs.30,000/- dated 08-09-2023 vide deposit slip# 7466204457.
	The proposed proprietary name / brand name	**MISOTOL 200mcg Tablet**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Tablet Contains: Misoprostol-HPMC 1% Dispersion Eq. to Misoprostol … 200mcg
	Pharmacotherapeutic Group of (API)	Synthetic prostaglandin E_1 analog
	The status in reference regulatory authorities	CYTOTEC 0.2mg Tablet, USFDA approved.
	For generic drugs (me-too status)	BREEKY 200mcg Tablets of SAMI Pharmaceuticals (Pvt.) Limited.
	Proposed Pack size & Price	As per SRO
	Reference to Finished product specifications	International Pharmacopoeia Specifications

Evaluation by PEC:

WARNINGS

CYTOTEC (MISOPROSTOL) ADMINISTRATION TO WOMEN WHO ARE PREGNANT CAN CAUSE BIRTH DEFECTS, ABORTION, PREMATURE BIRTH OR UTERINE RUPTURE.

UTERINE RUPTURE HAS BEEN REPORTED WHEN CYTOTEC WAS ADMINISTERED IN PREGNANT WOMEN TO INDUCE LABOR OR TO INDUCE ABORTION. THE RISK OF UTERINE RUPTURE INCREASES WITH ADVANCING GESTATIONAL AGES AND WITH PRIOR UTERINE SURGERY, INCLUDING CESAREAN DELIVERY (see also **PRECAUTIONS** and **LABOR AND DELIVERY**).

CYTOTEC SHOULD NOT BE TAKEN BY PREGNANT WOMEN TO REDUCE THE RISK OF ULCERS INDUCED BY NONSTEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDs) (see **CONTRAINDICATIONS**, **WARNINGS**, and **PRECAUTIONS**).

PATIENTS MUST BE ADVISED OF THE ABORTIFACIENT PROPERTY AND WARNED NOT TO GIVE THE DRUG TO OTHERS.

Cytotec should not be used for reducing the risk of NSAID-induced ulcers in women of childbearing potential unless the patient is at high risk of complications from gastric ulcers associated with use of the NSAID, or is at high risk of developing gastric ulceration. In such patients, Cytotec may be prescribed if the patient

- has had a negative serum pregnancy test within 2 weeks prior to beginning therapy.
- is capable of complying with effective contraceptive measures.
- has received both oral and written warnings of the hazards of misoprostol, the risk of possible contraception failure, and the danger to other women of childbearing potential should the drug be taken by mistake.
- will begin Cytotec only on the second or third day of the next normal menstrual period.

Decision: Approved with Box warning.

Agenda Item No. 02: Deferred applications of previous meetings

37.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s Ray Pharma (Pvt.) Ltd., S-58, S.I.T.E., Ext., Karachi.**
	Name, address of Manufacturing site.	M/s Ray Pharma (Pvt.) Ltd., S-58, S.I.T.E., Ext., Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form-5F Dy. No. 21302 dated 29-AUG-2023
	Details of fee submitted	PKR 30,000/- dated 07-02-2023 Challan / Receipt # 78510326056
	The proposed proprietary name / brand name	**MULTIGESIC 1% Gel**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each gm Gel contains: Diclofenac Diethylamine B.P eq. to Diclofenac Sodium … 1%
	Pharmacotherapeutic Group of (API)	M02AA15, Anti-inflammatory preparations, non-steroids for topical use
	Reference to Finished product specifications	BP Specifications

	The status in reference regulatory authorities	VOLTAREN EMULGEL (Health Canada Approved).
	For generic drugs (me-too status)	FASTAID GEL by M/s Platinum Pharmaceuticals Pvt. Ltd.
	Proposed Pack size	20gm, 30gm and 50gm
	Proposed unit price	Rs. 160, Rs. 240 and Rs. 350.

Decision of 340th meeting of Registration Board: Registration Board deferred the case for submission of reply to the cited shortcomings.

Evaluation by PEC-XXI:

The following deficiencies / shortcomings have been submitted by the firm:

Sr. No.	Observations	Firm's response
i.	3.2.P.8 Please provide Stability Study Data - Summary Sheets, Chromatograms and Raw Data / Calculation Sheets etc. for 6th Month Study Time Point (Accelerated and Real Time).	Firm has submitted Stability Study Data - Summary Sheets, Chromatograms and Raw Data / Calculation Sheets etc. for 6th Month Study Time Point (Accelerated and Real Time).
ii.	Please provide DRAP AD (I&E) Clearance for import of relevant batch of API (Diclofenac Diethylamine B.P).	Firm has submitted Clearance Certificate No. E-2551804246795 for Diclofenac Sodium, and application on Form - 4 for Diclofenac Diethylamine BP.

Decision: Approved with change of brand name.

Agenda of Mr. Waqar

1.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Horizen Healthcare (Pvt) Ltd. 35-A, Punjab Small Industrial Estate, Taxila.**
	Name, address of Manufacturing site.	M/s. Horizen Healthcare (Pvt) Ltd. 35-A, Punjab Small Industrial Estate, Taxila.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 27572 dated 24-11-2023.
	Details of fee submitted	Rs.75,000/- vide slip No. 923950339 dated 20-10-2023.
	The proposed proprietary name / brand name	**Dketofen 50mg/2ml Injection**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each 2ml Ampule Contains: Dexketoprofen (as Dexketoprofen trometamol) ……. 50mg
	Pharmacotherapeutic Group of (API)	NSAIDS
	Reference to Finished product specifications	Innovator's Specifications.
	The status in reference regulatory authorities	Enantyum 50mg / 2ml Injection. Keral 50mg / 2ml Injection. HPRA Ireland Approved.
	For generic drugs (me-too status)	New Formulation.
	Proposed Pack size	As per SRO.

Evaluation by PEC :

Decision: Approved.		
2.	**Name, address of Applicant / Marketing Authorization Holder**	**M/s. Hudson Pharma (Pvt) Ltd.** **D-93, North West Industrial Zone, Port Qasim Authority, Karachi.**
	Name, address of Manufacturing site.	M/s. Hudson Pharma (Pvt) Ltd. D-93, North West Industrial Zone, Port Qasim Authority, Karachi.
	Status of the applicant	☒ Manufacturer ☐ Importer ☐ Is involved in none of the above (contract giver)
	Application Form Dy. No / Tracking ID & date of submission	Form 5F: Dy. No 26683 dated 06-11-2023.
	Details of fee submitted	Rs.30,000/- vide slip No. 5500501370 dated 03-08-2023.
	The proposed proprietary name / brand name	**Dorson-T Eye Drops**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml Contains: Dorzolamide Hcl Equivalent to Dorzolamide…..20mg Timolol Maleate Equivalent to Timolol ….. 5mg.
	Pharmacotherapeutic Group of (API)	Anti-Glaucoma
	Reference to Finished product specifications	USP Specifications.
	The status in reference regulatory authorities	Cosopt Eye Drop. US FDA Approved.
	For generic drugs (me-too status)	Dozypress-T Eye Drop (Registration No. 050877) Manufactured by. Remington Pharmaceutical Pvt Ltd.
	Proposed Pack size	Pack size 5ml x 1's, MRP As per SRO.
Evaluation by PEC :		
Decision: Approved.		

Export Facilitation Desk

Registration Board 343 Meeting Additional/Supplementary Minutes:

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
1	**Alpenglow pharmaceutical pvt Ltd** Plot A/7 export processing zone Risalpur, Nowshera, KPK (**000918**) Tracking ID: (7J6-QBZ-NJXZ, 2024-11-28) Fee Paid: 75000.0 Paid Date: 2024-09-18 Case Category: PRV-I **(Muhammad Usman)**	Proposed Name: **Zakintos** 1500 mg As per Importing Country RRA Status: This medication meets GMP Standereds and as manufactured in china , india and usa Me Too Status: Not avaliable Pack Size(s):
	Evaluation Remarks: No me too and no RRA status is available No drug with similar composition i.e Each vial contains :Ceftriaxone as sodium (1000mg) & Sulbactam as Sodium (500mg) is registered/available	
	Decision: Approved Registration Board, in order to facilitate export, advised to issue registration letter for export purpose without waiting for finalization of minutes.	

Registration Board 343 Meeting Additional/Supplementary Minutes:

Sr. No	Name of Applicant, Manufacturer & Fee Details	Product Info
1	**STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE (**000130**) Tracking ID: (42Y-418-255V, 2024-11-14) Fee Paid: 75000.0 Paid Date: 2024-09-12 Case Category: PRV-I **(Muhammad Usman)**	Proposed Name: **Neostar Injection** Each ml contains:- Neostigmine methylsulfate....0.5 mg (equivalent to 0.334 mg Neostigmine). (USP Specifications) As per Importing Country RRA Status: ADWIGMINE Categories: ANTI-SPASMODIC Dosage: INJECTABLE SOLUTION Bureau 175, 90 South Road 2nd Sector, 5th Settlement New Cairo, Egypt Me Too Status: not available Pack Size(s):
	Evaluation Remarks: For Registration of Veterinary Product for Export only. No Me too and no RRA reference is available	
	Decision: **The Drug Registration Board decided to accede to the request of the firm.**	

Registration Board 343 Meeting Additional/Supplementary Minutes:

Sr. No.	Name of Applicant, Manufacturer & Fee Details	Product Info
1	**Wilson's Pharmaceuticals** Plot No. 387-388 & 366 Sector I/9 Industrial Area, Islamabad (**000239**) Tracking ID: (51B-S8L-ANZU, 2024-09-26) Fee Paid: 65000.0 Paid Date: 2024-09-26 Case Category: PRV-II **(Muhammad Zubair)**	Prescot 150mg Capsule (Reg. No. 081948) Each capsule contains: Pregabalin…..... 150mg (BP Specifications) Date of Reg.: 07-11-2016 Last Renewal Submission: 16-11-2021

Evaluation Remarks:
The case was considered in 134th PRVC wherein the Committee decided as follows:
Acceded to request of firm for change in MAH to M/s Wilson's Pharmaceuticals, Plot No. 387-388 & 366 Sector I/9 Industrial Area, Islamabad along with grant of permission of contract manufacturing from M/s Scotmann Pharmaceuticals, Plot No.5-D, I-10/3, Industrial Area, Islamabad subject to submission of differential fee of Rs. 28000/-, NOC from M/s Scotmann Pharmaceuticals & evidence of regularization of last renewal.
The firm has submitted the differential fee of Rs. 28000/-, NOC from M/s Scotmann & application for regularization of last renewal along with differential fee of Rs. 15000/-.

Decision:

Acceded to request of firm for change in MAH to M/s Wilson's Pharmaceuticals, Plot No. 387-388 & 366 Sector I/9 Industrial Area, Islamabad along with grant of permission of contract manufacturing from M/s Scotmann Pharmaceuticals, Plot No.5-D, I-10/3, Industrial Area, Islamabad along with regularization of renewal w.e.f. 07-11-2021.

2	**Genome Pharmaceuticals (Pvt.) Ltd,** Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. (**000454**) Tracking ID: (H36-NRH-RZ86, 2024-11-29) Fee Paid: Paid Date: Case Category: Export Registration **(Muhammad Zubair)**	Proposed Name: **Kymoze Tablets** Each enteric coated tablet contains; Trypsin ……..1mg (2500 I.U) Bromelain .....50mg (20000 I.U) As per Importing Country RRA Status: Worbenzyl Tablet Me Too Status: Kontab Tablets Pack Size(s):

Evaluation Remarks:
The proposed brand name is already registered in name of M/s Akhai Pharmaceuticals (Pvt.) Ltd., Karachi for Export Purpose. M/s Akhai Pharmaceuticals (Pvt.) Ltd., Karachi has provided NOC in name of M/s Genome Pharmaceuticals, Hattar exclusively for obtaining approval for a change of brand name with DRAP specifically for Export registration. The firm further stated that this NOC is strictly limited to Export registration purposes and is not valid for local registration or any distribution within Pakistan.
However, the firm has not applied for change of brand name of its own product.

Decision:

Registration Board advised M/s Akhai Pharmaceuticals (Pvt.) Ltd., Karachi to provide alternate brand names for their registered product as they have provided the NOC in name of M/s Genome Pharmaceuticals, Hattar. Registration Board further advised that if the firm provides alternate names, then there will be no need to again present the case before Registration Board.

3	**Genix pharma** 44-45 B korangi creek road. karachi(**000351**) Tracking ID: (QX5-L3M-3EYA, 2024-11-14) Fee Paid: 75000.0 Paid Date: 2024-08-08 Case Category: Export Registration **(Muhammad Zubair)**	Proposed Name: **Gen-M SUPP. 50mg** Each suppository contains: Artesunate……. 50mgAs per Importing Country RRA Status: WHO (EXPORT ORDER IS ATTACHED) Me Too Status: N/APack Size(s):

Evaluation Remarks:
The said formulation is not registered in any RRA. However, it is available in WHO NEML.

Decision:

Registration Board approved the product for Export Purpose only.

4	**Wilson's Pharmaceuticals** Plot No. 387-388 & 366 Sector I/9 Industrial Area, Islamabad (**000239**) Tracking ID: (S62-V17-N9RD, 2024-09-26) Fee Paid: 65000.0 Paid Date: 2024-09-26 Case Category: PRV-II **(Muhammad Zubair)**	Prescot 150mg Capsule (Reg. No. 081894) Each capsule contains: Pregabalin……100mg (BP Specifications) Date of Reg.: 07-11-2016 Last Renewal Submission: 16-11-2021

Evaluation Remarks:
The case was considered in 134th PRVC wherein the Committee decided as follows:
Acceded to request of firm for change in MAH to M/s Wilson's Pharmaceuticals, Plot No. 387-388 & 366Sector I/9 Industrial Area, Islamabad along with grant of permission of contract manufacturing from M/s Scotmann Pharmaceuticals, Plot No.5-D, I-10/3, Industrial Area, Islamabad subject to submission of differential fee of Rs. 28000/-, NOC from M/s Scotmann Pharmaceuticals & evidence of regularization of last renewal.
The firm has submitted the differential fee of Rs. 28000/-, NOC from M/s Scotmann & application for regularization of last renewal along with differential fee of Rs. 15000/-.

Decision:

Acceded to request of firm for change in MAH to M/s Wilson's Pharmaceuticals, Plot No. 387-388 & 366 Sector I/9 Industrial Area, Islamabad along with grant of permission of contract manufacturing from M/s Scotmann Pharmaceuticals, Plot No.5-D, I-10/3, Industrial Area, Islamabad along with regularization of renewal w.e.f. 07-11-2021.

5	**Wilson's Pharmaceuticals** Plot No. 387-388 & 366 Sector I/9 Industrial Area, Islamabad (**000239**) Tracking ID: (SYW-G29-PAJT, 2024-09-26) Fee Paid: 65000.0 Paid Date: 2024-09-26 Case Category: PRV-II **(Muhammad Zbair)**	Prescot 75mg Capsule (Reg. No. 081893) Each capsule contains: Pregabalin……75mg (BP Specifications) Date of Reg.: 07-11-2016 Last Renewal Submission: 16-11-2021

Evaluation Remarks:
The case was considered in 134th PRVC wherein the Committee decided as follows:
Acceded to request of firm for change in MAH to M/s Wilson's Pharmaceuticals, Plot No. 387-388 & 366Sector I/9 Industrial Area, Islamabad along with grant of permission of contract manufacturing from M/s Scotmann Pharmaceuticals, Plot No.5-D, I-10/3, Industrial Area, Islamabad subject to submission of differential fee of Rs. 28000/-, NOC from M/s Scotmann Pharmaceuticals & evidence of regularization of last renewal.
The firm has submitted the differential fee of Rs. 28000/-, NOC from M/s Scotmann & application for regularization of last renewal along with differential fee of Rs. 15000/-.

Decision:

Acceded to request of firm for change in MAH to M/s Wilson's Pharmaceuticals, Plot No. 387-388 & 366 Sector I/9 Industrial Area, Islamabad along with grant of permission of contract manufacturing from M/s Scotmann Pharmaceuticals, Plot No.5-D, I-10/3, Industrial Area, Islamabad along with regularization of renewal w.e.f. 07-11-2021.

6	**Weather Folds Pharmaceuticals,** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. Tracking ID: (MPW-XN3-JBS1, 2024-10-25) Fee Paid: 75000.0 Paid Date: 2024-10-25 Case Category: Export Registration **(Muhammad Zubair)**	Proposed Name: **Chemdot Injection** Each Autoinjector (2.0mL/2.0mL) Contains: Atropine*.....2mg/2.0mL Pralidoxime Chloride..... 600Mg/2.0mL RRA Status: N/A Me Too Status: N/A Pack Size(s):

Evaluation Remarks:

Evaluated as per SOP. The strength of Atropine in RRA product is different i.e. 2.1mg/7ml from applied formulation i.e. 2mg/2ml but the applicant has provided purchase order from UAE and requested to approved the applied formulation.

Decision:

Registration Board acceded to, for Export Purpose to UAE only subject to verification of availability of auto injector manufacturing facility.

Case No.01: Registration of Drug (s) of M/s Swiss Pharmaceuticals (Pvt.) Ltd, A/159, S.I.T.E. super Highway, Karachi,for export purposes only.

Following product of M/s Swiss Pharmaceuticals, Karachi was deferred in 334th meeting of Registration Board as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form 5
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML.	Copy of DML provided. Approval of relevant section verified from cGMP inspection report dated 18-03-2022.
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP certificate based / on inspection dated 18-03-2022.
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.	Nystat Oral Drops (100,000 IU/ml) Each ml contains: Nystatin USP..... 100,000IU	Nilstat by M/s ICI	Dy. No. 1130/23 (22.09.2023) Rs.30,000/- (12.09.2023)

Decision of 107th PRVC:

"The Chairman Registration Board on recommendation of Committee considered the case and acceded to request of the firm for registration of above-mentioned products for Export Purpose Only subject to submission of more brand names for product at sr. no. 177."

The aforementioned brand name is registered in name of M/s Pliva Pakistan (Pvt.) Ltd. The firm has also submitted the copy of NOC from M/s Pliva Pakistan. But, M/s Pliva is not changing its brand name and submitted the following justification:

> "M/s Pliva is the official manufacturer of Nystat Oral Drops for Royal Group for many exporting countries. Moreover, M/s Royal Group usually receives orders from exporting countries of a single product in large quantities, which is not possible to fulfill the demand of different countries by a single manufacturer that is why Royal Group splits the orders into multiple manufacturers for a single product country-wise. Nystat Drops is registered in our name but the product owner is Royal Group."
>
> M/s Pliva Pakistan has requested to grant registration to M/s Swiss Pharma with brand name "Nystat Drops".

Decision of 334th meeting:

Registration Board deferred the case for submission of following:

- *Application for change of brand name of Nystat Drops by M/s Pliva Pakistan OR*
- *More brand names by M/s Swiss Pharma Karachi which do not resemble with already registered products.*

M/s Pliva Pakistan (Pvt.) Ltd., has now submitted that Nystat Drops are being manufactured for Export by M/s Royal Group. There is no objection if M/s Royal Group chooses to have the same product using same brand name manufactured by any other manufacturer, including M/s Swiss Pharmaceuticals (Pvt.) Ltd., for Export purposes.
Pliva Pakistan (Pvt.) Ltd., requests that Drug Registration Board approve the registration of brand name "Nystat" for export purposes to M/s Swiss Pharmaceutical (Pvt.) Ltd.

Discussion:

Registration Board was apprised by PR-II Section that the firm M/s Swiss Pharmaceuticals has submitted an appeal in Appellant Board against the decision of 334th meeting of Registration Board. However, representative of Pharma Bureau informed the Board that the firm has withdrawn its appeal. The representative of Legal Affairs Division then confirmed that the firm has applied for withdrawal of appeal which will be placed in Appellant Board for decision.

Decision:

Keeping in view the above discussion; Registration Board advised PE&R Division to take confirmation from Legal Affairs Division of the Appeal of M/s Swiss Pharmaceuticals and if the Appellant Board dispose of the appeal of M/s Swiss Pharmaceuticals as withdrawn then advise M/s Pliva Pakistan (Pvt.) Ltd. to provide alternate brand names for their registered products as they have provided the NOC in name of M/s Swiss Pharmaceuticals (Pvt.) Ltd., Karachi. Registration Board further advised that if the firm provides alternate names, then there will be no need to again present before Registration Board and Chairman Registration Board is authorized for issuance of registration letter and for change in brand name of M/s Pliva Pakistan (Pvt.) Ltd.

Case No. 1 M/s. United International Plot no.MR-1/122, Medina Centre, 3rd floor, Gali No.02, Marriott Road, Karachi

Sr. No.	Reg. No.	Brand Name & Composition	Date of Reg. PRV (If any)	Tracking ID Fee submitted	Validity granted by Board
1.	047642	Dexamethasone Sodium Phosphate Injection Each ampoule contains Dexamethasone Sodium Phosphate U.S.P equivalent to Dexamethasone Phosphate ....4mg **Manufactured by:** Wuhan Grand Pharmaceutical Group. Co. Ltd., China	07.06.2008	RGN-2G1-SM8H Rs.30000/- Dated 21/05/2024 & Slip No. 32399232988 Rs.3,30,000/- Dated 02/12/2024	**Renewal is granted w.e.f. 07.06.2023 to 06.06.2028**

Remarks:

The Renewal application for year 2023 was submitted after 60 days but within one year. Now the firm has submitted differential fee and requested for regularization for above mentioned products.

Decision: Registration Board regularized the renewal of registration of above product and granted validity of product as mentioned against each case.

Meeting ended with a vote of thanks to and from the Chair

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